INTRODUCTION

Each year American University receives awards for research, training, and technical assistance from outside sources, including the federal government and private organizations. Sponsored programs are diverse and complex, and those planning a funded project should become familiar with this handbook.

The handbook will guide faculty, staff, and administrative officers from the development of a research idea through the administration of an award. In addition to answering the most common questions, the handbook lists several policies affecting sponsored programs. The full texts of many of these policies appear as attachments in the appropriate sections.

For additional information, call the OFFICE OF SPONSORED PROGRAMS (OSP) at x3440. OSP is the only office principal investigators need to call for most technical and procedural questions related to sponsored projects. OSP staff are trained to answer questions, find solutions to unusual problems, and work with principal investigators to follow existing University policies and procedures that apply to sponsored project activities. Colleges and teaching units should be contacted for questions related to resource allocation.

OFFICE OF SPONSORED PROGRAMS

Purpose

Federal, state, and local governments, along with numerous private and nonprofit entities, provide a range of funds for colleges and universities to create new programs, expand research opportunities, and undertake developmental activities that benefit both the general public and the educational institution itself. The OFFICE OF SPONSORED PROGRAMS (OSP) provides services and support to encourage faculty and staff to obtain such outside sponsorship. Among its various functions, OSP:

- **Assists** in locating potential funding sources;
- **Disseminates** information pertinent to the availability of (and deadlines for) external funding opportunities for research, training, and services;
- **Maintains** applications, source materials, bulletins, announcements, and guidelines for use by faculty and staff;
- **Guides** faculty in preparing proposal applications, including budgets, to ensure conformity with university policy, sponsor criteria, and federal, state and local regulations;
- **Negotiates** terms and conditions of grants and contracts, in coordination with the principal investigator, and prepares such grants and contracts for acceptance by an official authorized to commit the university to the performance of the proposed projects;
- **Coordinates** compliance with federal and District of Columbia regulations and university policies;
- **Prepares** administrative briefs for all awards for distribution to appropriate faculty and staff;
- **Prepares** subcontracts and subgrants, as appropriate;
- **Maintains** official university award files;
- **Monitors** projects for adherence to sponsor terms and conditions, including rebudgeting actions, and requests for extensions, continuations, supplements or renewals of existing awards;
- **Assists** in matters relating to patents, copyrights, and publication agreements;
- **Coordinates** matters of compliance with regulations relating to the use of animals, human subjects, and radioactive and hazardous materials;
- **Directs** faculty in compliance with sponsor requirements regarding the administrative close-out of awards, and
- **Serves** as official liaison between the university and the sponsor.

Organization

The Director of OSP reports to the Assistant Provost, who acts on behalf of the Provost in matters relating to grants and contracts. The OSP staff consists of the Director, who also serves as the University Compliance Administrator, an Assistant Director, an Operations Administrator, four Grant and Contract Managers, a Grant and Contract Coordinator, and support staff.

TABLE OF CONTENTS

PROPOSAL AND DEVELOPMENT ACTIVITY

A proposal is a request for external financial support of a research, training or technical assistance project. The Office of Sponsored Programs (OSP) personnel assist faculty and staff with all phases of proposal preparation and submission, including:

- identification of potential funding sources;
- pre-submission procedures;
- proposal and budget preparation;
- internal review, routing, and approval, and
- timely submission to a sponsor.

OSP staff are assigned to specific colleges and teaching units. Individuals are encouraged to contact the OSP staff member assigned to their particular area when first considering external funding for research or training projects.

Office of Sponsored Programs Mission Statement

The Office of Sponsored Programs (OSP) provides a supportive, proactive, and dynamic environment for conducting research, training, and technical assistance by: (1) stimulating interests in the intellectual life of the AU community; (2) encouraging creative approaches to the development of new opportunities; (3) promoting interdisciplinary and interdepartmental cooperation; and (4) fostering the enrichment of students and teaching. OSP is committed to reducing the administrative burden on faculty, administrators, and staff by providing efficient, effective, personal and professional service. In addition, through the application of pre-award and post-award knowledge and skills, OSP seeks to safeguard the University by ensuring compliance with internal and external regulations, policies and procedures.

Adopted by the Office of Sponsored Programs (formerly the Office of Research Services) on February 24, 1993. Revised with the merger of the Office of Contract Education with the Office of Research Services on March 20, 1995.

OSP STAFF ASSIGNMENTS

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Kogod School of Business **Office of Campus Life** **School of Public Affairs** **WAMU**	**College of Arts and Sciences** • Anthropology • Art • Biology • Computer Science, Audio Technology and Physics (CAP) • Chemistry • Economics • National Center for Health Fitness • Philosophy and Religion • Psychology	**College of Arts and Sciences** • Education • History • Language and Foreign Studies • Literature • Mathematics and Statistics • Performing Arts • Program Development Office • Sociology **School of Communication**	**Center for Global Peace** **School of International Service** **Office of International Affairs** **Public Safety**	**Washington College of Law**

Those units not assigned should contact the Director of the Office of Sponsored Programs at (202)885-3457

THE PRINCIPAL INVESTIGATOR

The individual responsible for conceiving and enacting a sponsored project is known as the principal investigator. When this individual takes on the task of preparing a proposal for submission to an outside source, he or she agrees to manage the ensuing grant or contract in compliance with the terms, conditions, and policies of both the sponsor and the University.

In general, only one principal investigator should be named to permit clear lines of responsibility for project management. In some instances, a colleague central to the project may be named deputy principal investigator or be given another appropriate title.

University Affiliation for Institutional Awards

The principal investigator must be a member of the full-time faculty, professional, or senior staff, or be an administrative officer of the University. Depending on the nature of the proposal, individuals with other University appointments may serve as principal investigators with the approval of the Provost and that individual's department head. Naming an individual in the proposal who is not already an employee of the University does not commit the institution to employing that individual.

In most instances, it is more appropriate to have the full-time faculty or staff member who will be responsible for the management and supervision of the project serve as the principal investigator and name the external individual as the Project Director. Any exceptions to this policy must have the written approval of the Dean of the unit and the Assistant Provost. On rare occasions, it may be in the best interest of the university to have an individual who is not an employee of the university serve as the principal investigator on a university proposal. All such exceptions to policy should be discussed by the Dean of the unit with the Assistant Provost well in advance of a proposal submission.

Unless otherwise indicated in the proposal, principal investigators are expected to be in residence at the University during the period of project operation. Principal investigators seeking a leave of absence during this period must obtain written authorization from the sponsor through OSP. Principal investigators must also secure the approval of their Dean and the Assistant Provost.

Occasionally, the person responsible for a project might not be from the unit delivering the program. In such instances, the person might be named principal investigator, and a faculty member from the teaching unit might be named as educational director.

All sponsored projects that utilize campus facilities (laboratories, classrooms, etc.), involve human subjects, animals, radioactive materials, or toxic substances, involve any other faculty, staff or graduate fellows as part of the project budget, or in any way affect the University, are subject to all University compliance regulations and must be submitted through OSP. Likewise, individual awards using University facilities are subject to University review and approval.

Individual Awards

Faculty and staff members may submit proposals for individual awards and fellowships, such as the Fulbright Scholar Program and the John Simon Guggenheim Memorial Foundation Fellowships. Unless specified by the sponsor, application for these awards does not require University approval, and awards are made directly to the individual. The awards generally provide remuneration for research being conducted during sabbatical leaves, leaves without pay, or in addition to regular University responsibilities. The OSP staff are available to assist faculty in identifying potential sources of funding, obtaining guidelines and application materials, and securing letters of nomination from the University administrators when necessary. The OSP staff will facilitate delivery of final proposal packages.

Conflicts of Interest

Conflicts of interest arise when employees use or appear to use their positions with the University for private gain at the expense of the University. Members of the University faculty and staff must avoid such conflicts of interest. The University has adopted the principles set forth by the American Council on Education in "On Preventing Conflicts of Interest in Government-Sponsored Research at Universities." **It is the policy of the Office of the Provost that an AU faculty member cannot serve as the Principal Investigator on a grant that goes through another institution. The AU Faculty Manual, Section 21-b, states that:**

> "Faculty members must ensure that outside activities do not conflict with responsibilities assigned them within the University and do not lead to fundamental conflicts of interest. Such conflicts include situations where a research or service activity that could and ordinarily would be carried on with the University is conducted elsewhere to the disadvantage of the University and its legitimate interests; situations where consulting or other services are provided to an organization that would put the University at a competitive disadvantage; involvement in a relationship that might enable (or appear to enable) the faculty member to influence the University's dealings with any outside organization in ways leading to personal gain or to other conflicts of interest."

Clarification regarding specific circumstances should be discussed with the Dean of the School/College and the Office of the Assistant Provost.

PROPOSAL DEVELOPMENT AND SUBMISSION RESPONSIBILITIES

In the course of developing and preparing a proposal, Principal Investigators, the OSP staff, the School/College Deans, and the Office of the Provost work together to ensure that a complete product is submitted to the sponsoring agency. Specific responsibilities are delineated below.

The Principal Investigator-

- Contacts OSP at early stages of project conceptualization.
- Writes technical narrative with guidance from OSP.
- Drafts list of costs for project.
- Discusses with teaching unit head and School/College Dean the intent to submit a proposal, and its benefits and implications.
- Secures approval of compliance committee(s) (for animal subjects, human subjects, or radioactive materials).

The OSP Staff Member-

- Identifies possible funding sources.
- Develops budgets and budget narratives within appropriate guidelines, verifying salaries and confirming costs.
- Coordinates with the University Development Office.
- Coordinates University pre-approval process in advance of proposal submission for those proposals over $250,000 and those proposals of any dollar amount that are sent to an international address.
- Completes proposal forms required by the University and the sponsor.
- Prepares capability statements appropriate to the project.
- Drafts transmittal letters to the proposed sponsor.
- Compiles complete proposal packages.
- Coordinates the University review process, securing necessary approvals and signatures.
- Has proposal packages copied and bound for submission.
- Submits proposal and copies to sponsor.
- Arranges for courier service, hand-delivery, or express mail.
- Distributes copies to signatories.
- Makes follow-up phone calls to monitor status of proposals.
- Coordinates budget revisions and re-submissions as necessary.
- Arranges for debriefings with prospective sponsors, as appropriate.

The School/College Dean -

- Reviews substantive content of proposal and examines proposal objectives in terms of the goals of the college and teaching unit.
- Allocates cost share resources for direct cost items.
- Allocates college resources to ensure that adequate space, facilities, equipment, and support services are available.

- Approves course release time and determines teaching replacement needs.

The Office of the Provost assisted by the Director of the Office of Sponsored Programs -

- Presents all requests for unilateral waivers of indirect costs requested by deans and principal investigators to the Provost for consideration.
- Approves exceptions to policy in consultation with the Provost.
- Confirms all faculty appointments pursuant to existing appointment procedures.
- Reviews proposals to determine that academic, legal, and financial interests of the University are preserved.

DEVELOPMENT AND MARKETING ACTIVITY

Funding Sources

The identification of potential funding sources for a research, training, or technical assistance project is the first step in designing a funding strategy. OSP provides a number of valuable services to faculty at this stage of securing outside support.

OSP maintains a library of source materials on private and federal sponsors. Many program descriptions, bulletins, newsletters, annual reports, and announcements are received regularly and are available for review. Faculty may visit OSP to browse through the library, or they may contact their assigned OSP staff member for a report on potential funding sources. For a brief overview of the general funding information publications, federal program guidelines, and private program guidelines in the OSP collection, see **Attachment I-A.**

A central component of the funder identification process at OSP is the use of a web-based database and matching service. SPIN (Sponsored Programs Information Network) is a listing of national and international government and private funding sources, updated daily. SPIN searching is used for one time searches of the database. SMARTS (SPIN Matching and Research Transmittal System) matches investigator profiles with the funding opportunities in the SPIN database and delivers automatic daily updates by email. GENIUS (Global Expertise Network for Industry, Universities and Scholars) holds profile data, both for use in SMARTS, and if desired by the investigator, for use by other investigators. If you complete the optional fields in the GENIUS profile, and release your profile for public searching, researchers seeking collaborators will be able to use GENIUS to match their interests to yours and to contact you.

To use SPIN, SMARTS, or GENIUS, go to http://www.infoed.org/officemenu.asp and select either SPIN, to do a one time search from any computer on campus, or GENIUS, to create or update a SMARTS/GENIUS profile from any internet capable computer. Instructions for database use and profile creation and editing are available on the InfoEd website. You can also access SPIN, SMARTS, and GENIUS from the OSP home page at http://www.american.edu/academic.depts/provost/osp/osphome.htm. If you need assistance with SPIN, SMARTS, or GENIUS, please call OSP at x3440.

After a library review or computer search, faculty will be prepared to choose one or more sponsors from whom they may wish to request financial support. In most cases, copies of program descriptions, application guidelines, and application forms will be available in OSP. Otherwise, the assigned OSP staff member will request the necessary application information from the sponsor.

Individuals interested in conducting sponsored research, training, or technical assistance projects are advised to visit OSP to discuss their interests with the assigned OSP staff member. If they advise OSP before they have a specific sponsor or approach in mind, the assigned staff member can inform them of funding opportunities in their areas of interest as these opportunities arise.

Proposal Types

A proposal to a funding agency for sponsored research may either be solicited or unsolicited. Solicitations are usually government-generated "Requests for Proposal" (RFP) or "Requests for Quotation" (RFQ) on a specific research, training, or technical assistance project. In such cases, the intended scope of work is pre-determined by the soliciting agency, and specific requirements for the format and content of both technical and cost proposals are presented in the published requests. The successful solicited proposal may result in either a contract or a grant. Government RFPs and RFQs are widely advertised and are monitored regularly by OSP staff.

Unsolicited proposals may be initiated by individuals at any time. Many funding entities have general requirements for the format of unsolicited proposals. OSP staff can contact the sponsor for guidelines or other indications of sponsor requirements.

Contract education and training is also supported by OSP and the Assistant Provost. OSP helps facilitate sponsored training and education programs by developing proposals with faculty and teaching units.

Pre-Submission Procedures

Particularly when unsolicited proposals are involved, it is wise to contact a program officer within a government or private funding agency to discuss a project idea before actually submitting a formal proposal. Most program officers welcome advance contact of this nature since it allows them to help potential principal investigators focus their research on areas of interest to their organizations. **In no case, however, should a private foundation or corporate entity be contacted with a funding request without the concurrence of the central University Development Office.** OSP staff members are responsible for obtaining concurrence from the central Development Office.

Agency contacts are made through (1) a telephone inquiry or agency visit; (2) a letter of inquiry; (3) a letter of intent; or (4) a preliminary proposal:

(1) Individuals are encouraged to make telephone inquiries on their own after discussing their projects with OSP staff. In some cases, the OSP staff member may make the initial agency contact on behalf of the faculty or staff member. Likewise, an individual may visit a potential sponsor alone or accompanied by a representative of OSP. Throughout the course of such calls or visits, no commitments of University resources should be made, nor should detailed budget figures be discussed.

(2) A letter of inquiry is a general presentation of a project idea designed to elicit feedback from a potential sponsor. As in telephone inquiries or agency visits, no commitments should be made. Individuals need not process such letters through OSP, and no formal routing or review is necessary, unless required by teaching unit heads or college deans. Individuals are encouraged, however, to forward a copy of such correspondence to their assigned OSP staff member so that OSP may be prepared for proposal development resulting from such inquiries.

(3) A letter of intent expresses the intention to submit a proposal in response to a particular program announcement or Request for Proposal (RFP). Letters of intent are generally solicited by the sponsor in conjunction with announcements expected to generate widespread interest. Agencies

generally require that such letters present only a general statement of the intended research theme. **If the letter of intent contains budget estimates or ranges, it should be reviewed by and routed through OSP prior to submission.**

(4) Preliminary proposals, like letters of intent, are generally solicited by sponsor agencies. A pre-proposal usually includes a one- to five-page description of the project. It may also require an outline budget and some indication of the University's willingness to support the project through a commitment of resources. **Any document that mentions budget figures or commits University space and other resources is subject to the review and approval of teaching unit heads, college deans, and the Assistant Provost.** The review and approval process is coordinated through OSP (see "Processing of the Proposal" for more information).

Note: The various sponsor approaches described above, while applicable to many situations, do not reflect the multiplicity of sponsor options. Unless the potential principal investigator has had previous experience with a particular agency or unless the program announcement/RFP states a specific course of action, the principal investigator should contact the OSP assigned staff member to determine the most appropriate avenue of approach.

University Pre-Approval Procedures

The Provost pre-approves proposals with a cumulative dollar amount of $250,000 or more, up to $499,000. Allow one week to obtain this approval. The following types of proposals will require additional time for university routing as the Provost, the Vice President for Finance and Treasurer, and the President review them.

- Proposals with a cumulative dollar amount of $500,000 or more.
- Proposals addressed to a funding source with a non-US address of any dollar amount.

Allow at least three weeks prior to the submission date for the review of such proposals. Contact your OSP staff member well in advance of such a submission so the review can be coordinated among the different offices.

Any proposals for programs requiring additional office space must be pre-approved by the Office of the Provost and the Office of the Vice-President for Finance and Treasurer. Any proposal that offers to bring foreign nationals to the United States for a program must be coordinated with the Office of International Student Services. Contact your assigned OSP staff member in advance of such a submission to begin the process.

Special Types of Funding

Intergovernmental Personnel Assignment Agreements (IPAs): Under the Intergovernmental Personnel Act of 1970, University faculty and staff may arrange to work with government agencies on a temporary basis, or federal government employees may arrange to work at the University. Since such assignments may incur fiscal commitments and liability on the part of the University, IPAs must be signed by an authorized University official.

To ensure accuracy and completeness, all IPAs must be directed through OSP for review, processing, and submission to the appropriate agency. The IPA should be forwarded with a Sponsored Programs Approval Form (used for routing proposals) and be signed by the appropriate

teaching unit and college officials, along with an acknowledgment of any cost-sharing commitments that may be required.

When government personnel come to work at the University under an IPA arrangement, such individuals serving in a faculty capacity are subject to the same appointment processes as other individuals being considered for faculty status. In all cases, teaching unit heads and college deans must be consulted to determine the impact of proposed IPA arrangements.

Government Fellowships: Some graduate fellowship programs sponsored by government agencies (such as the Fulbright-Hays through the U.S. Department of Education) require submission through the University. Students cannot be principal investigators, even if the fellowship is intended for them.

Compliance Issues

Important restrictions govern the use of human and animal subjects, radioactive isotopes, controlled substances, toxic materials, and hazardous chemicals, and research involving such items must adhere to federal, District of Columbia, and University policies. For more information and for the full texts of relevant policies, see **Section IV-Compliance Policies** of this Handbook.

Classified Research: The University does not accept sponsorship of research projects restricting publication of the results of the project, or prohibiting the free exchange of ideas. Investigators, however, may be required to protect product or by-product proprietary rights against disclosure.

Many funding agencies require that results and reports be submitted to the sponsors for the information, review, and comment before publication. The University accepts this practice, provided that such comment time does not prevent publication for more than 60 days. The University does not accept contracts requiring sponsor review and approval.

THE TECHNICAL PROPOSAL

When preparing proposals, remember to FOLLOW SPECIFIC SPONSOR INSTRUCTIONS regarding length, subject matter and organization. Your OSP staff member will ensure that all instructions for duplication, presentation and submission of the proposal are followed.

Preparation of the Technical Proposal

In general, proposals consist of two parts: the technical proposal, and the cost proposal or budget. The principal investigator is responsible for preparing the technical proposal in accordance with sponsor guidelines and requirements. Cost proposals are prepared by OSP with input from the principal investigator and, of course, the approval of the teaching unit head and the college dean. OSP prepares internal budgets, required sponsor budget forms, and internal routing forms explicating important financial arrangements and specifying the commitment of University resources. OSP staff also prepares all application forms accompanying the proposal submissions.

A good technical proposal is a concise and coherent explanation of a research or programmatic plan with specific and reasonable goals. These goals, and the methods that will be used to achieve them, must be stated clearly. Project objectives should conform to the interests and guidelines of the sponsoring agency. The technical proposal must also demonstrate a convincing need for the proposed activity, either by showing that it fills an important gap in existing knowledge, or by showing that it serves the needs of a specific clientele of particular concern to the funding source.

Concurrent with the preparation of a technical proposal, the principal investigator should contact the teaching unit head and college dean to seek approval and support for the project. Issues of time commitments, space, facilities, course releases, overload, and over base situations should be resolved prior to submission. OSP can aid the principal investigator on issues such as hiring additional staff or consultants, leasing space off campus, and/or entering into subcontractual agreements. Some of these require liaison between OSP and other University offices.

In addition, OSP prepares any subcontract documents in accordance with applicable sponsor policy. For example, the federal government mandates that certain terms and conditions must be included in all subcontracts involving federal "pass-through" funds; other sponsors may have similar requirements. In such instances, OSP transmits relevant material to the subcontractor for review and signature.

OSP also prepares "Teaming Agreements." These are understandings between two organizations working together on a proposal. "Teaming Agreements" must be routed in the same manner as a proposal to ensure that the school or college Dean is aware of the commitment to propose.

Checklist for Principal Investigators Developing a Proposal

To ensure the quality of the technical proposal, principal investigators should prepare answers to the following:

- What title or project name will reflect the name of the proposed research?
- What is the research problem or need for this activity? Have you reviewed current literature to determine the need for such a project or conducted a needs assessment?
- What do you hope to accomplish specifically as a result of this project?
- How will you accomplish the project goal? Why is your approach particularly suited to the problem? Discuss the activity concept, project structure, and/or formal methodology.
- How will you prove your results? An evaluation plan complete with measures of efficiency, effectiveness, or outcomes as appropriate to the project design and methodology should be described.
- What special compliance issues and risks are associated with the project? Discuss plans for IRB and /or Animal Care and Use Committee Approval, use of hazardous materials, or other risk management issues.
- Where will the project be conducted? Have space needs been evaluated?
- When will work on the project begin? When will it conclude?
- What are the qualifications for serving as the principal investigator on this particular project? Identify other skills and qualifications necessary to the activity and where/how you will provide that expertise.
- How much will it cost for you to perform this work? (This question can be fully answered only after the cost has been prepared with the assistance of the OSP staff. Effective technical proposals, however, should indicate bottom-line costs, along with the levels of effort to be invested by principal investigator and other key project personnel.)

After an initial draft of the technical proposal has been completed, the cost proposal, or project budget, can begin to be formalized.

General Format

Most sponsoring agencies have specific format guidelines for preparing proposals. In the absence of such guidelines, the following format may be useful.

Title Page

The title page should include:

- the title of the proposed research;
- the name and address of the sponsor to whom the proposal is submitted;
- the name and address of American University;
- the University department where the work will be carried out;
- the proposed period of performance;

- total requested support (in multiyear projects, include the total for the Year 1 as well as the total request);
- name and title of the principal investigator (see **Attachment I-B** for title page example.)

Abstract

While an abstract is not required by all sponsors, it is a highly effective means of presenting a project to a reviewer or review board. The abstract should highlight the scope of the proposed research, including its objectives and the intended methodology, the anticipated results, and a statement of potential significance. Abstracts should not exceed one typed, double-spaced page.

The abstract should stand alone as a complete description of the proposed project. Do not refer to figures, tables, or literature appearing in any other part of the proposal.

Table of Contents (List of Illustrations/Tables)

A table of proposal contents should be included immediately following the abstract page. A list of illustrations or tables should also be prepared, if appropriate. Since the abstract precedes the table of contents, it is not listed there.

Introduction to Proposal

While usually brief, the proposal introduction is one of the most important parts of the grant application. The introduction should engage the reviewer's attention, encouraging a full reading of the proposal. Statistically, proposals that are read through at one sitting have a higher rate of success. Here are some general guidelines for the preparation of the proposal introduction:

- tailor the introduction and the technical narrative to the specific guidelines or funding criteria of the sponsor;
- state the problem, but emphasize why you and/or the University should be funded to address the problem;
- mention your previous accomplishments in the area of research proposed;
- describe your ability to carry out the project proposed;
- construct the final paragraph of the introduction to lead into the next section of the proposal.

Note: Follow sponsor guidelines on length; in the absence of detailed guidelines, the introduction should not exceed two pages.

Description of Proposed Research

This description is a detailed extension of the proposal abstract. It should include a statement of past work that has suggested or made possible the proposed study, as well as a specific description of recent research. Indicate how the research will relate to and reflect the current state of the art. Explain project goals and methodology carefully. To the extent possible, describe in detail a research plan for six to twelve months.

It may be appropriate to justify certain budget requests in the technical proposal, especially if they are unusual or expensive (such as equipment that reviewers might expect to be part of the

University's facilities), or if the proposed research will require an unusual amount of costs for travel, publications or supplies.

Explain the tasks to be completed by all project personnel. Include current curricula vita for all senior project personnel. If postdoctoral associates and/or graduate or research fellows are known, submit their vita as well. OSP recommends that all curricula vita submitted follow a similar format. Always check sponsor guidelines for vita requirements with regard to required information, presentation, and length.

Bibliographies, tables, charts, illustrations, reprints and other supplementary materials may be included if they enhance the effectiveness of the presentation. Many sponsors, however, limit the number of pages of text; check to see if supplemental materials, such as appendices, are included in the page limit.

Proposal Typing

It is expected that Principal Investigators will do all proposal typing and formatting.

THE COST PROPOSAL

Procedure

Cost proposals detail the budget necessary to meet the objectives of the project. OSP, in cooperation with the principal investigator, is responsible for preparing the budget to ensure that it complies with specific sponsor requirements and University policies and practices. Budget formats vary according to sponsor guidelines. In addition to budget forms required by the sponsor, OSP prepares an "internal budget" adhering to University format.

The internal budget may include more categories than the sponsor's form, and is often submitted with the full proposal. The internal budget can also be used if the sponsor does not provide any budget forms.

The principal investigator should begin estimating costs as soon as the parameters of the technical proposal are established. OSP can assist in preparing a draft budget based on that information. In preparing budgets, there are University guidelines that must be followed. A "Summary of Budget Assumptions for the Preparation of Proposals" and an annotated sample budget are provided in **Attachment I-C**.

Budgets for credit instructional programs, or projects that provide training for private sponsors are developed with the consultation and approval of the University Budget Office. The OSP staff assist in such instances. Such budgets follow an internal format prescribed by the University.

Components

Budgets include two categories of costs: Direct and Indirect Costs.

DIRECT COSTS

Usually, Direct Costs consist of the following:

Salaries & Wages: All personnel who will devote time to the project are listed in the budget. Include titles, the percentage of time to be spent on the project, base salaries, and the amount the sponsor is asked to pay to support each person for the budget period (or their individual period of performance).

Proposed salaries are estimates and are paid in accordance with established University guidelines. Salary estimates beyond the current fiscal year should include merit increases (which are not guaranteed) based on the approved Budget Assumptions. Pursuant to federal regulations issued by the Office of Management and Budget (OMB), salaries charged to sponsored agreements may never exceed the proportionate share of the employee's base salary for that period (based on level of effort applied to the project). OMB regulations further instruct that rates of pay may not be other than the employee's base salary with the University. These regulations apply only to federal contracts or to Principal Investigators who have a combination of federal and private funding.

Staff positions committed at 80 percent or more of time to a sponsored project and on some other university supported work are considered full-time. New staff must be classified and recruited by the Office of Human Resources. OSP can assist in obtaining a "provisional" classification and salary base from Human Resources. The twelve-month salary for a staff person is the base salary. Staff supported by sponsored funds may be permanent or temporary appointments hired for the project specifically.

Faculty salaries are based on nine months of full-time service during the twelve-month academic year (AY). This income is the base salary. Sponsors differ on providing funds for the summer salary. In general, the federal government permits faculty members to earn up to 133% of base salary in a twelve month period, including summer teaching, summer research, and administrative stipends, if the faculty member is being paid with federal funds. The University is responsible for the administration and compliance with this policy. Therefore, a faculty member who performs additional work during the three summer months may earn up to one-third (33%) of base salary in that period, depending, of course, on availability of funds. Faculty working on projects with non-federal sponsors (and not having any concurrent federally sponsored activity) may exceed 133% if funds are available.

Some proposals involve course releases, a reduced workload, or a workload reallocation for a faculty member to work on an externally funded grant or contract. The faculty member's time may be paid for by the funding source or may be cost-shared by the University. For budget preparation and research planning purposes, the University uses the following assumptions about the allocation of a faculty member's time:

- teaching, 60%
- research, 30%
- service, 10%

Based upon the University's average five (5)-course load for tenured and tenure track faculty a course release can be calculated in two ways. The first is done by allocating 24% of effort during a semester to a sponsored project. The second is done by allocating 12% of effort for the entire academic year to a sponsored project. If more than one course release is requested in a year, the allocations will change. These are guidelines, however, and the final decision regarding course releases are made by the respective dean, based on the teaching unit's needs.

Graduate research appointments are for eight months of academic year support, with a possibility of additional summer support. University sponsored graduate finanacial aid awards do not include a service requirement; however, graduate students working on a sponsored project will be required to work to receive a stipend and up to eighteen (18) hours of remitted tuition. Monthly stipend and tuition remission are appropriate charges to some sponsors.

Fringe Benefits: Fringe benefits consist of the University's contributions to Social Security (FICA), retirement programs (such as TIAA/CREF), health insurance, disability insurance, life insurance, workers' compensation, unemployment compensation, and tuition remission. Fringe benefits are calculated as a percentage of salary.

A fringe benefit rate of 25.5% is charged on the salaries of full-time faculty and staff. A rate of 8% is charged on the salaries of part-time employees, student employees, and faculty working during the summer months. The fringe benefit rates are predetermined for a specified period from

the University's cognizant government agency; the current rates are in effect until April 30, 2008 and are provisional after that time.

Consultants: Consultants provide expertise from outside the University. Consultant rates are subject to approval by the sponsor. Supporting documentation for the rate based on education, work experience, specialized technical expertise, and prior rates of pay as a consultant should be available upon request. Each consultant must sign a consultant agreement, prepared by OSP in advance of the work performed. **Attachment I-D** is an example of a consultant agreement document developed by OSP. Additional clauses necessary for an effective agreement vary depending upon circumstances.

Intra-university consulting is normally undertaken as a University obligation with no additional compensation. In some instances, when consulting is performed in addition to one's regular teaching unit load, compensation above base salary may be possible if approved in writing by the sponsor and the Assistant Provost.

The following are some helpful definitions that are used for accounting purposes or purposes of negotiating grants and contracts. These definitions do not apply to non-sponsored arrangements such as occasional overload teaching, which is discussed in the Faculty Manual.

- **base salary -** the amount of salary a faculty member is paid for nine months of full-time service during the academic year.
- **overbase situation -** when a faculty member performs additional work during the summer months (June, July, and August) resulting in payment beyond the contracted salary base. Overbase beyond 133% of base salary is not permitted for faculty working all or in part on federally sponsored projects. Faculty working on projects with non-federal sponsors (and not having any concurrent federally sponsored activity) may exceed 133% during the summer or academic year.
- **overload payments -** when a faculty member commits more that 100% of their time to teaching, research, and consulting activities. Overload for teaching is discouraged, as stated in the **Faculty Manual**. Overload payments for sponsored activity are not permitted during the academic year without advance approval of the Assistant Provost, with the concurrence of the School/College Dean.

Subgrants and Subcontracts: Subcontracts are made with companies or organizations that will provide outside expertise to a grant or contract. Before an agreement is made with an outside contractor, efforts should be made to see if the expertise could be secured within the university. The subcontractor should provide a scope of work and a detailed budget for its portion of a sponsored program. Subcontractors may also provide cost-share for a program. Both types of commitments must be sent to the university in writing and signed by a person authorized to commit the organization. If 50% or more of the requested funding will go to a subcontractor, a justification should be prepared by the PI and included on the routing form. If an award is made, a subcontractor must sign an agreement prepared by the university.

Capital Equipment: Principal investigators should discuss potential equipment purchases with the OSP staff to ensure adherence to University and sponsor policies.

Travel: Sponsors will generally pay international or domestic airfare if such travel is necessary to the project and is so justified and approved. For federally sponsored projects, all international travel must be on U.S. flag carriers. In accordance with University policy, food and lodging must be shown as reimbursable expenses. Also included should be local transportation costs, such as mileage and parking. While per diem reimbursement for travel on government contracts is set by the federal government on a city-by-city basis (and published in The Federal Register), the use of these rates still requires prior University approval, requested from the Controller's Office through OSP.

University employees are required to report international travel in advance of the trip to their academic units so that special international travel insurance may be arranged for them at no additional cost. In the case of students traveling abroad on a sponsored project, this insurance must be arranged for them through the university and the cost of the insurance must be charged to the grant budget. Please see **Attachment I-E** for further details. This information is also accessible at http://www.american.edu/finance/rmo/insurance.html.

Other Direct Costs may include:

- Supplies and other expendable materials, such as film;
- Computer software;
- Equipment maintenance and repair;
- Printing and publishing;
- Photocopying;
- Publication costs, such as page charges and reprints;
- Communications: telephone, postage, express mail, fax, and courier service costs;
- Meeting expenses;
- Conference registration costs;
- Space (lease or rental of off-campus space);
- Insurance.

INDIRECT COSTS (Facilities and Administration Costs) - Also Known as Overhead

Indirect Costs (F&A Costs) are expenses incurred by the University for its facilities and services. Indirect costs are not profit, but are real costs to the University to support sponsored activities. Examples include building maintenance and operation, utilities, libraries, computer services and other facilities, payroll, accounting, purchasing, research administration, departmental administration, personnel services, and general administration. The University attempts to recover all of these support costs, in accordance with guidelines in the Office of Management and Budget Circulars, through the inclusion of indirect costs in proposal budgets.

Indirect costs must be included in the budget of every proposal. The University uses separate indirect cost rates for sponsored projects on and off campus. The University and the U.S. Department of Health and Human Services (DHHS), which is its cognizant federal agency for indirect rate negotiation, have agreed on the current negotiated indirect cost rate for federal contracts and grants in specified fiscal years. An equivalent rate must be applied to projects that are

funded by private and nonfederal sources, pursuant to the agreement with DHHS and the Office of Management and Budget (OMB), Circulars A-21 and A-110.

American University has a new Negotiated Indirect Cost Rate Agreement effective May 1, 2005 and valid through April 30, 2008. The new rate assesses indirect costs on a Modified Total Direct Cost basis. The OMB Circular A-21 G.2 states that the Modified Total Direct Costs basis excludes assessment of indirect costs on tuition, capital expenditures, space rental, sub grants or subcontracts in excess of $25,000, and participant support costs. Participant support costs are defined as pass-through costs to support program participation directly attributable to an individual who is not an employee of AU or a consultant providing a service.

The new rate agreement may be viewed on the web page of the Office of the Controller at http://www.american.edu/finance/genacct/. The circular may be found at (http://www.whitehouse.gov/omb/circulars/a021/a021.html).

Some sponsors, particularly some foundations, have specific written policies that preclude the use of the full indirect cost rate. Some agencies limit indirect costs for instructional (or training) programs. Pursuant to approval of the Provost, the Director of OSP will honor sponsor prohibitions, or limitations on indirect cost recovery, that represent the written regulations of the sponsor. By contrast, for unilateral waivers of all or part of indirect costs by the University, a written justification from the principal investigator with the concurrence of the school or college dean, must be submitted to the Director of OSP through the established process. After OSP review, the request is submitted to the Provost through the Assistant Provost for final decision. Budgets with less than full indirect cost recovery must be justified on the basis of their special value to the University, or on the resulting competitive advantage.

Cost Sharing

Occasionally, sponsors require the University to make a contribution to a project's total cost needs. **Cost sharing must have the concurrence of the teaching unit head and School/College Dean since their budgets bear such direct costs. Each college has a budget to cost share new expenses, and the authority to commit existing "on-budget" resources for sponsored projects. OSP has no resources for direct cost share or tuition remission.**

Since cost sharing is examined and audited by the sponsor organizations, the budget proposal must specify the exact amount of contributions anticipated. The term "in-kind services" (for example, in the case of faculty time donated to a project) is difficult to audit and should be avoided. Instead, the budget proposal should include the dollar value of all such services, to ensure the project receives full credit. Contact the OSP staff member for assistance with cost-sharing issues.

Subagreements

A subagreement may be either a subcontract or a subgrant, each of which is an agreement between the University and a third party to transfer a portion of the University's obligations on a sponsored project to that party.

If a proposal includes the use of subagreements, the principal investigator should include an explanation of why the price to be paid to the subcontractor or subgrantee is appropriate and

reasonable. Estimates obtained from the proposed subcontractor should be attached to the budget proposal. Federal agencies often require a separate Cost and Pricing Proposal and appropriate Subcontractor Certifications, in accordance with the Truth-in-Negotiations Act.

Principal Investigators should identify each subagreement separately in the budget proposal. Sponsor approval of the proposal normally constitutes approval of the subagreements that are included in it.

Subagreements are not executed until the grant or contract has been awarded. Subagreements are undertaken through the University's regular procurement process. OSP prepares and negotiates subagreements to conform to appropriate federal requirements.

Subagreements are developed by the assigned OSP staff working closely with the Principal Investigator. Once the subagreement has been finalized, OSP sends it to the Director of Procurement and Contracts under the Office of the Vice President for Finance and Treasurer (VPFT) for the university signature.

PROCESSING THE PROPOSAL

After the technical and cost proposals are complete, the principal investigator prepares the other forms to be included in the application packet. Proposals are submitted with a transmittal letter from the Assistant Provost, the Dean of the School or College, or the Director of OSP to the sponsoring agency. Transmittal letters often clarify the University policies on budgeting or other issues. OSP prepares the transmittal letter, and processes the proposal through the University's routing and approval procedure.

The University has a standard Sponsored Programs Approval Form, which must accompany each proposal through the University's approval process. A copy of the form is provided in **Attachment I-F.**

Routing through the University

Once the approval form, the technical proposal, the budget proposal, and all attachments are prepared, OSP will obtain the required signatures.

The final submission represents an offer by the University to perform the activities specified in the proposal. The review and approval process ensures compliance with both sponsor and University policies.

As the certifying official for the university, the Institutional Signatory requires sufficient time to review and sign proposals. A proposal must be in the office of the Institutional Signatory twenty-four (24) hours before it is due. Proposals that reach the office on the day they are due will not be signed unless the Dean of the School or College makes a special request.

For proposals under $250,000 going to a U.S. address, you should allow a minimum of one week for the review and signing of the approval form. Proposals that have a cumulative total of $250,000 and more and proposals of any amount going to an international address must have completed the University's pre-approval process as detailed on page 1-9. Allow three weeks prior to the submission date of such proposals for the pre-approval process.

Signatures required vary with the type of project being proposed. When the principal investigator signs the approval form, he or she is approving the entire proposal and assuming responsibility for

- the scope of scientific and technical effort,
- preparation of required technical reports, and
- management of the project within the budget and time constraints of the proposal in compliance with sponsor regulations and University policies.

The principal investigator may not delegate his or her authority to approve proposals.

Teaching unit heads and college deans certify the academic soundness of the project, facility and space availability, cost sharing (other than any indirect cost waiver that is a documented sponsor policy), course release arrangements, and the compatibility of the project's goals with the teaching unit's objectives.

Proposals are routed through the teaching unit, School/College Deans, and the Assistant Provost/Director of OSP. A project involving faculty or staff from more than one unit must be routed through all units involved. Projects that provide credit as part of the overall project must be priced by the University Budget Office as well as approved on the routing form. OSP can assist in the preparation of these budgets but receives final approval for pricing from the Budget Office.

Photocopying and Presentation

OSP does all copying in-house unless the sponsor requires certain types of copying which OSP cannot provide. In such a case, OSP will arrange for the proposal to be copied commercially. In order to provide this service, OSP will need sufficient lead time to process proposals.

Submission of Proposal

After a proposal has been reviewed and approved, OSP will forward the required number of copies to the sponsor, along with a transmittal letter. Copies of the completed proposal package will be distributed internally to each university signatory after submission to the sponsor.

Responses to RFP's or special programs notices must be sent to the address indicated on the cover sheet of the RFP and *must be received* by the time and date indicated on the RFP. Sponsors can reject late proposals.

While unsolicited proposals may be submitted at any time, principal investigators should allow six to nine months between the date of submission and the anticipated starting date for the project. In general, proposals to be funded in a particular federal fiscal year (which ends September 30) should be submitted no later than February.

Electronic Proposal Submission

Frequently sponsors require electronic submission of proposals. Systems range in complexity from the National Science Foundation's Fastlane to requests for e-mail files. OSP maintains upgraded computer equipment and staff resources to assist Principal Investigators with electronic submission.

Due to the difficulties inherent in the electronic submission process, OSP cannot guarantee the timely submission of proposals that are sent less than 48 hours before the due date. Proposals that do not meet the advance submission requirement of 48 hours will be accepted and OSP will attempt to send the proposal. Missing the advance submission requirement will mean that, should the sponsor system be having difficulty, OSP may not be able to make alternative arrangements with the sponsor in time for the legal due date.

Delivery

The letter of transmittal, the original signed proposal and budget, and all the required copies are delivered by courier in the D.C. area, or mailed to the sponsor via first-class, certified mail with return receipt requested. OSP facilitates delivery of the proposal to the sponsor, including arrangements with an air courier or express mail service when necessary.

Submission of Revisions

Revisions to the cost proposal are often necessary as a result of negotiations with the sponsor prior to the award of the grant or contract. Sometimes the technical proposal must also be revised. Review and approval of budget and technical revisions should follow the same procedures as indicated for the original submission.

Attachment I-A

DATABASES, PUBLICATIONS, AND GUIDELINES AVAILABLE AT OSP

The following source materials are among the most widely used in OSP by faculty and staff:

Federal Grants and Contracts Weekly -
Published by Capitol Publications, Inc., Alexandria, VA. Lists grants offered by the Department of Education, HUD, DOD, HHS, NEA, NRC, EPA, and offers basic rules for grant applications.

The Grant Advisor -
Published monthly, distributed to colleges and universities. Grant opportunities from federal agencies and private sources, including a deadline listing, in the fine arts, humanities, sciences, social sciences, education, international, and health related areas.

Files for each federal agency and department, with application packages and recent announcements, are also maintained in the OSP library.

In addition, the following annotated list is an overview of other source materials available in OSP.

DATABASES

The Chronicle of Philanthropy's Guide to Grants -
The *Guide to Grants* is an electronic database of all corporate and foundation grants listed in *The Chronicle of Philanthropy* since 1995.

The Foundation Directory Online -
Find funders fast with the most comprehensive and current online database of foundations and their grants. *The Directory* includes weekly information updates, direct links to foundation and other nonprofit tax returns and websites, daily search tips and quick-links to free web resources, a subscribers-only message board to share tips and strategies, and search tutorials that give you step-by-step instruction on how to develop effective search strategies and reliable prospect lists.

GrantsDirect -
The GrantsDirect database focuses on tracking and profiling new foundation creation nationwide. The GrantsDirect.com database lists thousands of organizations that have received grants from hundreds of foundations.

National Directory of Corporate Giving -
Published annually by the Foundation Center, this comprehensive directory features up-to-date information that helps fundraisers tap into their share of grant money earmarked by companies for nonprofit support. Provides current data on close to 4,000 corporate grantmakers and includes over 7,600 descriptions of recently awarded grants.

PUBLICATIONS

Arts & Culture Funding Report -
A monthly report on federal, state, private, and non-profit sector financial aid for arts and cultural projects. Includes foundation and federal grants alerts as well as a "spotlights on the arts" feature.

Chronicle of Higher Education -
The *Chronicle* has a regular grants feature in this weekly publication. The grants section highlights a range of opportunities and recent awards and summarizes recent legislation and regulations affecting higher education. It is also a source for identifying individual award opportunities.

Chronicle of Philanthropy -
Published biweekly, this publication covers news of corporate and individual giving, foundations, fundraising, and other issues of special interest to non-profit organizations.

Federal Acquisition Circular -
This publication is issued by DOD and NASA as an update on Federal Acquisition Regulations (FAR) applying to sponsored contracts. The updates focus on clarification of the FAR for DOD/NASA contractual issues, although the FAR is applicable to all federal agencies and departments.

Federal Grants Management Handbook -
How to comply with federal requirements for non-discrimination, environmental, historic preservation, labor standards, drug-free workplace, freedom of information, privacy, disclosure, and patents and copyrights. Reviews prohibited activities, the judicial and administrative process, and procedures and controls.

Foundation & Corporate Grants Alert -
A monthly newsletter with updates on funding opportunities, new foundations and hard to find regional funders. Detailed grant notices alert you to upcoming proposal deadlines, funding levels, funders' priorities, and the program officer's name and phone number.

NASA Grant and Cooperative Agreement Handbook -
Handbook issued by NASA detailing regulations for administration of NASA research grants and cooperative agreements.

National Science Foundation Bulletin -
The *NSF Bulletin* provides monthly news about NSF programs, deadline dates, publication meeting, and sources for information, including telephone numbers.

NIJ Reports -
NIJ Reports is a bimonthly journal of the National Institute of Justice, the research area of the U.S. Department of Justice that announces the Institute's policy-relevant research results, publications, and initiatives.

Report on Research Compliance -
A monthly newsletter (and free email versions of the monthly) with practical news you can use on your campus with the best information there is to help institutions avoid the negative publicity, financial setbacks, and management problems that compliance requirements can create.

REFERENCE BOOKS

A Guide to Managing Federal Grants for Colleges and Universities
This comprehensive 900+ page looseleaf handbook helps colleges and universities manage federal funds effectively and provide the necessary tools to reduce the chances of disallowed costs, lost funding, compliance problems and public relations nightmares.

Directory of Operating Grants -
A reference directory identifying general operating grants available to nonprofit organizations.

Federal Yellow Book -
Provides information on how to contact more than 31,000 top people in the Executive Branch. Provides phone numbers, addresses, and titles. Listed by department and office.

Guide to Greater Washington DC Grantmakers -
A yearly publication, this directory lists foundations by asset size, grants awarded, and independent, corporate, and community sponsorship. Foundations are divided by assets of over or under $1 million.

SRA Journal -
The journal of the Society of Research Administrators contains several essays discussing the role of research administrators, issues in research administration, and management theory and practice.

SRA Membership Directory -
Index of members of the Society of Research Administrators.

Attachment I-B:

SAMPLE TITLE PAGE

"Creating Clean Waters in the Tributaries of the Potomac River"

A Proposal Presented to

Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

by

American University
College of Arts and Sciences
Department of Biology
4400 Massachusetts Avenue, NW
Washington, DC 20016

Period of Performance: September 1, 2005 - January 15, 2007

Amount Requested: $244,562

Principal Investigator: Dr. Mary Jones, Professor

Attachment I-C

Summary of Budget Assumptions for Preparation of Proposals

I. PERSONNEL

1. Faculty and Staff salaries

a. All faculty and staff salaries are verified at the beginning of the budget process with the Office of the Dean, or Executive Head of the proposing unit.

b. New staff salaries are estimated (generally at mid-point of range) in consultation with the Human Resources Office.

c. Proposed salaries are estimates and will be paid in accordance with established University guidelines.

d. Faculty salaries are based on a 9-month Academic Year (AY) even if they are paid on a 12-month basis.

e. Faculty are limited to 133 % of base salary in a 12 month period if the faculty member is being paid partially or in full on a federal grant. If no federal funds are involved, faculty may exceed the 133% limit.

f. Staff salaries are based on a 12-month Fiscal Year (FY) or Calendar Year (CY).

2. Stipends for Graduate Assistants

Different stipend rates may be used if published and approved as a distinct class or cohort of fellowship by the University. Each School/College is responsible for establishing and publishing fellowship opportunities and job descriptions as well as stipend amounts. The OSP Staff can assist in establishing stipend rates for the proposal.

For succeeding academic years, the OSP Staff can provide pricing information for budgeting purposes.

3. Graduate Study Grant Recipients receive no stipend.

4. Hours (for calculation of level-of-effort costs) for Staff

a. Calendar Year/Full Year (CY/FY) -

	Based on a 40-hr. week	Based on a 35-hr. week
Hours:	2,080	1,820
Days:	260	260
Months:	12	12

b. Academic Year (AY) -

Based on an 8-hour day	
Hours:	1,560
Days:	195
Months:	9

c. Staff hired at 80% time for 9 months are considered full-time, permanent positions (which must be classified by and recruited through the Human Resources Office). Costs may not be calculated at an hourly rate.

d. The academic year for Graduate Assistants/Graduate Study Grant Recipients is September 1 through April 30 (8 months); the summer is May through August.

5. Salary increases

a. This sentence should be included in a footnote on all proposals:

"Salary estimates include merit increases, which are not guaranteed."

b For purposes of preparing subsequent year budgets, full-time faculty salaries should reflect a 5% increase each September.

c. For purposes of preparing subsequent year budgets, full-time staff salaries should reflect a 5% increase each September.

6. Graduate students

a. Externally Sponsored Graduate Assistants: The full-time service requirement is 20 hours per week, or half-time at 10 hours per week, September-December, January-May, for 32 weeks during the academic year. They receive a stipend and up to 24 hours of remitted tuition.

b. Externally Sponsored Graduate Study Grant Recipients: The full-time service requirement is 10 hours per week, or half-time at 5 hours per week, September-December, January-May, for 32

weeks during the academic year. They do not receive a stipend, but they do receive up to 24 hours of remitted tuition.

c. Summer Research: There may be opportunities for summer research work. Arrangements for such opportunities need to made with the Principal Investigator and with the approval of the School or College.

d. Research Assistant: An option for employment of graduate students is to hire them on an hourly wage basis under the labor code "Research Assistant." For students employed in this manner, there are no tuition remission benefits.

e. Both Graduate Assistants and Graduate Study Grant Recipients must be full-time students in good standing at the University.

f. Exceptions to these policies must be approved in advance by the Assistant Provost

II. FRINGE BENEFITS

1 A rate of 25.5% will be charged on the salaries of full-time faculty during the AY and staff during the CY.

2. A rate of 8% will be charged on the salaries of part-time and student employees (but not graduate assistants) during the academic year and the summer.

3. All full-time faculty are considered "part-time" for accounting purposes in June, July and August, and a rate of 8% is charged on their salaries during the summer months. There are no contributions to retirement during this period.

4. These rates will remain in effect until April 30, 2008 per the University's rate agreement with its cognizant government agency. The rates are provisional after that date.

5. Vacation, holiday, sick leave pay and other paid absences are included in salaries and wages, and are routinely charged to grants and contracts, and separate charges for the cost of these absences are not made.

6. The costs of the following benefits are included in the full-time employees' fringe benefit rate:

FICA (Social Security)
Workers' compensation
Unemployment compensation
Health insurance
Life insurance
Disability insurance
TIAA/CREF (Retirement)
Tuition remission

7. The cost of the following benefits are included in the part-time employees' fringe benefit rate:

FICA
Workers compensation
Unemployment compensation
Note: These are the benefits paid for full-time faculty who are employed by the University during the summer.

III. TRAVEL

1. Mileage: Please check with OSP Grant and Contract Manager. The University uses the IRS published rate. As of January 2006, this rate $0.445 per mile.

2. Per Diem:

A. Reimbursement for travel on government contracts is limited to per diem travel rates established by the federal government for the specific city. For international travel (as well as Alaska and Hawaii) per diem rates visit http://www.state.gov/m/a/als/prdm/. For per diem rates for domestic travel, excluding Alaska and Hawaii visit http://www.gsa.gov/Portal/gsa/ep/channelView.do?pageTypeId=8203&channelId=-15943 You can obtain further information by calling an OSP staff member.

B. As a general rule, flat rate per diem payments on sponsored projects do not require original receipts or other documentation unless required by the grant or contract. **Prior written approval from the Office of the Controller through OSP is required, however, to use flat rate per diem**.

C. Travel performed under a sponsored project is subject to restrictions imposed by the sponsor.

IV. TUITION

1. Graduate student tuition remission for academic year 2005-2006 is $989/credit hour. For succeeding academic years and other categories of tuition remission (e.g., undergraduates and law students), the OSP staff member can provide pricing information for budgeting purposes.

2. Tuition remission may not exceed 24 hours per year without prior approval of the School/College Dean, and the Assistant Provost. Unused tuition remission hours cannot be carried forward to a subsequent academic year.

3. Research Assistants (not a Graduate Assistant or Graduate Study Grant Recipient-see I.5.d. of this Attachment) working solely on an hourly wage (part-time or temporary) are not entitled to tuition remission.

V. OTHER

1. Printing and typesetting costs: Estimates are provided by University Publications (Ext. 5970).

2. Equipment maintenance: Estimates are provided by the Purchasing Office (Ext. 3811).

3. Maximum consultant rate: Consultant rates are subject to approval by the sponsor. Supporting documentation for the rate based on education, work experience, specialized technical expertise, and prior rates of pay as a consultant should be available upon request. All consultant rates for nonfederal sponsors are subject to approval by the Dean of Academic Affairs.

4. Animal care costs: Please check with Compliance Administrator in OSP.

VI. INDIRECT COST RATES *on a Modified Total Direct Cost basis. The OMB Circular A-21 G.2 states that the Modified Total Direct Costs basis excludes assessment of indirect costs on tuition, capital expenditures, space rental, sub grants or subcontracts in excess of $25,000, and participant support costs. Participant support costs are defined as pass-through costs to support program participation directly attributable to an individual who is not an employee of AU or a consultant providing a service* - 5/1/05 -4/30/08

On-campus All Programs 39%

Off-campus adjacent (within 50 miles of AU) All Programs 13.1%

Off-campus non-adjacent (more than 50 miles from AU) All Programs 11.1%

Note: if 50% or more of the indirect cost rate base is on-campus, the entire project is considered on-campus.

1. This statement should be included in each budget submission:

"The University's full indirect cost rate is applied in accordance with the effective Indirect Rate Agreement negotiated with The Department of Health and Human Services, the University's cognizant auditing agency."

2. No overhead charges are allowed on IPA Agreements. They are viewed strictly as personnel actions (Title IV of the IPA Act, Chapter 334 — this is an all-federal policy). On occasion, if allowed by the Sponsor, an administrative fee of up to 10% is requested for an IPA.

Sample Budget

Title: Creating Clean Waters in the Tributaries of the Potomac River
Sponsor: Environmental Protection Agency (EPA)
Duration: September 1, 2002 - August 31, 2003
Year: 1 9/1/02 - 8/31/03

				EPA	NOTES
I. Personnel					
A. Principal Investigator/Project Director					
Dr. Mary Jones					
1. 9/1/02 - 1/15/03					
	24%effort @	$33,450	/AY	4,014	Faculty salaries are based on the 9 month academic year (AY). For this sample budget, we are assuming that both Drs. Jones and Smith have a five course teaching load. 24% effort may yield one course release during one semester.
2. 1/16/03 - 5/31/03					
	20%effort @	$33,450	/AY	3,345	
3. 6/1/03 - 8/31/03					
	100%effort @	$33,450	/AY	11,150	Calculated at 1/9 of the AY salary for each summer month
B. Project Coordinator					
Dr. John Smith					
1. 9/1/02 - 5/31/03					
	12%effort @	$31,700	/AY	3,804	12% effort may yield one course release during the full academic year.
2. 6/1/03 - 8/31/03					
	100%effort for 1 month @	$31,700	/AY	3,522	Calculated at 1/9 of the AY salary for each month of the summer.
C. Administrative Assistant					
To be selected					Staff salaries are based on a 12 month full (FY) or calendar (CY) year. A staff person is considered to be a full-
1. 9/1/02 - 8/31/03					
	100%effort @	$18,000	/FY	18,000	

		time employee if he/she works at a minimum of 80% effort.
D. Graduate Fellow		
To be selected		Graduate Fellows must be full-time students. The full-time service requirement for Graduate Fellows is 20hrs/wk Sept.-April. They receive a stipend and tuition remission.
1. 9/1/02 - 4/30/03		
Stipend @ $8,500	8,500	
		Fellowships may be considered.
2. 5/31/03 - 8/31/03		
Stipend @ $8,500	8,500	The full-time service requirement for Graduate Fellows in the summer is 40hrs/wk May-Aug. They receive a stipend and tuition remission.
E. Graduate Assistant		
To be selected		Graduate Assistants must be full-time students. The full-time service Requirement for Graduate Assistants is 10hrs/wk Sept.-April. They do not receive a stipend, but do receive tuition remission.
1. 9/1/02 - 4/30/03		
Tuition remission only		
(See "Other Direct Costs")		
F. Research Assistant		
To be selected		Graduate students may be hired on an hourly wage basis. They do not receive tuition remission.
1. 9/1/02 - 4/30/03		
100 hrs @ $13/hr	1,300	
G. Student Assistance		
To be selected (5)		Undergraduate students may be hired on an hourly basis to assist on grant/contract work.
1. 9/1/02 - 8/31/03		
125hrs x 5 students @ $8/hr	5,000	
Subtotal Personnel	$67,135	
II. Fringe Benefits		
@ 25.5% of IA1,2,B1,C		A rate of 25.5% is charged on the salaries of

	base:	$29,163	7,437	full-time faculty and staff.
@	8% of IA3,B2,F,G base:	$20,972	1,678	A rate of 8% is charged on the salaries of part-time and student employees. Faculty
	Subtotal Fringe Benefits		$8,969	are considered part-time in June, July and August.

III. Consultants

To be selected

1. 2 @ $400/day x 4 days	3,200	
2. 1 @ $200/day x 5 days	1,000	
Subtotal Consultants	$4,200	

IV. Subcontract

A. Arbour Water Analysis, Inc.

1. Data collection and water testing	27,455	
Subtotal Subcontract	$27,455	

V. Travel

A. Project Director, Project Coordinator and Graduate Fellow travel to annual meeting of professional society

1. Air Fare RT: DC - LA - DC 3 @ $570	1,710	
2. Per Diem 5 days @ $145/day x 3 in Los Angeles	2,175	Current federal per diem rate for Los Angeles.
3. Ground transportation (To/from home/airport/hotel) 3 @ $50/person/trip	150	
4. Local transportation 5 days @ $10/day x 3	150	
5. Conference registration fees 3 x $425/person	1,275	

B. Local transportation costs

1. Mileage to river sites/from AU		Based on the current federal mileage
11 miles RT @ $.36/mi x 20 trips	79	allowance.
2. Metro/taxi costs to EPA from AU @ $10/trip x 6	60	
Subtotal Travel	$5,599	

VI. Supplies			
	A. Hardware and guard columns for LC	500	
	B. Chemicals, glassware	800	
	C. General office supplies @ $20/mo	240	
	D. Computer software	600	
	Subtotal Supplies	$2,140	
VII. Other Direct Costs			
	A. Electron Capture Detector for GC	4,100	
	B. IBM-compatible computer	1,500	
	C. Interface	500	
	D. Printer	475	
	Subtotal Equipment	$6,575	
VIII. Other Direct Costs			
	A. Communications costs		
	1. Long distance telephone @ $15/mo	180	
	2. Postage, courier, FedEx @ $35/mo	420	
	3. Photocopying @ $20/mo	240	
	B. Equipment maintenance @ $13/mo	156	
	C. Immunization of staff	300	
	D. Hardware and guard columns for LC	500	
	E. LC maintenance @ $42/mo	504	
	F. Tuition Remission		
	1. Graduate Fellow		Cost per graduate credit effective 9/1/02
	24 hrs @ $827/hr	19,848	for the '02/'03AY. For Graduate Fellow:
	2. Graduate Assistant		up to 18 hrs/AY, 6hrs/SR. For Graduate
	18 hrs @ $827/hr	14,886	Assistant: up to 18hrs/AY, 6hrs/SR.
	Subtotal ODC	$37,034	
IX. Total Direct Costs		$159,255	TDC (total direct costs) are ALL costs associated with project, before indirect costs are applied.
X. Indirect Costs			
	Modified Total Direct Costs @ 39.0%		Denotes on-campus project based on the
	EPA base: $156,800	$61,152	audited predetermined indirect rate.
XI. Total Project Costs/Year 1		$220,407	Total sum of direct and indirect costs.

Title: Creating Clean Waters in the Tributaries of the Potomac River

Sponsor: Environmental Protection Agency (EPA)

Duration: September 1, 2003 - August 31, 2004

Year: 2 9/1/03 - 8/31/04

				EPA	NOTES
I. Personnel					
A. Principal Investigator/Project Director					
Dr. Mary Jones					
1. 9/1/03 - 1/15/04					For budgeting purposes, a 5% salary
20% effort @	$35,122	/AY		3,512	increase occurs on September 1 of each year for all faculty. Only actual rates are billed.
B. Project Coordinator					
Dr. John Smith					
1. 9/1/03 - 1/15/04					
20% effort @	$33,285	/AY		3,328	
C. Administrative Assistant					
To be selected					
1. 9/1/03 - 1/15/04					For budgeting purposes, a 5% salary
100% effort @	$18,900	/FY		7,087	increase occurs on September 1 of each year for all full-time staff. Only actual rates are billed.
D. Graduate Assistant					
To be selected					
1. 9/1/03 - 12/31/04					
Tuition remission only					
Subtotal Personnel				$13,927	
II. Fringe Benefits					
@ 25.5% of IA,B,C					
base:	$13,927			3,551	
Subtotal Fringe Benefits				$3,481	
III. Supplies					
1. General office supplies @ 20/mo				90	
Subtotal Supplies				$90	
IV. Other Direct Costs					
A. Communications costs					
1. Long distance telephone @ $15/mo				68	

2. Postage, courier, FedEx @ $35/mo		158	
3. Photocopying @ $70/mo		315	
B. Equipment maintenance @ $13/mo		59	
C. LC maintenance @ $42/mo		189	
D. Publication costs		500	
E. Tuition remission			
9 hrs @ $877/hr		7,893	Any increases in tuition remission are based on an anticipated 5% increase each year. Only actual tuition rates will be billed.
Subtotal ODC		$9,182	
V. Total Direct Costs		$26,680	
VI. Indirect Costs			
Modified Total Direct Costs @ 39.0%			
EPA base:	26,750	$10,433	
VII. Total Project Costs/Year 2		$37,183	
VIII. TOTAL PROJECT COSTS for Years 1 and 2		$257,590	

Attachment I-D: Sample Consultant Agreement

Consultant Agreement No. CA-11-xxxxxx-3xxxx-xx

CONSULTANT AGREEMENT

This Agreement is made this ____ day of _____ *2xxx*, by and between American University (AU) and _____ (Consultant).

WITNESSETH:

WHEREAS, AU is the recipient of the _____ Sponsor _____ Grant No. _____ entitled "_____ Program Title _____"; and

WHEREAS, AU desires to enter into an Agreement with the Consultant for professional services to the extent and upon the terms and conditions hereinafter set forth; and

WHEREAS, the Consultant is willing to enter into an Agreement governing the nature, extent and obligations of such professional service to AU upon the terms and conditions hereinafter set forth:

NOW THEREFORE, IT IS MUTUALLY AGREED, AS FOLLOWS:

1. **Statement of Work** - The services to be provided by the Consultant shall be set forth from time to time in separate task assignments issued pursuant to the terms of this Agreement and in accordance with the procedures and conditions discussed in Article 3 - Task Assignments. No work shall be started until a Letter of Authorization has been issued by AU and signed by both parties. Consultant shall perform all services efficiently and satisfactorily and to a high standard of professional care, skill, and diligence.

2. **Period of Performance** - The term or period of this Agreement shall commence on Month and Day, Year and shall continue to and include Month and Day, Year, unless sooner terminated as herein provided.

3. **Task Assignments**

A. Services to be performed under Article 1 - Statement of Work shall be described and set forth in separate Task Assignments issued pursuant to the terms of this Consultant Agreement. Task Assignments shall specifically define the work to be performed and shall be in the form of a Letter of Authorization executed by the Principal Investigator or his designated representative. No work shall be started until a Letter of Authorization has been signed by both parties. After a Letter of Authorization has been fully executed, the Consultant shall begin work as of the effective date in accordance with the Letter of Authorization requirements and the terms and conditions of this Consultant Agreement.

B. Letters of Authorization for task assignments shall be in writing and at a minimum shall include the following:

1. Numerical Designation of Task Assignment

2. Period of Performance

3. Statement of Work

4. Level of Effort

5. Reporting Requirements

6. Maximum Compensation for Services

C. It is agreed that AU is not required to order any minimum dollar amount of service under this Agreement.

4. **Compensation and Method of Payment**

A. For services performed by the Consultant and as full and complete compensation therefor, AU shall pay the Consultant $xxx.xx per day for each day worked up to the maximum number of authorized days specified in the Letter of Authorization. Consultant shall request payment for services performed by submitting a completed and signed AU Consultant Payment Form for each individual task assignment. Consultant shall indicate the applicable task assignment number on this form.

B. Authorized travel expenses shall be reimbursed in accordance with AU travel regulations. When travel is approved under a task assignment, travel expenses shall be claimed by submitting a completed and signed AU Travel Expense Report with supporting documentation (receipts) attached. Consultant shall indicate the applicable task assignment number on this form. Consultant shall not incur any other costs under a task assignment unless specifically approved in the Letter of Authorization.

C. Payment for services performed shall be made within fourteen (14) days after AU's receipt and approval of the AU Consultant Payment Form, provided Consultant has satisfactorily performed all services and has delivered any required reports to the Project Office. Final inspection and acceptance of all services and reports shall be performed by the Principal Investigator, Name. Failure to perform the services satisfactorily or provide specified reports in an acceptable manner may result in the withholding or adjustment of monies due the Consultant for compensation of services.

5. **Confidentiality** - Except as otherwise specifically authorized in writing, information, data and reports developed, acquired or furnished by Consultant in performance of this Agreement shall not be disclosed to any third party without the written consent of AU. Information and reports furnished to AU by Consultant shall become the sole property of the AU, or if required by the grant agreement, the property of Sponsor.

6. **Termination** - AU reserves the right to terminate this Agreement upon written notice in the event of termination of AU's ____Sponsor____ Grant. Also, either AU or Consultant may terminate performance under this Agreement at any time by notifying the other party in writing at least thirty (30) days in advance.

7. **Award Conditions** - Consultant recognizes and understands that the work is being performed under AU's Grant with _____Sponsor_____. Except as otherwise provided herein, the Consultant shall be bound by all applicable award conditions of Grant No: _____, including provisions incorporated by reference or otherwise.

8. **Conflict of Interest** - Consultant knows of no agreements or transactions in which his rights, duties, obligations, or interests conflict or are inconsistent with those of AU, ____ Sponsor_____, or this Agreement.

9. **Notice of Delays** - Consultant shall notify AU promptly of any expected delay in performance of services as required and requested by AU. Neither AU nor Consultant shall be liable for delays in performance beyond their reasonable control and without their fault or negligence.

10. **Independent Contractor** - The Consultant is retained by AU only for the purpose and to the extent set forth in the Agreement, and his relation to AU during the period of his engagement and for the services hereunder, shall be that of independent contractor; he shall not act as nor be a joint venture, partner, agent or employee with or of AU. All of Consultant's activities shall be at his own risk and Consultant is hereby given notice of his responsibility for arrangements to guard against physical, financial, and other risks as appropriate. Consultant, as an independent contractor, shall not be considered as having an employee status with AU or be extended coverage under employment and worker's compensation insurance, or be entitled to participate in any plans, arrangements, or distributions by AU pertaining to or in connection with any pension, health, bonus or welfare benefit plans. All consultant payments shall be reported to the Internal Revenue Service on Form 1099.

11. **Indemnification** - Consultant shall assume, bear and indemnify and hold harmless AU from any claim, damage, liability, injury, expense or loss arising out of Consultant's performance under this Agreement. In consideration of the mutual agreements herein set forth, the Consultant does hereby relieve, acquit and forever discharge AU of and from any and all actions, courses of action, claims, demands and damages on account of, or in any way stemming from any accident or occurrence transpiring during and under the terms of this Agreement, unless it is established that such accidents arose out of the negligent acts of AU, its agents or employees.

12. **Assignment** - This Agreement shall not be assigned by Consultant; any attempt to do so shall be void and have no effect.

13. **Delivery of Notices** - Notices shall be made by special delivery or first class mail between the parties addressed to AU as follows:

American University
Office of Sponsored Programs
4400 Massachusetts Ave., NW
Washington, DC 20016-8066

and to Consultant at his/her address set forth beneath his/her signature to this Agreement.

14. **Entire Agreement** - This Agreement constitutes the complete understanding of the parties and supersedes any other prior agreements, and shall be governed by the law of the District of Columbia. No subsequent modifications of this Consultant Agreement shall be of any force or effect unless in writing signed by the Consultant and the authorized agent of the University.

IN WITNESS WHEREOF, AU has caused this Agreement to be executed in its corporate name by its authorized agent, and the parties hereto have set their hands as of the day and year first above written.

AMERICAN UNIVERSITY

By: _____
Director, Procurement and Contracts

Date: _____

CONSULTANT

By: _____
Consultant

Date: _____

Address: _____

SS#: xxx-xx-xxxx

Note: Use the following clause when you wish to hire an independent contrator to complete a specific task that will result in a product and you want that product to belong to the university, including all intellectual property rights (e.g., design and content of brochures, web pages, etc.).

Intellectual Property Rights - All intellectual property rights in the Services, including but not limited to, any deliverable furnished to AU as part of the Services or any modifications, customizations and interfaces developed with respect to a deliverable (the "Deliverables"), in whole or in part, provided to AU by Service Provider under a Statement of Work and this Agreement shall be solely the property of AU. Service Provider hereby assigns au right, title and interest in and to and exclusive ownership of such Services and Deliverables to AU and Service Provider shall take all actions necessary to transfer exclusive ownership of the same to AU. AU and the Service Provider agree that any product created, conceived, and/or prepared by the Service Provider in the performance of the services contained in this Agreement shall in all respects be considered a "work made for hire" within the meaning of the federal copyright and patent laws and that no other right in this Work shall inhere in the Service Provider, or in the Service Provider's representatives, heirs, or assigns. The Work shall be owned by AU and AU may, at its option and expense, seek copyright or patent registration for the Work. As owner of the copyright or patent, AU shall have all rights attendant to that ownership, including, but not limited to, rights of reproduction, preparation of derivative works, distribution, and display.

ATTACHMENT I-E

Global Accident & Health Protection

Office of Finance and Treasurer Risk Management Office

Emergency Preparedness | Environmental Health and Safety | Insurance | Home

INTERNATIONAL TRAVEL

Insurance and Requests for Country-specific Information

Overview

American University provides health-care insurance for its faculty, staff and students while on university-sponsored international travel that is not in their country of permanent residence. Please refer to the links under Global Accident & Health for the procedures to obtain coverage and the benefits provided by the insurance policy.

Country-specific information is also available by request. The information includes, travel warnings, weather conditions, country customs, documentation needed to enter the country, risk analysis, immunizations needed, etc. Please call Pat Kelshian at x3284 to obtain a country-specific report.

For more information or questions email: RMO@american.edu

Office of Finance and Treasurer

Office of Finance and Treasurer Risk Management Office

Emergency Preparedness | Environmental Health and Safety | Insurance | Home

INSURANCE

INTERNATIONAL TRAVEL

GLOBAL ACCIDENT & HEALTH PROTECTION

Coverage for Faculty, Staff and Students Traveling or Stationed Abroad Not in Their Country of Permanent Residence

All participants are required to carry coverage when on university sanctioned travel. Participant information must be emailed to pat@american.edu prior to travel. The e-mail must include:

- Name of traveler
- Status: Faculty, staff or student
- Department arranging travel
- Destination
- Number of weeks of travel (a partial week should be counted as one whole week
- Purpose of travel

The university will pay premiums for faculty and staff. As of 09/01/01 departments are being charged for student's coverage.

Insurance Provider and Claim Information

AceUSA provides this primary coverage for international travel Policy #GLM NO 0173587

In the event of a medical claim:

- Provide policy number at the hospital or clinic. Admission is guaranteed.

- Doctor or facility payment options:

o Payment can be arranged directly by wire transfer from AceUSA to doctor or facility

o Participant can make payment directly and file a claim for reimbursement

Health benefit coordination:

- Participant should first submit claims that occurred during international travel to AceUSA. After receiving the determination of benefits, any expenses that are not covered can be submitted to participant's domestic health care insurance provider.
- Executive Assistance®

o 24-hour telephone access to specially trained representatives who will respond to traveling faculty, staff and students needs in the following ways: medical, travel, personal, legal or security assistance.

o Inside the USA or Canada call 1-800-766-8206

o Outside USA or Canada collect 1-202-659-7777

For more information or
questions email: RMO@american.edu
Office of Finance and Treasurer

INTERNATIONAL TRAVEL

Insurance and Requests for Country-specific Information

Overview

American University provides health-care insurance for its faculty, staff and students while on university-sponsored international travel that is not in their country of permanent residence. Please refer to the links under Global Accident & Health for the procedures to obtain coverage and the benefits provided by the insurance policy.

Country-specific information is also available by request. The information includes, travel warnings, weather conditions, country customs, documentation needed to enter the country, risk analysis, immunizations needed, etc. Please call Pat Kelshian at x3284 to obtain a country-specific report.

For more information or
questions email: RMO@american.edu

Office of Finance and Treasurer

ATTACHMENT I-F

Sponsored Program Approval Form

OSP Contact:	**OSP Proposal No.:**	**Deadline:**
Principal Investigator:	**Proposal Status:**	**Sponsor:**
Project Title:		**Funding Source:**
College:	**Department:**	
Project Period: -	**Est. Award Date:**	**CFDA:**
Ultimate funding source for sub-grant/sub-contract or pass-through:		
Budget Type:	**Project Location:**	**Project Type:**
Type of Award Anticipated:	**Submission Type:**	**Relevant AU Acct:**

Budget Form	Sponsor	AU Cost Share	Other Cost
Direct:			
Indirect:			
Fee:			
Total:			

Does the Project Involve:	
Human Subjects?	
Animal Subjects?	
Radioactive/toxic materials?	
Subcontracts?	
Consultant Agreements?	
New Personnel?	
Taxation of Foreign Nationals?	
International Agreements?	
International travel?	
Special Insurance Needs?	
A Significant International Component?	

Additional Questions:	
Have equipment costs been cleared with the Purchasing Office?	
Does this project involve proprietary data, copyrights, or patents?	
Has submission been cleared with the Office of Development?	
Has International Student Services been informed of visa needs?	
Is there tuition remission cost share for graduate fellowships/assistantships?	
Does the proposal include lapsed salary?	
Lapsed salary amount:	
Proposed number of tuition hours remitted:	
Availability of adequate space has been approved by:	
How will additional space will be provided?	
Necessary facilities and space yet to be acquired:	

Notes:

Approvals:					
Signature	**Date**	**Signature**	**Date**	**Signature**	**Date**
Signature	**Date**	**Signature**	**Date**	**Signature**	**Date**

Print | Exit | Next

Indirect Cost Analysis		
Description:	**Amount ($)**	**Explanation**
A. AU on- or off-campus indirect rate:		
B. Indirect costs allowed by sponsor:		
C. Indirect costs requested:		
D. Mandatory cost-share of indirect costs (A-B):		
Note: Voluntary waivers of indirect costs are an exception to AU policy. Waivers must be requested by the dean of the academic unit and approved by the Provost.		

Cost Share Analysis			
INDIRECT			
Object Code/Description	**Type**	**Amount ($)**	**Provided by:**
None			
DIRECT			
None			
		Total Cost Share $0.00	
Total Mandatory $0.00	**Voluntary** $0.00	**Internal Cost** $0.00	**Cash outlay** $0.00

Notes on Indirect Costs or Cost Share

New Personnel:			
Position	**FT/PT**	**Start Date**	**End Date**
None			

Note:
1. Full-time positions require 28 hours/week for at least 10 months. Approved position descriptions are required before hiring.
2. If new full-time personnel are named in the proposal, affirmative action/EEO policies of the University must be applied;attach written rationale for exceptions.
3. The Principal Investigator is responsible for initiating all personnel actions.

Overload Request:				
Name	**Time Period**	**% of Time**	**$ Value**	**Justification**
None				

Note: Overload situations are approved in special circumstances and are always subject to approval within University guidelines.

Course Release:			
Name	**Semester(s)**	**# of Releases**	**Comments**
None			

How will the replacement costs be funded?

Equipment:

Describe the new equipment to be purchased for this project:

Who retains control of equipment after project termination?

How will equipment be maintained after project termination?

Notes on Personnel or Equipment:

OSP Proposal Number:	**Date:**
Principal Investigator:	**Award Period:** to
Project Title:	

Direct Cost			
Salaries and Wages	**Sponsor**	**Cost-Share**	
Sub-total			
Fringe Benefits			
Other Professional Costs			
Sub-total			
Travel			
Sub-total			
Equipment			
Sub-total			
Other Direct Costs			
Sub-total			
Total Direct Cost			

Indirect Cost		
Applicable Rate (50650)	**Sponsor**	**Cost-Share**
Sponsor Indirect		
Indirect CS AU Direct CS		
Indirect CS Sponsor Direct		
Total Indirect Cost		
Fee (50660)		
Total		

Print | Exit | Prior

CONTRACT AND GRANT ADMINISTRATION

WHEN A PROPOSAL BECOMES AN AWARD

Acceptance of Award

An award to the university from a sponsoring agency obligates the university to a contractual commitment. An award may simply be in the form of a letter issued by an authorized agent of the sponsor, or it may consist of a detailed contract.

The Office of Sponsored Programs (OSP) normally receives notification of sponsor acceptance or rejection of proposals. If award notices or letters of rejection come directly to the applicant, original copies should be forwarded to OSP.

Upon receipt of an award, the assigned OSP staff member informs the principal investigator and submits the appropriate acceptance documents to the sponsor. When appropriate, the OSP staff member meets with the principal investigator to review the contract, ensuring that it conforms to the proposal and that timetables, work statements, and deliverables are acceptable. The OSP staff member will assist the principal investigator in managing a contract or grant within university and sponsor guidelines. If a faculty member receives documentation regarding an awarding of a project, please contact your OSP staff member as soon as possible.

Awards for proposals not authorized by the university and not having a completed Sponsored Programs Approval Form may be declined by the university. In all cases, the university reserves the right to reject an award.

The university does not permit work to be performed on any proposed project until the sponsor has granted the award. No charges may be incurred against a sponsored project until OSP has received and processed the formal award notification from the sponsor and an account number has been issued. No commitments to personnel or subcontractors should be made prior to receipt of an official award document. On occasion, the actual sponsor document authorizing project expenditures may be delayed. If a short delay will impede the progress of the project, the principal investigator may request approval for limited early expenditures. Such requests are channeled through OSP. These and other exceptions to this policy are based on the written request of the principal investigator and the approval of the dean of the school/college or the unit executive head, and Assistant Provost.

OSP STAFF ASSIGNMENTS

Angela Wish **885-3451** **Email: wish**	**Jan Idyll** **885-3444** **Email: jidyll**	**Cathy Barton** **885-3445** **Email: bcathy**	**Conrad Hohenlohe** **885-3474** **Email: chohenl**	**Lacey Bergin** **885-3994** **Email: bergin**
Kogod School of Business **Office of Campus Life** **School of Public Affairs** **WAMU**	**College of Arts and Sciences** Anthropology Art Biology Chemistry Computer Science, Audio Technology and Physics (CAP) Economics Philosophy and Religion Psychology Health and Fitness	**College of Arts and Sciences** Education History Language and Foreign Studies Literature Mathematics and Statistics Performing Arts Program Development Office Sociology **School of Communication**	**Center for Global Peace** **School of International Service** **TraCCC** **Public Safety**	**Washington College of Law**

Those units not assigned should contact the Director of the Office of Sponsored Programs at (202) 885-3457

Negotiations

OSP negotiates the type of agreement, its terms, and financial arrangements including the budget, while the principal investigator and the sponsor negotiate the technical aspects of a proposal. **The technical aspects of a project, however, should not be negotiated without notice to OSP, since changes in the project scope may affect the costing arrangements and other contractual aspects, especially the performance period.** It is mutually beneficial for the principal investigator and the university to work to develop strategies and options in negotiating. OSP is the official negotiator concerning budget and implementation and interpretation of university policy.

If negotiations result in major contractual or technical changes to the original proposal, the revised proposal must be resubmitted through the established process for approval.

The university reserves the right to determine the extent to which it will continue or terminate negotiations with any sponsor.

CONTRACT AND GRANT ADMINISTRATION RESPONSIBILITIES

After a proposal becomes a contract or grant, the principal investigator, the assigned OSP staff member, and the dean of the school/college work together to manage the award. In general, the faculty member performs the technical and administrative aspects of the award, while the OSP staff member, in partnership with the dean's office, handles the contractual and financial aspects.

The Principal Investigator:

- Ensures that the program is carried out in a timely fashion.
- Ensures the appropriate level of effort by designated faculty or staff members according to grant or contract provisions.
- Consults with teaching unit heads and the school/college dean, as appropriate.
- Manages the budget.
- Recruits and hires the appropriate personnel in accordance with university policies, including affirmative action.
- Ensures adherence to university policies and procedures.
- Supervises project personnel according to the criteria established by the contract or grant.
- Prepares and submits interim and final project reports to the sponsor with copies to the dean of the school or college and to OSP.

The Assigned OSP Staff Member:

- Informs principal investigator, teaching unit head and school/college dean of award.
- Reviews aspects of contract with principal investigator when appropriate.
- Negotiates contract and financial arrangements with sponsor.
- Prepares and distributes the project brief and authorized budget.
- Assists in funding changes.
- Serves as a resource to the dean's office regarding whether school/college approved project expenditures adhere to sponsor and university guidelines.
- Approves project expenditures at a pre-determined level and ensures that project expenditures adhere to university and sponsor guidelines. With the exception of CAS, which has its own contract administrator, OSP staff approve personnel, consultant and unbudgeted equipment expenditures, as well as expenditures when the total amount is $5,000 or more.
- Provides information on copyright and patent procedures.
- Liaison with sponsor as the primary point of contact.
- Coordinates contractual matters with Controller's Office and other departments.
- If need arises, coordinates with other departments to resolve internal or external issues.
- Ensures that project expenditures adhere to university and sponsor guidelines.
- Prepares consulting agreements and subcontracts.
- Handles negotiations in areas of property disposal or transfer at conclusion of project.
- Advises on project closeout.

The Office of Grants Accounting:

- Prepares and submits billings to sponsor.
- Prepares financial reports to sponsors.
- Monitors expenditures for allocability and allowability.
- Coordinates financial audits by sponsors.
- Directs compliance with OMB Circular A-133 Audit and Reporting Requirements.
- Prepares OMB Circular A-21 Cost Rate Studies (F&A Rate).

The School/College Dean:

- Develops sponsored program and research action plan.
- Achieves revenue goals.
- Allocates college and teaching unit resources involved in implementing research proposals and resulting from research awards.
- Advises OSP negotiators concerning negotiating strategies and options preferred.
- Reviews and revises college proposal commitments based on negotiations.
- Ensures that all principal investigators follow university policies and assume project administrative responsibilities.
- Reviews and authorizes appropriate forms initiated by the principal investigator for payroll authorizations, new hires, purchases, and other project related expenses.
- Provides cost-sharing data to OSP staff member for submission to the sponsor. Note that it is the responsibility of the principal investigator/department/school/college to keep accurate information on cost sharing as these costs will appear on the projects' ledgers.

The Office of the Provost assisted by the Director of the Office of Sponsored Programs:

- Approves exceptions to policy.
- Serves as final arbitrator of university's negotiating position.
- Determines all legal actions relative to sponsored projects and coordinates resolution of financial issues through OSP in consultation with the Office of General Counsel and the Vice President for Finance and Treasurer.

PROJECT ADMINISTRATION

Project Account Number

Once a contract or grant has been awarded it is assigned a restricted project account number, obtained by OSP from the Office of Accounting in the Controller's Office. No university funds should be expended for the project until this number has been assigned. Each project is fiscally accounted for by a separate restricted account. When necessary to differentiate between various aspects of a single project, two or more account (or subaccount) numbers may be assigned.

Project Brief

After establishing the project account number, the OSP staff member prepares and distributes a project start-up checklist, a project brief, and an authorized budget. The checklist provides a quick review of standard policies and specific issues **(**see **Attachment II-A)**. The project brief summarizes the terms and conditions of the agreement, particularly those directly affecting the principal investigator. Each project brief indicates the name of the assigned OSP staff member and the accountant. The "Remarks" section details the sponsor approvals required before the university can begin expenditures **(**see **Attachment II-B)**. As agreements are amended, the OSP staff will prepare and distribute revised project briefs reflecting the changes.

Technical Reports

Most sponsored projects require both interim reports and a final report. Unlike the donors' unrestricted gifts, the project sponsors expect to be informed of results. Failure to submit reports on a timely basis may not only affect adversely the principal investigator's (and the university's) ability to receive further support from the sponsor, but may result in a loss of payment for costs already incurred. To help avoid such potentially disastrous oversights, OSP has developed an award management reminder that will inform principal investigators of due dates for technical reports and project close-out by listing those dates on the front page of the project brief.

As of September 30, 2005, all principal investigators with active grants will be required to send copies of all technical reports to the office of their dean or executive unit head as well as to the Office of Sponsored Programs. This supercedes the previous policy in which only the final technical report was required to be sent to the Office of Sponsored Programs

Recently some agencies, including the Department of Education and the Department of Justice, have developed electronic submission procedures for technical reports that require certification by the Institutional Official. In order to provide the certification to the agency, the principal investigator must route the report to the dean of the school or college. After review and signature by the dean, the report will be routed to the Institutional Official who will review it and authorize the electronic submission.

Financial Reports

Financial reports are prepared by the Office of Accounting when required. The accountant uses the guidelines supplied by the sponsor to complete such reports. Completion of financial reports is done according to the schedule supplied by the sponsor.

Property Control

Title of ownership to capital equipment purchased through sponsored funding is subject to university property control procedure. Each grant or contract should be reviewed for specific conditions related to ownership. General guidance can be found in OMB Circular A-110 in Section 34 as listed below. If title to equipment is vested in the university, the principal investigator cannot dispose of equipment without the approval of the teaching unit head and the Assistant Provost.

OMB Circular A-110, Section 34

http://www.whitehouse.gov/omb/circulars/a110/a110.html#34

Equipment.

(a) Title to equipment acquired by a recipient with Federal funds shall vest in the recipient, subject to conditions of this section.
(b) The recipient shall not use equipment acquired with Federal funds to provide services to non-Federal outside organizations for a fee that is less than private companies charge for equivalent services, unless specifically authorized by Federal statute, for as long as the Federal Government retains an interest in the equipment.
(c) The recipient shall use the equipment in the project or program for which it was acquired as long as needed, whether or not the project or program continues to be supported by Federal funds and shall not encumber the property without approval of the Federal awarding agency. When no longer needed for the original project or program, the recipient shall use the equipment in connection with its other federally-sponsored activities, in the following order of priority: (i) Activities sponsored by the Federal awarding agency which funded the original project, then (ii) activities sponsored by other Federal awarding agencies.
(d) During the time that equipment is used on the project or program for which it was acquired, the recipient shall make it available for use on other projects or programs if such other use will not interfere with the work on the project or program for which the equipment was originally acquired. First preference for such other use shall be given to other projects or programs sponsored by the Federal awarding agency that financed the equipment; second preference shall be given to projects or programs sponsored by other Federal awarding agencies. If the equipment is owned by the Federal Government, use on other activities not sponsored by the Federal Government shall be permissible if authorized by the Federal awarding agency. User charges shall be treated as program income.
(e) When acquiring replacement equipment, the recipient may use the equipment to be replaced as trade-in or sell the equipment and use the proceeds to offset the costs of the replacement equipment subject to the approval of the Federal awarding agency.
(f) The recipient's property management standards for equipment acquired with Federal funds and federally-owned equipment shall include all of the following.

(1) Equipment records shall be maintained accurately and shall include the following information.
(i) A description of the equipment.
(ii) Manufacturer's serial number, model number, Federal stock number, national stock number, or other identification number.
(iii) Source of the equipment, including the award number.
(iv) Whether title vests in the recipient or the Federal Government.
(v) Acquisition date (or date received, if the equipment was furnished by the Federal Government) and cost.
(vi) Information from which one can calculate the percentage of Federal participation in the cost of the equipment (not applicable to equipment furnished by the Federal Government).
(vii) Location and condition of the equipment and the date the information was reported.
(viii) Unit acquisition cost.
(ix) Ultimate disposition data, including date of disposal and sales price or the method used to determine current fair market value where a recipient compensates the Federal awarding agency for its share.
(2) Equipment owned by the Federal Government shall be identified to indicate Federal ownership.
(3) A physical inventory of equipment shall be taken and the results reconciled with the equipment records at least once every two years. Any differences between quantities determined by the physical inspection and those shown in the accounting records shall be investigated to determine the causes of the difference. The recipient shall, in connection with the inventory, verify the existence, current utilization, and continued need for the equipment.
(4) A control system shall be in effect to insure adequate safeguards to prevent loss, damage, or theft of the equipment. Any loss, damage, or theft of equipment shall be investigated and fully documented; if the equipment was owned by the Federal Government, the recipient shall promptly notify the Federal awarding agency.
(5) Adequate maintenance procedures shall be implemented to keep the equipment in good condition.
(6) Where the recipient is authorized or required to sell the equipment, proper sales procedures shall be established which provide for competition to the extent practicable and result in the highest possible return.
(g) When the recipient no longer needs the equipment, the equipment may be used for other activities in accordance with the following standards. For equipment with a current per unit fair market value of $5000 or more, the recipient may retain the equipment for other uses provided that compensation is made to the original Federal awarding agency or its successor. The amount of compensation shall be computed by applying the percentage of Federal participation in the cost of the original project or program to the current fair market value of the equipment. If the recipient has no need for the equipment, the recipient shall request disposition instructions from the Federal awarding agency. The Federal awarding agency shall determine whether the equipment can be used to meet the agency's requirements. If no requirement exists within that agency, the availability of the equipment shall be reported to the General Services Administration by the Federal awarding agency to determine whether a requirement for the equipment exists in other Federal agencies. The Federal awarding agency shall issue instructions to the recipient no later than 120 calendar days after the recipient's request and the following procedures shall govern.
(1) If so instructed or if disposition instructions are not issued within 120 calendar days after the recipient's request, the recipient shall sell the equipment and reimburse the Federal

awarding agency an amount computed by applying to the sales proceeds the percentage of Federal participation in the cost of the original project or program. However, the recipient shall be permitted to deduct and retain from the Federal share $500 or ten percent of the proceeds, whichever is less, for the recipient's selling and handling expenses.
(2) If the recipient is instructed to ship the equipment elsewhere, the recipient shall be reimbursed by the Federal Government by an amount which is computed by applying the percentage of the recipient's participation in the cost of the original project or program to the current fair market value of the equipment, plus any reasonable shipping or interim storage costs incurred.
(3) If the recipient is instructed to otherwise dispose of the equipment, the recipient shall be reimbursed by the Federal awarding agency for such costs incurred in its disposition.
(4) The Federal awarding agency may reserve the right to transfer the title to the Federal Government or to a third party named by the Federal Government when such third party is otherwise eligible under existing statutes. Such transfer shall be subject to the following standards.
(i) The equipment shall be appropriately identified in the award or otherwise made known to the recipient in writing.
(ii) The Federal awarding agency shall issue disposition instructions within 120 calendar days after receipt of a final inventory. The final inventory shall list all equipment acquired with grant funds and federally-owned equipment. If the Federal awarding agency fails to issue disposition instructions within the 120 calendar day period, the recipient shall apply the standards of this section, as appropriate.
(iii) When the Federal awarding agency exercises its right to take title, the equipment shall be subject to the provisions for federally-owned equipment.

Insurance - Travel

Faculty and staff who are traveling overseas as part of a sponsored program need to inform their designated unit representative in advance of a trip so that they will be covered by the university's international insurance. Students traveling overseas on sponsored projects also need to be covered by the university's international insurance. The cost of student insurance must be charged to the grant unless the unit decides to pay for the insurance. These arrangements must also be made well in advance of the proposed trip. For more detailed information, see **Attachment I-E** in Chapter I.

Insurance - Vehicles

If rental vehicles are required to carry out university business, the Office of the Vice President for Finance and Treasurer should be notified. Vehicles are rented in the name of the university, with the faculty or staff member indicated as the authorized driver.

Insurance coverage on vehicles rented in the United States or its possessions is provided in the university's blanket insurance policy. Additional insurance is not required. Foreign coverage, however, is not provided under the university's blanket policy. Accordingly, faculty and staff renting vehicles in foreign countries must obtain the appropriate insurance coverage from the rental agency.

When using personal vehicles for university business, faculty and staff members are responsible for obtaining and maintaining the mandatory vehicle insurance coverage required by state regulations.

Faculty who wish to use university-owned vehicles for sponsored projects should refer to the university's "Vehicle Safety Policy and Guidelines" (see **Attachment II-C**). An application for driving privileges at available at http://www.american.edu/finance/rmo/vspolicy.html.

Insurance – Equipment

All equipment purchased through a sponsored project must be insured under the university blanket insurance policy. The blanket insurance policy has a $25,000-per-loss deductible. If a smaller deductible is needed, it can be arranged only if funded through the project. Computers, printers, and other peripherals, however, are not covered under the university's blanket insurance policy. Special arrangements for their coverage must be made with the Office of the Vice President for Finance and Treasurer.

Insurance/Risk Management

Projects that pose unusual risk exposures (such as construction, diggings, water craft, toxic wastes, chemical intrusion into the human body, etc.), or projects that involve bringing groups to the university campus to participate in a sponsored activity, for example, groups of international students or groups of minors, are not covered under the university's blanket insurance policy. OSP can facilitate discussions with the Executive Director, Risk Management Office who can provide guidance about the level of additional insurance required.

These projects are subject to the individual review and endorsement of the insurance carrier. Unless the carrier agrees to provide coverage, the project may not be implemented.

Academic Fraud

Academic fraud—including fabrication or falsification of data, theft of ideas or direct plagiarizing, and deliberate interference with the integrity of others' work—will result in disciplinary action as outlined in American University's Manual of Information and Procedures (Section XIX, August 1987, revised 1989). Additional guidelines for dealing with fraud in academic research have been developed by the Association of American Universities, the National Association of State Universities and Land-Grant Colleges, and the Council of Graduate Schools (see **Attachment II-D**).

INTELLECTUAL PROPERTY

Copyrights & Patents

In September 1997, the Provost combined the Copyright Committee and the Patent Committee into a single committee, known as the Intellectual Property Committee. The Intellectual Property Committee administers the copyright and patent policies of the university pursuant to the policies and guidelines found in this handbook

Copyright

In regard to copyrights, the university believes that the publishable work of its faculty, staff, and student body should be available to all interested scholars. The university also believes that the author should be given full credit for any work, and should be entitled to retain proprietary rights to the product of the individual's own initiative and independent labors. Occasionally, however, faculty and staff produce materials as a result of specific university assignments. In such cases, the university reserves the right to determine whether or not the material will be copyrighted, and in whose name, and what rights, if any, the author will retain to the materials. Normally, when materials published under the university's copyright are distributed or sold for educational or scientific purposes only, the author receives no payments. If the materials are marketed commercially, however, the author often receives royalty payments based upon an agreed rate.

Any arrangement relating to copyright matters involving a sponsored project must be referred to OSP. Some sponsors have established regulations governing the copyright and/or publication of the results of investigations they finance. Limitations imposed by government agencies seek to keep research findings within the common domain. Occasionally, restrictions are designed to prevent the release of information that might prove contrary to the national interest or detrimental to the interest of the sponsor. Before entering a sponsored project, an understanding among the principal investigator, the university, and the sponsor should be reached regarding the rights to any copyrightable materials produced by the project.

Traditionally, the right of first publication is the property of the author, unless the terms of the grant or contract specify otherwise. Copyrights secured for the university or any of its units are placed in the name of the university, and become university property. The OSP grant and contract manager will provide interested persons with information concerning the procedures to be followed in applying for a copyright.

Patents

In regard to patents, the university policy is that discoveries or inventions resulting from a sponsored project that are judged by the principal investigator to be patentable must be brought to the attention of the University Intellectual Property Committee. This committee determines whether and to what extent the university has a property interest in the discovery or invention. To safeguard the interests of the university, the public, and potential inventors, the Provost has established a patent policy applicable to all university project personnel (see **Attachment II-E**).

For information on the university's Intellectual Property matters, please contact Catherine Kirby, Director, Office of Sponsored Programs at (202) 885-3457.

DRUG-FREE WORKPLACE

American University is committed to maintaining a workplace free from illegal drugs and alcohol or drug abuse. The abuse of alcohol and the use of illegal drugs by members of the American University community are incompatible with the goals of the institution. In order to further the university's commitment to provide a healthy and productive educational environment, and in compliance with the Drug-Free Schools and Communities Act Amendments of 1989 and the Drug-Free Work Force rules promulgated by the Department of Defense and other agencies, the university has established the following policy on alcohol and other drugs.

As a condition of employment, university employees agree to abide by the terms of this policy and to notify their supervisor of any criminal drug conviction no later than five (5) working days after the conviction. For the purposes of this policy "employee" refers to all full-time faculty and staff, adjunct faculty, and part-time staff.

Employees of American University engaged in government grants and contracts may be subject to additional drug-free workplace compliance requirements where required by government grant, contract, or law. These requirements may include, but are not limited to, drug and alcohol testing. (see **Attachment II-F**)

CHANGES IN A CONTRACT OR GRANT

Change of Principal Investigator

During a sponsored project, circumstances may arise warranting the designation of a new principal investigator. The appointment can be made only with the approval of the teaching unit head, school/college dean, Assistant Provost, and sponsor. The request for designation of a new principal investigator should state the reasons for such a change and include the curriculum vitae of the proposed principal investigator.

Transfer of Contract or Grant

From Another Institution

A faculty member coming from another institution may wish to transfer a sponsored project to the university. Such a transfer requires the approval of both the home institution and the sponsoring agency. To initiate the transfer process, a new or revised proposal is prepared and sent through OSP's normal routing process.

To Another Institution

A principal investigator who is transferring out of the university may wish to continue his or her sponsored project at a new institution. A request to transfer the unspent portion of the grant or contract must proceed through OSP, obtain the consent of the teaching unit head, the school/college dean, and the Assistant Provost, and secure the approval of the sponsor.

The university may elect to retain the project; if so, a new principal investigator will be nominated to replace the individual leaving the university, following the process described above. Approved transfers occur only after a final accounting and release from the Accounting Office, certifying the funds remaining and available for transfer.

No-Cost Extensions

Occasionally, the completion of grant or contract work may require more time than originally specified. If no additional funds are necessary, a no-cost extension may be requested from the sponsor. The principal investigator must notify OSP in writing of the need for a no-cost extension at least 60 days prior to the project expiration date so that OSP may obtain the sponsor's approval.

Changes in Research Plan

Research shifts that create a redirection of the statement of work described in the original proposal must be discussed with the sponsor. The principal investigator must obtain the approval of the teaching unit head, the college dean, and the Provost, and must send the sponsor a letter explaining the proposed change. If the change necessitates rebudgeting, the project brief—both the summary of agreement and the budget—must be revised and filed with OSP.

Rebudgeting

Should significant funds need to be transferred from one object code to another, the project brief will be revised. The principal investigator must request such action from OSP in writing. If sponsor approval is required, OSP will obtain the approval before revising the project brief. For general guidance on re-budgeting for federal projects refer to OMB Circular A-110, Section 25 - Revision of Budget and Program Plans as listed below.

OMB Circular A-110, Section 25

http://www.whitehouse.gov/omb/circulars/a110/a110.html#25

Revision of budget and program plans.

(a) The budget plan is the financial expression of the project or program as approved during the award process. It may include either the Federal and non-Federal share, or only the Federal share, depending upon Federal awarding agency requirements. It shall be related to performance for program evaluation purposes whenever appropriate.
(b) Recipients are required to report deviations from budget and program plans, and request prior approvals for budget and program plan revisions, in accordance with this section.
(c) For nonconstruction awards, recipients shall request prior approvals from Federal awarding agencies for one or more of the following program or budget related reasons.
(1) Change in the scope or the objective of the project or program (even if there is no associated budget revision requiring prior written approval).
(2) Change in a key person specified in the application or award document.
(3) The absence for more than three months, or a 25 percent reduction in time devoted to the project, by the approved project director or principal investigator.
(4) The need for additional Federal funding.
(5) The transfer of amounts budgeted for indirect costs to absorb increases in direct costs, or vice versa, if approval is required by the Federal awarding agency.
(6) The inclusion, unless waived by the Federal awarding agency, of costs that require prior approval in accordance with OMB Circular A-21, "Cost Principles for Educational Institutions," OMB Circular A-122, "Cost Principles for Non-Profit Organizations," or 45 CFR part 74 Appendix E, "Principles for Determining Costs Applicable to Research and Development under Grants and Contracts with Hospitals," or 48 CFR part 31, "Contract Cost Principles and Procedures," as applicable.
(7) The transfer of funds allotted for training allowances (direct payment to trainees) to other categories of expense.
(8) Unless described in the application and funded in the approved awards, the subaward, transfer or contracting out of any work under an award. This provision does not apply to the purchase of supplies, material, equipment or general support services.
(d) No other prior approval requirements for specific items may be imposed unless a deviation has been approved by OMB.
(e) Except for requirements listed in paragraphs (c)(1) and (c)(4) of this section, Federal awarding agencies are authorized, at their option, to waive cost-related and administrative prior written approvals required by this Circular and OMB Circulars A-21 and A-122. Such waivers may include authorizing recipients to do any one or more of the following.

(1) Incur pre-award costs 90 calendar days prior to award or more than 90 calendar days with the prior approval of the Federal awarding agency. All pre-award costs are incurred at the recipient's risk (i.e., the Federal awarding agency is under no obligation to reimburse such costs if for any reason the recipient does not receive an award or if the award is less than anticipated and inadequate to cover such costs).
(2) Initiate a one-time extension of the expiration date of the award of up to 12 months unless one or more of the following conditions apply. For one-time extensions, the recipient must notify the Federal awarding agency in writing with the supporting reasons and revised expiration date at least 10 days before the expiration date specified in the award. This one-time extension may not be exercised merely for the purpose of using unobligated balances.
(i) The terms and conditions of award prohibit the extension.
(ii) The extension requires additional Federal funds.
(iii) The extension involves any change in the approved objectives or scope of the project.
(3) Carry forward unobligated balances to subsequent funding periods.
(4) For awards that support research, unless the Federal awarding agency provides otherwise in the award or in the agency's regulations, the prior approval requirements described in paragraph (e) are automatically waived (i.e., recipients need not obtain such prior approvals) unless one of the conditions included in paragraph (e)(2) applies.
(f) The Federal awarding agency may, at its option, restrict the transfer of funds among direct cost categories or programs, functions and activities for awards in which the Federal share of the project exceeds $100,000 and the cumulative amount of such transfers exceeds or is expected to exceed 10 percent of the total budget as last approved by the Federal awarding agency. No Federal awarding agency shall permit a transfer that would cause any Federal appropriation or part thereof to be used for purposes other than those consistent with the original intent of the appropriation.
(g) All other changes to nonconstruction budgets, except for the changes described in paragraph (j), do not require prior approval.
(h) For construction awards, recipients shall request prior written approval promptly from Federal awarding agencies for budget revisions whenever (1), (2) or (3) apply.
(1) The revision results from changes in the scope or the objective of the project or program.
(2) The need arises for additional Federal funds to complete the project.
(3) A revision is desired which involves specific costs for which prior written approval requirements may be imposed consistent with applicable OMB cost principles listed in Section ___.27.
(i) No other prior approval requirements for specific items may be imposed unless a deviation has been approved by OMB.
(j) When a Federal awarding agency makes an award that provides support for both construction and nonconstruction work, the Federal awarding agency may require the recipient to request prior approval from the Federal awarding agency before making any fund or budget transfers between the two types of work supported.
(k) For both construction and nonconstruction awards, Federal awarding agencies shall require recipients to notify the Federal awarding agency in writing promptly whenever the amount of Federal authorized funds is expected to exceed the needs of the recipient for the project period by more than $5000 or five percent of the Federal award, whichever is greater. This notification shall not be required if an application for additional funding is submitted for a continuation award.
(l) When requesting approval for budget revisions, recipients shall use the budget forms that

were used in the application unless the Federal awarding agency indicates a letter of request suffices.

(m) Within 30 calendar days from the date of receipt of the request for budget revisions, Federal awarding agencies shall review the request and notify the recipient whether the budget revisions have been approved. If the revision is still under consideration at the end of 30 calendar days, the Federal awarding agency shall inform the recipient in writing of the date when the recipient may expect the decision.

Carryover of Funding

Sponsor policies vary in their handling of funds unspent at the end of a budget period. Principal investigators working under multiyear awards should check with OSP to avoid potential losses. Requests for the carryover of funds must be routed through OSP to the sponsor, explaining why such funds exist and how they will be used during the next budget period.

Supplemental Funds

Requests for supplemental funds should include a budget showing how the funds will be spent and an explanation of why they are needed and relevant to the research. Such requests must be approved by the teaching unit head and the college dean and processed through OSP.

Cost Overruns

Since principal investigators serve as the budget managers for sponsored projects, it is their responsibility to keep the budget in order and within limits. If it appears that costs will exceed the budget, contact OSP at once. Cost overruns will be charged to the principal investigators' department/school/college.

Prior Approval Requirements

During the performance of project it may be appropriate for funds to be reallocated to support advancement of a project. While grantees have some discretion to re-budget, there are some actions that require specific prior written approval from the agency. Most common instances of need for prior sponsor approval are:

- Changes in project scope or objectives
- Changes in key personnel
- Approval for the absence of the principal investigator/project director for more than three months or a 25% reduction in time for the same individual
- The need for additional funding

There are other approvals prescribed by the circulars and individual agency guidelines. Talk with your assigned OSP staff member who will provide guidance about whether the requested budget change for your project will fall within the prior approval requirements.

CONCLUSION OF THE CONTRACT OR GRANT

Termination of Project Personnel

Personnel whose employment ends with the sponsored project should be notified well in advance of the termination date of the grant or contract. The university's policy on "Externally Funded Positions – Terminal Appointments" is as follows:

> "In cases of externally funded positions, the university will give written notice at least 30 days prior to the effective date of termination of funding. When an employee's term of appointment has ended as specified on the Human Resources Action Form, payment ceases automatically unless that appointment is renewed. A Request for Personnel Action stating either formal separation or renewal of appointment must be submitted. The university will not pay for accrued annual leave beyond the specified termination date. In cases where positions have been funded by external agencies, it may be necessary to use all or some of the 30-day period as annual leave because leave cannot be paid as additional time in these cases."
>
> *From the Staff Manual of Personnel Policies*
> *Includes updates as of January 2002 and revisions as of April 29, 2005.*

Should the employee's appointment be renewed, a Payroll Authorization Form indicating renewal of appointment must be submitted.

Project personnel interested in continuing at the university beyond the sponsored project should be referred to the Human Resources Office for possible relocation.

Close-Out Procedures

OSP has developed an award management system to remind principal investigators of project close-out dates. In order to alert principal investigators to an upcoming project close-out date, the assigned OSP staff member will send out a notice asking that the principal investigator contact OSP with regard to the project status. Typically, the principal investigator would indicate the status as one of three:

- Close as scheduled
- Request a no-cost extension from the sponsor
- Put in a request for continued or additional funding

If there are other matters affecting close-out or if the principal investigator needs guidance, these matters can be discussed before the official end date of the project. For reference, a project close-out checklist can be found in **Attachment II-G**.

At contract or grant termination, OSP, in conjunction with the principal investigator and the Accounting Office, reviews items on the contract/grant closure form (**see Attachment II-H**). This form ensures that:

- All required technical and financial reports have been submitted to the sponsor in a timely manner;
- Any agency requirements for the transfer or disposal of property owned by the government have been met;
- Patent and/or copyright procedures have been followed, and
- Personnel hired only for the duration of the project have been officially terminated from employment with the university.

OSP handles all necessary negotiations regarding property disposal or transfer, while Accounting prepares the final financial report including all charges to date. The principal investigator is responsible for notifying Accounting of pending financial charges so that appropriate arrangements can be made for billing the sponsor. **Charges received after the financial report has been submitted to the sponsor will be charged to the principal investigator's teaching unit**.

Records Retention

Generally, records generated by a sponsored project are retained for a period of five (5) years with exceptions per OMB Circular A-110, Section 53b (http://www.whitehouse.gov/omb/circulars/a110/a110.html#53), beginning from the date of final payment or the final audit, whichever is later. Sponsor requirements for records retention may vary; check with the OSP staff member to verify the number of years for retention specified in the grant or contract.

Attachment II-A

PROJECT START-UP CHECKLIST

Grant #: _____
Grant name: _____
PI: _____

_____ Preparation and Routing of Personnel Forms
_____ Signature Authorization Form
_____ Annual Leave Policy for Personnel on Restricted Accounts
_____ Consultants, Subgrants, and Subcontracts
_____ Project Brief and Budget
_____ Requests for Rebudgeting
- Rebudgeting Authorized By Award Document
- Rebudgeting Requiring Sponsor Approval

_____ Financial Reporting by Accounting
_____ Submission of Technical Reports by P.I.
- Copies to OSP

_____ OSP Approval of Project Expenditures
_____ Taxation of Foreign Nationals
_____ Dean's Office Level of Expenditure Approval
_____ Monitoring Project Expenditures on Datatel
_____ Procedure for Requesting Grant/Contract Modifications
_____ Purchasing
- Delegation of Signature Authority
- Purchase Requisitions / Purchase Orders
- Blanket Purchase Orders and Pre-paid Purchase Orders
- Central Supplies

_____ Travel, Transportation, and Per Diem
- AU Travel Policy
- Travel Expense Report
- Travel Advance Request
- Travel Office
- International Travel

_____ Computer Services
- Technical Assistance
- Approval of Computer Equipment & Software Purchases

_____ Lease Agreements for Off Campus Space
_____ Special Insurance Requirements
_____ Tuition Remission
_____ Cost Sharing
_____ Human Subjects, Animal Use, Radiation and/or Hazardous Materials
_____ Copyrights Policy
_____ Patents and Inventions Policy
_____ Drug Abuse Policy
_____ Program Income
_____ Other_____

Attachment II-B

SAMPLE PROJECT BRIEF

PROJECT BRIEF

OSP Proposal No.: XXX100502 Project Brief #: Date: CFDA #:
Award #: University Acc. #: 11--xxxxx-
Award Period:
Sponsor:
Principal Investigator:
Project Title:
College/Department:
Select...

Funds provided by this action: $0.00
Previously awarded: $0.00 Total awarded to date: $0.00

Is more funding anticipated? Significant International Component?
If this is a subcontract, subgrant, or pass-through funding, list ultimate funding source, if known:

FUNDING SOURCE:	AWARD TYPE:	PROJECT TYPE:
PROJECT LOCATION:	BUDGET TYPE:	AWARD CATEGORY:
FISCAL INFO:	PAYMENT TERMS:	
INDIRECT RATE:	TOTAL COST-SHARE COMMITMENTS:	

REPORTING REQUIREMENTS Technical: Financial:

ADMINISTRATIVE/FINANCIAL CONTACTS

	Name:	Telephone:	E-mail:
Sponsored Programs:			
Accounting Office:			
Unit/School:			
Sponsor:			

NOTES

DISTRIBUTION

BUDGET ACTION FORM

Project Brief

University Acc. #: 11--xxxxx- Award Period: Date:
Principal Investigator: Project Brief #:
Project Title:
Reason for budget action:

DIRECT COSTS	This Action			Previous Budget		Revised Budget	
Salaries and Wages	Sponsor	Cost -Share		Sponsor	Cost-Share	Sponsor	Cost-Share
Select...			IC CO			0	0
Sub-total	0.00	0.00		0.00	0.00	0.00	0.00
Fringe Benefits							
Select...	0.00	0.00	IC CO	0.00	0.00	0.00	0.00
Other Professional Costs							
Select...			IC CO			0	0
Sub-total	0.00	0.00		0.00	0.00	0.00	0.00
Travel							
Select...			IC CO			0	0
Sub-total	0.00	0.00		0.00	0.00	0.00	0.00
Equipment							
Select...			IC CO			0	0
Sub-total	0.00	0.00		0.00	0.00	0.00	0.00
Other Direct Costs							
Select...			IC CO			0	0
Sub-total	0.00	0.00		0.00	0.00	0.00	0.00
TOTAL DIRECT COSTS	0.00	0.00		0.00	0.00	0.00	0.00

INDIRECT COSTS	This Action			Previous Budget		Revised Budget	
Applicable Rate (50650)	Sponsor	Cost-Share		Sponsor	Cost-Share	Sponsor	Cost-Share
Sponsor Indirect	0			0.00		0.00	
Indirect CS AU Direct CS		0.00	IC CO		0		0.00
Indirect CS Sponsor Direct		0.00	IC CO		0		0.00
TOTAL INDIRECT COSTS	0.00	0.00		0.00	0.00	0.00	0.00
Fee (50660)	0.00	0.00	IC CO	0	0	0.00	0.00
TOTAL PROJECT COSTS	0.00	0.00		0.00	0.00	0.00	0.00

Save Exit

Attachment II-C

American University Vehicle Safety Policy and Guidelines

http://www.american.edu/finance/rmo/vspolicy.html.

Prepared by:

American University
Office of Finance and Treasurer
4400 Massachusetts Avenue, N.W.
Washington, DC 20016-8033
(202) 885-2700

VEHICLE SAFETY POLICY AND GUIDELINES

References:
#1 Application for Driving Privileges
#2 Driver Acceptability Guidelines
#3 Level of Offenses (comparable to university levels of offense)
#4 "How's My Driving" Comment Report Form

Introduction

While vehicle operation is an essential part of the services provided to the American University community, accidents, damage and abuse of vehicles represent a huge expenditure to the university. In many cases these costs are preventable. The purpose of this policy is to establish a uniform, university-wide program that:

- ensures the safe operation of university owned and leased motor vehicles
- ensures the safety of drivers and passengers
- minimizes losses, damages, and claims against the university.

This university policy and its associated programs apply to all drivers who may be engaged in the operation of any university owned or leased motor vehicles on either public or private property. This policy stipulates requirements in addition to those of other established programs such as campus traffic regulations and pedestrian safety, motor vehicle maintenance, and parking enforcement. Responsibility and authority for the enforcement of this policy has been delegated to the risk management office.

All drivers (including full-time and part-time staff and faculty, students, work-study students, and interns) must be authorized to drive university owned or leased motor vehicles. Authorization is valid for the term of one year and is completed through the risk management office with the review of driving records.

The university is currently responsible for the operation of a fixed fleet of over 60 owned and leased motor vehicles distributed among seven departments (consisting of approximately 275 full and part-time students and employees), as well as additional motor

vehicles that may be leased as needed. The university's automobile insurance coverage includes all university owned or leased motor vehicles and all authorized drivers with respect to property and liability claims.

University vehicles are to be used for authorized business only. All drivers must comply with all applicable laws and regulations concerning the operation of motor vehicles. University supervisory personnel are responsible for conducting evaluations of each driver's performance on a periodic basis, consistent with university performance evaluations and staff policies. The university maintains the right to suspend an employee's or student's privilege to operate a university motor vehicle at any time and for any reason.

Driver Training

All university drivers must complete a driver-training course. Students are required to complete the training each year and employees who regularly operate university owned vehicles are required to complete the training every three years. The course, Coaching the Van Driver II, can be either a self-paced instruction, or classroom lecture depending on the needs of the department. The course is provided by the National Safety Council and covers driver safety and the unique safety considerations of university vans. The risk management office can provide the training materials and in some cases, provide the training. Deans, directors, and department heads may develop additional training as they deem necessary, based on the needs of their department.

Drivers should also receive an orientation of the vehicle that he will be driving. The vehicle orientation should include:

- location of safety equipment such as flashers and first aid kits
- familiarization of the equipment
- vehicle operation
- safety considerations such as those associated with 15-passenger vans
- explanation of the routes to be driven
- pre-trip inspection procedures
- location of insurance and Emergency and Accident packets

Driver Qualifications

In order to receive authorization to operate a university motor vehicle, an employee or student must:

- possess a current and valid United States driver's license issued by the Department of Motor Vehicles from his/her state of residence or the District of Columbia for at least two (2) years (International driver's licenses are not acceptable)
- fill out completely the Application for University Driving Privileges and submit to the Office of Finance and Treasurer annually
- fall within the "approved" or "approved on probation" status on the driver acceptability guidelines
- successfully complete the university's safe driver training program (annually for students and every three (3) years for employees who regularly operate university

owned vehicles, or more frequently as required or deemed appropriate by supervisory personnel).

Driver Obligations

All drivers are expected to safeguard and maintain university vehicles. Improper attention to vehicle maintenance, safe operations, or violations of the university vehicle policy, may result in suspension of driving privileges. In addition to restrictions and requirements placed upon university vehicle drivers by individual departments, drivers must also:

- keep safety and accident prevention foremost at all times
- comply with all traffic laws
- have a valid driver's license
- use university vehicles for authorized business only
- not permit any unauthorized person to drive the vehicle
- assume all responsibility for any and all fines or traffic violations and citations associated with his/her use of a university vehicle
- not drive under the influence of drugs or alcohol
- not transport unauthorized passengers such as hitchhikers, family members, or friends
- use seat belts or other available occupant restraints and require all occupants to do likewise in accordance with state laws
- agree to operate university motor vehicles in accordance with applicable local and federal laws and university regulations, at all times, (this agreement is found on the bottom portion of the Application for Driving Privileges and must be signed by the driver at the time eligibility is conferred)
- turn off the vehicle, remove the keys, and lock the vehicle when it is left unattended
- drive the vehicle at posted speed limits or less depending on road conditions
- not drive the vehicle "off road" unless it is made for that use
- immediately report all accidents to university police at (202) 885-3636
- immediately report any violations or change in license status (i.e. if your license has been suspended or revoked) to the supervisor and risk management office within five (5) working days of any such change (if the license is revoked, operating privileges will be temporarily suspended or terminated)
- return all vehicles in good clean condition, removing all garbage and food items;
- be subject to applicable university disciplinary procedures for violations of university policy or rules
- before leaving the parking area or garage, inspect the vehicle for safety concerns,

checking the tires, wipers, lights, and other safety equipment for observable defects, and report any defects immediately to the prescribed authority to determine if the vehicle is safe to operate

- follow the safety guidelines as discussed in the driver-training course
- not transport more than ten passengers
- be aware of the load and handling characteristics associated with the vehicles.

Special Restrictions:

Athletic Department: A full-time or part-time coach or departmental-appointed program supervisor must be in a van being driven by a student, or be with the traveling party of vans in which students are driving, at all times.

Responsibilities
Departmental & University Sanctioned Groups

As a minimum requirement, each department or group that may use a university motor vehicle is required to maintain the program procedures outlined below. The development of department specific procedures is the responsibility of individual deans, directors, or department heads. Deans, directors, or department heads may institute additional policies or procedures, as they deem necessary. The risk management office may be consulted for advice relating to additional departmental procedures and may exercise at its discretion, the right to request copies of each specific department or group's written procedures for review. The department's or organization's program must:

- ensure only those individuals, who have been determined eligible and are authorized by the sponsoring department or group, operate a university motor vehicle
- establish and maintain an ignition key control system for issuing ignition keys in such a manner so as to prevent unauthorized use of university motor vehicles
- establish and maintain a current list of all persons within the department or group who have been determined eligible and are authorized by the sponsoring department or group to operate a university motor vehicle
- establish and maintain a sign-in and -out log and procedures that include at least the name of eligible driver requesting authorization to use vehicle, destination and estimated duration, activity or destination, and date and time signed in and out
- maintain each motor vehicle according to the motor vehicle manufacturer's recommendation and the physical plant operations department preventive maintenance schedules. (The physical plant vehicle maintenance contact phone number is extension 2350).

In addition to the procedures above, departmental programs should ensure the materials listed below are maintained in each university owned and leased motor vehicle:

- vehicle registration
- Emergency and Accident packet including the following:
    - vehicle accident report brochure

- First aid kit (optional)
- Fire extinguisher (optional except for athletic vehicles and shuttle buses)
- Emergency reflector triangles and battery-operated warning lights or U.S. Department of Transportation approved road flares (optional except for athletic vehicles and shuttle buses).

Departmental and university sanctioned groups are encouraged to establish fleet coordinators for monitoring fleet activities, ensuring compliance with this vehicle policy and serving as a liaison with the offices of risk management, public safety and physical plant operations.

Vehicle Maintenance and Damage

Vehicle maintenance is the responsibility of all departments and their drivers. The majority of the annual cost of vehicle body damage to the university is preventable. When there is damage to university vehicles, drivers should immediately report the damage to their department fleet coordinator who will in turn notify physical plant operations at extension 2350. Drivers should describe the incident that caused the damage in detail. If the damage was caused during an accident, the driver and department should follow the accident procedure described in this document.

Department of Public Safety

In the event of any accident on campus or off-campus involving a university motor vehicle, the Department of Public Safety shall:

- take action as detailed in their departmental manual
- notify Patricia Kelshian in the risk management office at x3284 of the accident and forward the accident investigation report as well as any photographs of the motor vehicles or accident scene to the risk management office within twenty-four (24) hours of the incident.

Department of Physical Plant Operations

The physical plant operations department shall provide the following services regarding university vehicles:

- routine preventative maintenance on vehicles
- registration and tag renewals
- emergency breakdown repairs
- manage vehicle inspection logs
- manage gas purchasing card program
- quarterly safety checks and yearly inspections.

Risk Management Office

In addition to providing resources to individual department in order to assist in complying with this program, the risk management office will also:

- verify and/or review drivers' qualifications and driving records
- notify individual's eligibility to operate a university motor vehicle to employee's or student's sponsoring department or group
- review accident investigation reports, identifying preventive measures, recommending the implementation of accident prevention measures to appropriate parties, and taking other action when necessary in conjunction with the department heads
- develop and coordinate safety activities with departmental fleet coordinators
- coordinate any claims made by or against the university with the university's insurance carrier and involved administrative groups in the event of a loss-producing accident
- arrange driver training resources as necessary
- monitor and coordinate actions relating to the unsafe driver incident reports from the "How's my driving?" telephone line.

Enforcement

Failure to comply with the procedures in this policy may result in disciplinary action comparable with the established university policy on conduct and discipline as specified in the University Staff Personnel Policies Manual, and may result in suspension or termination of motor vehicle operating privileges; please read the Levels of Offenses (comparable to university levels of offense)

In the event of an accident involving a university motor vehicle caused by a university driver while under the influence of drugs or alcohol, or in the event of gross negligence, the university may have grounds to make a claim for the recovery directly against the employee or student. In such a situation, the university may pursue legal action directly against the individual. The university reserves the right to arrange a blood test and/or urine test for alcohol and /or drugs in the event a driver is involved in an accident while operating a university motor vehicle.

Breakdowns and Emergencies

In case of a breakdown, please contact public safety at 885-3636. Once you are able to make arrangements with public safety, notify your supervisor immediately.

Accident Procedures

In the event of an accident on campus, the following procedures must be followed:
1. Immediately notify the department of public safety at 885-3636 of your name, location, and pertinent information about the accident.
2. Obtain the names, addresses, and telephone numbers of all witnesses.
3. Complete the accident report form (and accident questionnaire, if necessary) located in the motor vehicle glove box.

4. Report the accident immediately to your supervisor.
5. Never admit liability while at the scene of the incident. Insurance adjusters, and in some cases the courts, will determine liability after an investigation of the facts in accordance with applicable laws and regulations. Drivers should speak freely and accurately to university law enforcement personnel and insurance adjusters.

In the event of an accident on public property, drivers must follow the following procedures:
1. Notify the local Police Department by telephoning 911 and providing pertinent information concerning the accident. Do not leave the accident scene until the local police have responded.
2. Notify the department of public safety at 885-3636.
3. Obtain the names, addresses, and telephone numbers of all witnesses.
4. Complete the accident report form (and accident questionnaire, if necessary) located in the motor vehicle glove box.
5. Report the accident immediately to your supervisor.
6. Never admit liability while at the scene of the incident. Insurance adjusters, and in some cases the courts, will determine liability after an investigation of the facts in accordance with applicable laws and regulations. Drivers should speak freely and accurately to law enforcement personnel and university insurance adjusters.

For further guidance, note the instructions found in the Emergency Action Packet claims brochure. For additional copies of the brochure, contact the risk management office at extension 2706.

If a vehicle needs to be towed, any local towing company can be used. Vehicles are to be towed only to American University's physical plant garage located next to the Osborn Building.

Unsafe Driver Incident Observance

To ensure everyone that unsafe motor vehicle operating practices will not be tolerated, signs are posted on all university motor vehicles that state:

"How is my driving? Call 885-3145"

A comment report will be completed for all complaints and forwarded to the appropriate supervisor or department head for further action to be determined ("How's My Driving" Comment Report)

For more information or
questions email: RMO@american.edu

Office of Finance and Treasurer

[Print]

Office of Vice President and Treasurer

Risk Management & Safety Services

APPLICATION FOR DRIVING PRIVILEGES

Type: ☐ New ☐ Recertify

Employee Name:

Permanent Address:

Street: City:

State: Zip:

Dept:

Ext:

eMail:

Emergency Contact(s):

Contact #1 Name: Home Phone:

Contact #2 Name: Home Phone:

Personal Information:			
Driver's License #:		AU Employee/Student Number:	
State of Issuance:		List Years of Driving Experience:	
Sex:	☐ Male ☐ Female	Number of Moving Violations within the past three (3) years:	
Expiration Date of License:		Type of Violation(s):	
Social Security #:		Number of Chargeable Accidents within the past three (3) years:	

I, , understand and agree to the following:

- 1. To the best of my knowledge, the information on this application is correct. I understand that any misrepresentation or falsification of information may be sufficient cause for rejection of motor vehicle operating privileges.
- 2. I authorize American University to inquire and verify the information contained herein.
- 3. I agree to abide by all laws and regulations pertaining to the operation of motor vehicles, as well as university policy and driving regulations.

Signature of Applicant:		Date:	
Signature of Supervisor:			

Print Supervisor's Name:

Supervisor's Dept Address:

Please include a copy of your driver's license with this application and return to the **RISK MANAGEMENT OFFICE**

- Home
- Emergency Preparedness
- Environmental Health and Safety
- Insurance
- Public Safety
- Vehicle Policy
- Contact Us
- VP Finance & Treasurer

Driver Acceptability Guidelines

Major Violations Accident (at fault or charged)

*Driving while intoxicated or under the influence of drugs
*Driving while license is under suspension
Hit and Run
*Murder or assault with motor vehicle
*Negligent homicide
*Reckless driving
*Speeding
Theft of a motor vehicle and related offenses
(* see Non-Approved Status below)

Minor Violations

- Not obeying a traffic sign or light
- Seat belt violation

Approved Status

- Driver must have two (2) years driving history
- Less than six (6) points (DC point system or equivalent)
- No more than one (1) accident or moving violation charged against the licensee within the last three (3) years, none (0) within the last eighteen (18) months.
- No more than one (1) minor violation charged against the licensee within the previous three (3) years, none (0) within the last eighteen (18) months.

return to top

Approved on Probation Status

- ·Two (2) minor violations charged against the licensee within the previous three (3) years, none (0) within the last twelve (12) months.
- One (1) major violation (excluding the * non-approved status violations) within the last three (3) years, none (0) within the last twelve (12) months.

***Non-Approved Status**

- Reinstated license in effect less than one year after revocation.
- Any one (1) of the following violations within the last three (3) years
  - Driving while intoxicated or under the influence of drugs
  - Driving while license is under suspension
  - Murder or assault with motor vehicle
  - Negligent homicide
  - Reckless driving

- Speeding in excess of 25mph over the posted limit

- Conviction of three (3) or more ordinary traffic violations, or more than two (2) chargeable accidents, or more than two (2) of these violations in the past twelve (12) months.

return to top

Probation
Term - 6 months
A driver approved on probation can not receive any accountable minor/major violations within 6 months of the approval date or driving privileges will be revoked. A previously approved driver who receives two (2) accountable minor violations or one (1) accountable major violation will be placed on a 6-month probation period following the rule stated above and be required to take a driver training course.

Levels of Offenses

Levels of offenses listed below are comparable to the offenses indicated in the Staff Personnel Policies Manual.

- **Level I Offense**
  · Failure to replace cables or traffic barriers on campus
  · Parking in a manner that impedes traffic flow or blocks building entrances
  · Parking in a fire lane
  · Failure to properly log out a motor vehicle
  · Leaving keys unattended in a motor vehicle
  · Allowing passengers to ride in the back of an open motor vehicle
  · Failure to use a seat belt when provided in a university motor vehicle
  · One (1) valid Unsafe Driver Observance Citation within a one-year period
  · Allowing unauthorized passengers to ride in a motor vehicle

- **Level II Offense**
  · Failure to obey university or local traffic regulations
  · Operating a motor vehicle outside of the designated work area without proper cause
  · Driving over turf area, sidewalks, curbing, wire cables, or other material that may cause physical damage
  · Failure to obey directions from supervisory personnel concerning operation, use, or parking of university motor vehicles
  · Operating motor vehicle in a reckless or unsafe manner
  · Failure to report an accident while operating a university motor vehicle to your Supervisor, the Department of Public Safety, or the Office of Finance and Treasurer within twenty-four (24) hours.
  · Two (2) or more valid Unsafe Driver Observance Citations in a one-year period
  · Failure to secure motor vehicle, tools, and equipment after use

- **Level III Offense**
  · Operating a motor vehicle while under the influence of alcohol or drugs (see paragraph below)
  · Two (2) chargeable accidents in a six-month period while operating a motor vehicle
  · Unauthorized personal use of a university motor vehicle
  · Operating a university motor vehicle without a valid driver's license
  · Failure to report the suspension or revocation of your driver's license
  · Driving that results in the destruction of university property

In the event of an accident involving a university motor vehicle caused by a university driver while under the influence of drugs or alcohol, or in the event of gross negligence, the university may have grounds to make a claim for the recovery directly against the employee or student. In such a situation, the university may pursue legal action directly against the individual. The university reserves the right to arrange a blood test and/or urine test for alcohol and /or drugs in the event a driver is involved in an accident while operating a university motor vehicle.

return to top

contact: rmo@american.edu
4400 Massachusetts Avenue, NW * Washington, DC * 20016
202.885.2706 * Fax 202.885.3278

Office of Vice President and Treasurer Risk Management & Safety Services

"HOW'S MY DRIVING?" - LINE COMMENT REPORT

Today's Report Date:

Name of Caller:

Telephone Number:

Date and Time of Call:

Date of Incident:

Time of Incident:

Vehicle Number:

Vehicle Tag Number:

Location of Incident:

Comment:

Supervisor Name:

For more information or questions email: RMO@american.edu

Office of Finance and Treasurer

Attachment II-D

FRAMEWORK FOR INSTITUTIONAL POLICIES AND PROCEDURES TO DEAL WITH FRAUD IN RESEARCH

Association of American Universities

National Association of State Universities
and Land-Grant Colleges

Council of Graduate Schools

November 4, 1988

Table of Contents

Introduction

Fraud in research undermines the scientific enterprise in ways that go far beyond the waste of public funds. Although an uncommon event relative to the large scientific literature, violations of accepted standards inevitably appear in this as in all human pursuits. Institutions engaged in research have a major responsibility, not only to provide an environment that promotes integrity, but also to establish and enforce policies and procedures that deal effectively and expeditiously with allegations or evidence of fraud.

In dealing with this problem it is important not to create an atmosphere that might discourage openness and creativity. Good and innovative science cannot flourish in an atmosphere of oppressive regulation. Moreover, it is particularly important to distinguish fraud from the honest error and the ambiguities of interpretation that are inherent in the scientific process and are normally corrected by further research.

Many institutions have adopted and published policies to deal with these problems. The primary goal of this document is to assist institutions as they refine such policies or as they move to adopt new ones designed to assure careful and thorough handling of allegations of fraud. It expands upon the guidelines presented in two 1982 publications: "The Maintenance of High Ethical Standards in the Conduct of Research," by the Association of American Medical Colleges (AAMC), and the "Report of the Association of American Universities Committee on the Integrity of Research," by the Association of American Universities (AAU).

This document also has taken into consideration the 1986 Public Health Service (PHS) guidelines, "Policies and Procedures for Dealing with Possible Misconduct in Science"; and the 1987 regulations issued by the National Science Foundation (NSF), "Misconduct in Science and Engineering Research." The PHS guidelines and NSF regulations describe those agencies' preferred procedures for the institutional handling of allegations of research fraud. Those procedures normally have four stages:

- an inquiry to determine whether the allegation or related issues warrant further investigation,
- when warranted, an investigation to collect and thoroughly examine evidence,
- a formal finding, and
- appropriate disposition of the matter.

It is important to note that any new policies and procedures to deal with allegations of violations of the integrity of research must be incorporated into existing institutional policies and procedures for employment and academic conduct. Institutions must be vigilant to provide all parties with appropriate due process. It is reasonable to expect that different situations may require specific accommodations to insure the protection of the rights of all involved individuals. Institutions should be alert to possible harm to any parties throughout the process. An institution may choose, following an investigation, to refer any "findings" to it's standing disciplinary procedures, or to develop processes specific to cases of fraud and misconduct in research.

The several stages of an institution's review process are discussed in detail in the remainder

of this document. However, it seems useful to identify at the start the imperatives that should guide any institutional review process for dealing with allegations of fraud:

- Institutions should ensure that the process used to resolve allegations of fraud not damage science itself.

- Institutions should provide vigorous leadership in the pursuit and resolution of all charges.

- Institutions should treat all parties with justice and fairness and be sensitive to their reputations and vulnerabilities.

- Procedures should preserve the highest attainable degree of confidentiality compatible with an effective and efficient response.

- The integrity of the process should be maintained by painstaking avoidance of real or apparent conflict of interest.

- The procedures should be as expeditious as possible leading to the resolution of charges in a timely manner.

- Institutions should document the pertinent facts and actions at each stage of the process.

After resolving allegations, institutions should discharge their responsibilities both internally - to all involved individuals - and externally - to the public, the sponsors of research, the scientific literature, and the scientific community, to the extent that is appropriate and allowable.

Definition of Research Fraud

Research fraud is a form of scientific misconduct involving deception. It should be distinguished from honest error, which can occur inadvertently in any enterprise. It is often difficult when confronted with an allegation to determine where along the spectrum from error to fraud a particular case will lie.

There is significant debate within the scientific community and in government about the appropriate scope of policies for dealing with the problem and about the definition of behaviors covered by such policies. Specifically, there is no agreement on the definition of "fraud" or "misconduct." Until the debate over appropriate scope and definition is resolved, institutions may wish to simply reference in their policies the definitions contained in federal regulation. The NSF defines misconduct as follows:

> (a) "Misconduct" means (1) fabrication, falsification, plagiarism, or other serious deviation from accepted practices in proposing, carrying out, or reporting results from research; (2) material failure to comply with Federal requirements for protection of researchers, human subjects, or the public or for ensuring the welfare of laboratory animals; or (3) failure to meet other material legal requirements governing research.

The PHS has published the following definition in a pending Notice of Proposed Rulemaking (NPRM):

> "Misconduct" or "misconduct in science" as used herein is defined as (1) fabrication, falsification, plagiarism, deception or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research; or (2) material failure to comply with federal requirements that uniquely relate to the conduct of research.

However, some institutions, feeling that these definitions are too broad, may wish to adopt a more precise definition of scientific fraud, such as that contained in the 1982 AAU policy statement. That definition includes the following:

- *Falsification of Data* - Ranging from fabrication to deceptively selective reporting, including the purposeful omission of conflicting data with the intent to falsify results.

- *Plagiarism* – Representation of another's work as one's own.

- *Misappropriation of Other's Ideas* - The unauthorized use of privileged information (such as violation of confidentiality in peer review), however obtained.

In formulating such a definition of fraud, institutions should be aware of the need for policies and procedures to address allegations relating to other forms of scientific misconduct. Examples of this kind of conduct would include inability to produce verifiable primary data supporting reported research results or violations of governmental or institutional rules and regulations regarding the conduct of research.

Some institutions may choose to consolidate in a single policy their procedures for dealing with all forms of alleged scientific misconduct. In such a case, the institution may wish to leave the determination of the point at which misconduct becomes fraud to ad hoc determination on the basis of the particular facts of each case. Such an approach permits the development of an institutional "common law" articulating acceptable scientific research standards. If an institution has separate policies and procedures for dealing with forms of misconduct other than fraud, it is suggested that the relevant sections be included in an appendix to the policies and procedures designed to address fraudulent behavior.

Process for Handling Allegations of Research Fraud

Initiation of an Inquiry

The responsibility to pursue an allegation of research fraud belongs to the institution and must be carried out fully to resolve questions regarding the integrity of research. Even in the absence of a specific complaint, the institution should be alert to questionable academic conduct that might raise legitimate suspicion of fraudulent research. In the inquiry and any investigation that may follow, the institution should focus on the substance of the issues and should be vigilant not to permit personal conflicts between colleagues to obscure the facts.

In order to address all allegations of research fraud expeditiously, an institution should designate one or more senior administrators to whom allegations should be reported. Because universities are organized differently, they will choose to delegate this responsibility to meet the

needs of their own organizational structure. The designated individual(s) could also:

- provide education about fraud,
- interpret the institution's fraud policy,
- counsel staff, and
- disseminate the policy.

The designated senior administrator(s) should pursue all allegations to resolution. If there is a conflict of interest, the case should be referred to an alternate senior administrator. To avoid unnecessary delays and confusion, it is advisable to predetermine the administrative alternate(s).

Institutional policies should state clearly that the senior administrator will counsel confidentially any individual who comes forward with an allegation of fraud. Some concerns brought to the senior administrator's attention may not fall within the scope of the policies and procedures developed to address fraud. Regardless of the nature of the concern, the senior administrator should seek to assist in its resolution through whatever institutional processes may be appropriate to the particular case, such as referral to the department chairman, the personnel office, or the faculty grievance procedure. If the senior administrator determines that the concern is properly addressed through policies and procedures designed to deal with fraud in research, the inquiry and investigation procedures should be discussed with the individual who has questions about the integrity of a research project. If the individual chooses not to make a formal allegation, but the senior administrator believes there is sufficient cause to warrant an inquiry, the matter should be pursued; in such a case, there is no "complainant" for the purposes of this document.

Even if the respondent leaves the institution before the case is resolved, the institution has a responsibility to continue the examination of the allegations and reach a conclusion. Further, an institution should cooperate with the processes of other involved institutions to resolve such questions.

Inquiry

Structure

The inquiry process may be handled with or without a formal committee. Regardless of the approach chosen, it is the responsibility of the senior administrator to ensure that the inquiry is conducted in a fair and just manner. The inquiry phase is critical; institutions should consider whether more than one person should be involved in conducting the inquiry. If the committee method is utilized, the committee should be formed under the guidelines presented in the investigation section (see page II-31).

Individuals chosen to assist in the inquiry process should have no real or apparent conflicts of interest bearing on the case in question. They should be unbiased, and have appropriate backgrounds for judging the issues being raised.

Institutions should consult their own legal counsel to minimize the risk of liability for actions taken in the conduct of the inquiry and investigation. Institutions should also make clear any policies on providing legal counsel to complainants and respondents.

Purpose

Whenever an allegation or complaint involving the possibility of fraud is made, the designated senior administrator should initiate an inquiry - the first step of the review process. In the inquiry stage, factual information is gathered and expeditiously reviewed to determine if an investigation of the charge is warranted. An inquiry is not a formal hearing; it is designed to separate allegations deserving further investigations from frivolous, unjustified, or clearly mistaken allegations.

Process

Upon initiation of an inquiry, the senior administrator is responsible for notifying the respondent within a reasonable time of the charges and the process that will follow. If the committee method is to be used, the committee members should be appointed and convened.

Whether a case can be reviewed effectively without the involvement of the complainant depends upon the nature of the allegation and the evidence available. Cases that depend specifically upon the observations or statements of the complainant cannot proceed without the open involvement of that individual; other cases that can rely on documentary evidence may permit the complainant to remain anonymous. While it may be desirable to keep the identity of the complainant confidential during the inquiry phase, local laws that provide for open access to certain records may make such confidentiality impossible. During the inquiry, confidentiality is desirable in order to protect the rights of all parties involved.

The senior administrator should assume responsibility for disseminating the information to the appropriate individuals. Normally notification should be made in writing and copies filed in the office of the senior administrator. The safety and security of all documents must be assured.

When the inquiry is initiated, the respondent should be reminded of the obligation to cooperate by providing material necessary to conduct the inquiry. Institutional policies should state clearly that uncooperative behavior may result in an immediate investigation and other institutional sanctions.

Each institution should develop policies regarding the role of legal counsel in this and other phases of these proceedings. Those responsible for conducting the inquiry must be aware of the institution's policies.

Due to the sensitive nature of allegations of fraud, institutions should strive to resolve cases expeditiously. Deadlines should be established to facilitate the process. It is recommended that the inquiry phase be completed within 30 days of the initial written notification of the respondent. A 30-day period is consistent with the 1986 PHS guidelines and the 1987 NSF regulations. If the committee or whatever body is convened anticipates that the established deadline cannot be met, a report, citing the reasons for the delay and progress to date, should be submitted for the record and the respondent and appropriately involved individuals should be informed.

Findings

The completion of an inquiry is marked by a determination of whether or not an

investigation is warranted. There should be written documentation to summarize the process and state the conclusion of the inquiry. The respondent should be informed by the senior administrator whether or not there will be further investigation. If there is a complainant, he or she should be likewise informed.

Allegations found to require investigation should be forwarded promptly to the investigative body. Federal regulation requires that the agency sponsoring the research also be notified at this point.

If an allegation is found to be unsupported but has been submitted in good faith, no further formal action, other than informing all involved parties, should be taken. The proceedings of an inquiry, including the identity of the respondent, should be held in strict confidence to protect the parties involved. If confidentiality is breached, the institution should take reasonable steps to minimize the damage to reputations that may result from inaccurate reports. Policies should state that allegations that have not been brought in good faith may lead to disciplinary action.

The institution should seek to protect the complainant against retaliation. Younger, less senior people are particularly vulnerable. Individuals engaging in acts of retaliation should be disciplined in accordance with the appropriate institutional policies.

Investigations

Purpose

An investigation should be initiated when an inquiry issues a finding that investigation is warranted. The purpose of investigation is to explore further the allegations and determine whether fraud has been committed. In the course of an investigation, additional information may emerge that justifies broadening the scope of the investigation beyond the initial allegations. The respondent should be informed when significant new directions of investigation are undertaken. The investigation should focus on accusations of fraud as defined previously and examine the factual materials of each case.

Structure

The investigative body may take any of several forms: an ad hoc committee to handle one specific case, a combination of standing committee and one-time-only appointed members, or a standing committee. Members of the investigative body may be chosen from within or outside of the institution.

Regardless of the structure chosen, conflicts of interest must be examined scrupulously and any relationship with parties to the matter must be fully disclosed. Those investigating the allegations should be selected in full awareness of the closeness of their professional or personal affiliation with the complainant or the respondent. Any member of a standing committee who has an unresolvable conflict of interest in a given case should not be permitted to be involved in any aspect of the committee's handling of that case.

Whether a standing committee or an ad hoc committee is utilized, it is important that the committee have appropriate scientific expertise to assure a sound knowledge base from

which to work.

Process

Upon receipt of inquiry findings that an investigation is warranted, the senior administrator should initiate investigating promptly, and the complainant and respondent should be notified of the investigation. All involved parties are obligated to cooperate with the proceedings in providing information relating to the case. All necessary information should be provided to the respondent in a timely manner to facilitate the preparation of a response. The respondent should have the opportunity to address the charges and evidence in detail. The institutional procedures should address the role of legal counsel in the investigation.

Institutions may wish to adopt, as a matter of policy, a mechanism that would allow interim administrative action to be taken when justified by the need to protect the health and safety of research subjects and patients, or the interests of students and colleagues. Administrative action could range from slight restrictions to suspension of the activities of the respondent.

As previously noted, federal regulations require that the agency sponsoring a research project in which fraud is suspected should be notified as soon as the decision has been made to undertake an investigation. It is recommended that this practice be extended to include notification of all sponsors of research. The institution may wish, in turn, to seek assurances of the confidential treatment of this information. Significant developments during the investigation, as well as the final findings of the committee, should be reported to the sponsor. When the investigation is concluded, all entities initially notified of the investigation should be informed of its final outcome.

An institution's policy should require that an investigation be conducted as expeditiously as possible. The adoption of a specified time period of 120 days for the completion of an investigation is recommended, to reflect the seriousness with which an institution views accusations of fraud and to be in compliance with the PHS guidelines and NSF regulations. However, an institution may choose to acknowledge formally in its procedures that the nature of some cases may render the time period difficult to meet. It should be noted that an institution's ability to complete an investigation within a specified time period will depend heavily upon factors such as the volume and nature of the research to be reviewed and the degree of cooperation being offered by the subject of the investigation. An institution may choose to specify interim reporting to monitor the progress of an investigation. If the deadline cannot be met, an interim report should be submitted to the senior administrator with a request for an extension.

Findings

The findings of the investigative committee should be submitted in writing to the senior administrator. The respondent should receive the full report of the investigation. When there is more than one respondent, each shall receive all those parts that are pertinent to his or her role. All federal agencies, sponsors, or other entities initially informed of the investigation also must be notified promptly. The institution should retain the findings of the investigation in a confidential and secure file.

Investigations into allegations of fraud may result in various outcomes, including:

- a finding of fraud;
- a finding of serious scientific misconduct short of fraud;
- a finding that no culpable conduct was committed, but serious scientific errors were discovered;
- a finding that no fraud, misconduct, or serious scientific error was committed.

Thus, an investigation of fraud may disclose evidence that requires further action even in those cases in which no fraud is found.

If an investigation has been launched on the basis of a complaint, and no fraud or misconduct is found, no disciplinary measures should be taken against the complainant and every effort should be made to prevent retaliatory action against the complainant if the allegations, however incorrect, are found to have been made in good faith. If the allegations are found to have been maliciously motivated, disciplinary actions may be taken against those responsible.

Appeal/Final Review

Institutions may choose to provide respondents with an additional appeals process at this point through a written appeal of the investigative committee's decision. Appeals should be restricted to the body of evidence already presented, and the grounds for appeal should be limited to failure to follow appropriate procedures in the investigation or arbitrary and capricious decision-making. New evidence may warrant a new investigation. The appeal should be filed promptly after a finding has been made. The institution should specify a senior administrative official (e.g., Provost) to hear the appeal. After an appeal is concluded, an institution may also wish to provide for a final review by its chief executive officer or designee. The institution should note that the decision of the review is final.

Disposition

Responsibility for determining the nature and severity of disciplinary action should be specified in an institution's policy. This may, but need not necessarily, be done through the institution's regular faculty disciplinary or grievance procedures. Many actions may be available to the institution. Examples may include:

- Removal from particular project
- Letter of reprimand
- Special monitoring of future work
- Probation
- Suspension
- Salary reduction
- Rank reduction
- Termination of employment

Consideration also should be given to formal notification of other concerned parties,

not previously notified, such as:

- Sponsoring agencies, funding sources
- Co-authors, co-investigators, collaborators
- Editors of journals in which fraudulent research was published
- State professional licensing boards
- Editors of journals or other publication, other institutions, sponsoring agencies, and funding sources with which the individual has been affiliated
- Professional societies
- Where appropriate, criminal authorities

Appendix
PHS Guide (PHS regulations will be distributed when final)
NSF Regulations
1982 AAMC Report
1982 AAU Report

Revised 11/4/88
PFS/CRS/dmm

REPORT OF THE ASSOCIATION

OF AMERICAN UNIVERSITIES

COMMITTEE ON THE INTEGRITY OF RESEARCH

Approved by:

The Joint Committee on Health Policy

of

The Association of American Universities

The American Council on Education

and

The National Association of State Universities

and Land-Grant Colleges

Association of American Universities
Committee on the Integrity of Research

Chancellor William H. Danforth, Chairman
Washington University

Dr. Struther Arnott
Vice President for Research and Dean of the Graduate School
Purdue University

Dr. Albert A. Barbar
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Dr. James Anthony Ferrendelli
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Washington University
School of Medicine

Dr. Richard S. Ross
Dean of The Medical Faculty
The John Hopkins University

Dr. Howard G. Sachs
Associate Provost for Academic Affairs
Administration
Ohio State University

Mr. Cliff K. Travis
University Council
Indiana University

Introduction

Examples of fraud in research have recently been reported in great detail by the media; these reports have raised concern in the public as well as among the scientists. Many concerned citizens have wondered whether such activity has become more prevalent, whether it is being reported more often, whether it can be detected readily, whether institutions are organized appropriately to inquire into alleged frauds, and whether procedures for administering discipline are in place.

On October 20, 1981, the Association of American Universities voted to establish a Working Group on the Integrity of Research. The resolution read in part:

> "Incidents of misconduct that raise concern about integrity in scientific research have come to our attention. Although we believe such instances to be rare for such a large enterprise as university research, even rare occurrences are unacceptable.
>
> "The AAU therefore recognizes a need for universities to collaborate with professional societies and related organizations in the examination of the sources of such problems and remedies available to them."

The working group subsequently appointed by the Executive Committee of the AAU believes that the integrity of the research process is an essential part of our intellectual and social structure and must be maintained at all costs. Although serious violations of honesty in research may be rare, those that do occur strike at the very heart of the enterprise. Advances in knowledge depend on trustworthy data and honestly reported conclusions. Anything less will seriously undermine the total enterprise and erode public confidence in those responsible for its conduct.

The integrity of the research process must depend largely on self-regulation; it is the responsibility of all who engage in the search for knowledge. This principle has served science in an exemplary way for centuries. Advances are gleaned from rigorous application of scientific methods and in compliance with ethical codes rooted in intellectual honesty.

Deviations from the norm - even serious ones - have usually been dealt with informally and quietly. Although these methods may have generally worked well in the past, experience suggests that it is now appropriate to give serious thought to better methods for preventing and detecting irregularities and to the manner in which universities deal with them.

This committee has looked at some of the questions especially important to the operation of academic institutions. We encourage others such as scientific societies, editors, and funding agencies to look at the matter from their own perspectives.

Types of Fraud or Deviance in Academic Research

Deviant actions by researchers may be grouped in four categories - scholarly fraud by falsification of data, plagiarism, abuse of confidentiality, and deliberate violations of regulations.

Falsification of data undermines the basic principle on which the scientific process depends. Since scientific advances depend on accurate collection, analysis, and reporting of information, dishonest reporting misleads others and results in the waste of resources, both human and monetary.

If practiced in clinical research, falsification could even be directly dangerous to humans. Falsification of data ranges from sheer fabrication through selective reporting, including the omission of conflicting data.

Plagiarism is especially hurtful to individual researchers since it is an attempt by one individual to receive credit for the work of someone else. Outright plagiarism is generally easily detected in areas of research that are very actively pursued and is, therefore, rare. However, the academic community tolerates more than it should, more subtle deviations from the ideal. Inadequate citation and parsimony in referencing submission of the same data in more than one publication by the same author, and similar abuses, do occur with some regularity.

Abuse of confidentiality is a significant act of fraud in an environment that depends on peer review. It is quite distinct from plagiarism and more difficult to detect since such abuse does not usually involve verbatim duplication of another's work. In the present environment, researchers freely discuss their ideas in research proposals submitted to potential sponsors. Proposals usually include extensive data to support the ideas. The ideas and preliminary data may be reviewed by departmental colleagues, university committees and administrators, as well as extramural professional peers serving on review panels. In addition, detailed studies are submitted to professional journals and subjected to further review by professional colleagues long in advance of eventual publication. Opportunities to abuse confidentiality arise at many points during these processes. Moreover, abuse of confidentiality can occur not only by the actions of the primary reviewers but also by the actions of those with whom the reviewers have shared the privileged information. In many ways confidentiality is the easiest research ethic to abuse and the most difficult to detect.

Instances of *seemingly deliberate violations of regulations* applicable to research have also become a recent problem. Serious violations, especially of rules adopted by appropriate mechanisms to protect patients, research subjects, other persons, and animals, while not fraudulent in the traditional sense, must be considered so deviant as to undermine the integrity of the research process.

Prevention of Dishonesty in Scientific Research

The rewards associated with success tempt certain individuals into dishonest behavior. Scientific discoveries are rewarded by recognition by peers and, if sufficiently interesting or important, by the general community. In addition, productivity reaps tangible rewards, including career advancement, increase in salary, promotion, election to academic societies, receipt of prizes, funds for additional research, and other benefits.

Identification in advance of those susceptible to dishonest behavior is desirable. Careful explanation of the record of a prospective investigator can prove helpful. Special attention should be given to motivation and integrity at times of recruitment and advancement in responsibility. Credentials and claimed accomplishments should be examined carefully. Scholastic ability and technical competence do not necessarily indicate that the aptitude for science exists. It is often advisable to look beyond the most recent employment or educational experience for evidence of scientific aptitude and capability.

Since dishonesty is an unfortunate response to environmental temptations and since it is difficult if not impossible to detect in advance those most susceptible, major attention should be given to the following issues.

Encouragement of Intellectual Honesty Nothing can substitute for a pervasive attitude of intellectual honesty in the laboratory environment. A recommitment to the ethical standards of science by all its practitioners is absolutely essential. At a minimum these standards include: open communication, submission of work for peer review, avoidance of conflict of interest, and commitment to self-regulation. The encouragement of intellectual honesty is not the responsibility of a few but must be accepted by all persons in the university. Especially, the scientific leaders must set an example for all by assiduously complying with standards of intellectual honesty and must assume the responsibilities associated with the role of mentor. By maintaining high standards, scientific leaders create a climate that discourages dishonesty and fosters unquestionable integrity. It is our opinion that a positive attitude of intellectual honesty does more to prevent dishonesty than any other single factor.

Discouragement of "Success At Any Cost" Obviously this issue is a difficult one. It is impossible to eliminate productivity and success as determinants for promotion and recognition. To do so would discourage achievement and ambition and would probably markedly attenuate research activities. However, the emphasis on quality rather than quantity of research - especially publication - is strongly recommended. It should be recognized that pressure for more publications may not be explicit, but hidden pressures for more frequent reports and papers will prevail if responsible individuals are mute on the subject. An active and frequently expressed attitude stressing quality rather than quantity is necessary.

Acceptance of Responsibility by the Laboratory Director Although everyone involved in science must be active in the prevention of dishonesty, the director of a laboratory who is mentor or supervisor of research must assume special responsibilities. Personnel must receive appropriate supervision and students must be directed by experienced scientists. The director should supervise, teach, and encourage in-depth scrutiny and interpretation of results, emphasizing respect for primary data. Routine audit and review of all primary data by the laboratory director is strongly recommended. It is inadvisable for the director to delegate these important functions. The director must assume and should encourage the publication of as many primary data as possible.

Maintenance of Professional Interpersonal Relationships Interactions among laboratory personnel are important in determining attitudes concerning honesty and dishonesty. Laboratory directors should encourage investigators to work with other colleagues, to share data, and to discuss results freely. Secrecy about methods and data should be discouraged. Directors should also promote a close but open and professional interaction among investigators and between faculty and students. A sense of competition among laboratory personnel or between students and faculty must be avoided. Relationships should be sufficiently personal to encourage openness and freedom of expression but not so close as to interfere with objectivity.

Establishment of Well-Defined Experimental Protocol Well-designed and strictly-adhered-to experimental methods are important deterrents to dishonesty. Written, detailed, explicit procedures for data gathering, storage, and analysis are essential and should be available and practiced in all laboratories. Research that is blinded or coded and the repetition of experiments in the same or a different laboratory should be encouraged.

Appropriate Assignment of Credit and Responsibility A climate of integrity should include

generosity in recognizing the accomplishments of others. Adequate citation of the contributions of persons from other laboratories is especially important. Publications should list as authors only those who contributed significantly to the research, are prepared to stand behind the conclusions, and have reviewed the manuscript carefully.

Institutional Policies and Procedures

The committee recommends that all institutions prepare policies that state clearly the expectations for high standards of ethical behavior of those involved in research, the procedures for dealing with suspected deviations from intellectual honesty, and available sanctions. These policies and procedures must be consistent with the institution's policies on academic governance, freedom, responsibility, and due process, as well as with legal restraints.

The committee recommends that the adoption of such policies be given prompt attention by appropriate academic bodies in every university. Some institutions, after consultation with proper faculty committees, might find it suitable to adopt interim procedures with the understanding that a final document will be developed after further consideration.

This committee recommends that the policy statement deal with the following issues.

The Professional Responsibility of Researchers The policy should be explicit about the institutional standards for those engaged in research. In addition, the duties of those with oversight responsibilities should be clear. Mechanisms for periodic review of research policies may be included as necessary.

Procedures for Dealing with Deviations Institutions should have workable procedures for dealing with suspected deviations from intellectual honesty and the authority to apply appropriate sanctions when deviations are proved to the satisfaction of the appropriate body. (The excellent report, "The Maintenance of High Ethical Standards in the Conduct of Scientific Research," adopted by the Association of American Medical Colleges includes a helpful model for dealing with suspected fraud in research.)

Administrative Responsibility An officer or officers of the institution should be designated to inform investigators of policies that affect the conduct of research and to receive and pursue complaints concerning lack of integrity in research. Investigations should not be in the hands of associates from the laboratory in question, since personal relations may make objectivity difficult or impossible. The designated individual or individuals should see to it that appropriate institutional policies are followed and that adequate records are kept. When appropriate, an individual or a committee from within or outside the institution may be appointed to conduct an investigation. Anyone appointed to investigate suspected fraud must be objective and must possess the special competencies necessary to understand the research in question.

Reporting of Suspected Fraud Members of the academic community have a responsibility to report what they believe to be lack of integrity in research. Policies should provide assurance that such reports will be held in confidence to the extent possible. Persons giving information in good faith about questionable conduct should be protected against reprisals.

The Rights of the Individual A researcher under suspicion should be treated as a colleague

whose cooperation in providing access to data and procedures is expected. The individual in question should have ample opportunity to communicate with the investigator or the investigating committee in the course of the inquiry and prior to the formulation of conclusions. The individual should be advised of any decision to disseminate information about the investigation or to seek information about the research from others.

Confidentiality The mere suspicion of wrongdoing, even if totally unjustified, is potentially damaging to an investigator's career. Confidential handling of information about an investigation must be the responsibility of all involved. Thus, information concerning any investigation should be available only to those who need to know. Ideally, an inquiry should remain totally confidential until the results are established with reasonable certainty. Indeed, if the investigation were to conclude that no wrongdoing occurred, the suspicion should be obliterated from memory. However, this ideal is difficult or impossible to attain. This situation may be made easier by recognizing that research methods and results should always be open to inspection, evaluation, and criticism. In this spirit, all involved should be encouraged to accept an investigation of alleged misconduct as part of the process of the search for truth.

Use of Facilities and Equipment In some instances the institution might feel compelled to restrict or forbid the accused researcher's use of its premises, equipment, and resources. An institution should not limit or stop research in progress unless continued access to facilities by the alleged wrongdoer is deemed by knowledgeable and informed colleagues to pose a danger to the safety of the persons or property or to preclude fair and objective evaluation. Monitored continuation of research, pending resolution of the inquiry, might be considered.

Summary

The AAU-appointed Working Group on the Integrity of Research believes that the violations of honesty in research strike at the heart of the scientific enterprise. It is recommended that special attention be given to factors that foster a climate that encourages intellectual honesty. The directors of laboratories have the major responsibility for establishing appropriate standards. But all should share in this effort. It is recommended that each institution develop appropriate policies that include expectations for high standards of ethical behavior, procedures for dealing with suspected deviations, and appropriate sanctions for use when necessary.

Attachment II-E

AMERICAN UNIVERSITY PATENT POLICY

American University believes that its faculty and staff should be encouraged to contribute to the development of science and technology. For this reason, it is the objective of AU that any member of the university who invents a patentable device or procedure should benefit financially from its commercial exploitation, wherever possible. While AU could claim rights in all inventions of faculty or staff members that are in any way related to their employment, to do so would be inconsistent with that objective. At the same time, however, patentable inventions resulting from the creativity of AU faculty and staff also may reflect significant investments of university resources. Under some circumstances, therefore, it will be appropriate for AU to share in the proceeds of an invention's commercialization. The objective of this Patent Policy is to define the relative rights of faculty/staff inventors and AU in a variety of different situations.

Obviously, a policy such as this one cannot anticipate all cases that may arise or dictate exactly how each case will be categorized in terms of that policy when it does arise. Under this policy such determinations are to be made by the Provost of the university, acting on the advice of a standing Patent Committee, which shall have a membership of five, including no fewer than three members of the full time faculty, one of whom shall serve as chair. Decisions of the Patent Committee shall be made by a majority of the members present and voting at any regularly scheduled or specially called meeting, except that no decision of the Committee shall be effective unless it has the support of at least two full time faculty members.

In order for the provisions on the division of rights in inventions outlined below to be put into effect, this policy requires that any member of the AU faculty or staff who believes that he or she may have devised a patentable invention, under any circumstances and without regard to whether such invention was devised on university premises or with the use of university facilities, shall immediately notify the Patent Committee, using a reporting form prescribed by that committee, of the nature of the invention and the circumstances under which it was devised.

Faculty members engaged in outside consulting activities authorized by AU (see part B of this policy, below) are excused from this reporting requirement to the extent that those activities are governed by confidentiality agreements that expressly prohibit disclosure to the committee.

The committee shall have 90 days, or in the case of a notification received by it between May 15 and August 30, until October 15, whichever shall be longer, in which to respond to a report of a possibly patentable invention by indicating into which of the categories detailed in this policy that invention falls. During this period, the faculty/staff member may publish accounts of his or her invention, in accordance with the ordinary academic or professional practice.

If at the conclusion of this period the committee has not made a written response to the notification, the faculty or staff member will be deemed to be the sole proprietor of the rights, if any, in his or her invention. Where the Patent Committee responds by determining into which of the categories detailed in this policy an invention falls, the categorization, in turn, will determine the manner in which rights in the invention shall be apportioned between the individual inventor and AU.

A. Inventions resulting from wholly personal research:

These are inventions that a faculty or staff member has devised while working on non-university premises, without the use of university facilities, outside his or her regular working hours, and that have no other connection to his or her duties as a university employee.

Rights in the proceeds of these inventions belong exclusively to the inventor. In the event that he or she seeks university assistance in perfecting, protecting, and/or marketing the invention, an allocation of rights and proceeds will be negotiated between the inventor and AU.

B. Inventions resulting from authorized consulting activities external to AU:

These are inventions devised by a faculty member while pursuing projects on behalf of entities other than AU, as permitted by university policies on outside consulting activities.

Ownership of rights in inventions of this category is governed by the agreement between the inventor and the entity for which the work that gave rise to his or her invention was performed. AU claims no share in any proceeds from such inventions. In the event that the inventor seeks university assistance in perfecting, protecting, and/or marketing the invention, an allocation of rights and proceeds will be negotiated between the inventor and AU. To the extent that faculty consulting activities exceed the limits imposed by AU, rights in inventions arising from them will be governed by other provisions of this Policy, as appropriate.

C. Inventions resulting from "routine" use of AU facilities and resources:

These are inventions devised by faculty and staff members, in connection with their regular duties as university employees, but making use of no "special" university facilities or resources. This category includes inventions devised through the use or with the assistance of routinely available secretarial and administrative services, university mainframe computer support, general laboratory facilities, and the like.

Sole ownership of rights in inventions of this category may be claimed, at his or her option, by the individual inventor. In that case, AU will cede any claims that it might otherwise have to the invention in question. If the inventor wishes to have the assistance of the university in perfecting and/or commercializing his or her patent, however, he or she may so request. In the event that AU agrees to provide the requested assistance, the net proceeds of such commercialization will be shared between AU and the individual inventor on terms mutually agreed between them. In default of such agreement, each will be entitled to a 50% share of such proceeds.

D. Inventions resulting from the use of "special" AU facilities and services:

This category includes inventions that result from research projects receiving specific AU financial support, including Senate Research Grants and other special university awards, or that were devised using special equipment supplied by AU for the use of a particular researcher or research group.

Rights in the proceeds of inventions of this category shall be shared between AU and the inventor, and in default of an agreement to the contrary, each will be entitled to a 50% share of such proceeds.

E. Inventions devised in the course of performance of grants or contracts administered by AU:

This category includes all inventions that result from activities undertaken with external financial support.

The ownership of rights in inventions of this category will be governed, in the first instance, by the terms of the grant or contract in question. When those terms permit the retention of rights by the contractor or grantee, the inventor and AU each will be entitled to a 50% share, unless there has been an agreement to the contrary. AU and the inventor may negotiate mutually agreeable alternative arrangements with respect to such inventions at any time, but such negotiations shall not involve the grantor or contracting agency in any way.

Where this policy provides for negotiations between a faculty or staff research and AU concerning the allocation of rights in an invention or the proceeds from its exploitation, the officer negotiating on behalf of AU shall seek the advice of the Patent Committee prior to concluding any final agreement. In such event, the Patent Committee may advise for or against the conclusion of an agreement on particular terms, or recommend additional or alternative terms.

The Office of Sponsored Programs shall provide administrative support for the Patent Committee, and requests for information or patent notification forms should be addressed to the Director of OSP.

[*Attachment II-E is policy authorized by the Office of the Provost, July 1989.*]

Attachment II-F

DRUG ABUSE POLICY – *REVISED FEBRUARY 1998*

The Drug-Free Workplace Act of 1988 mandates that American University regularly publish its policy statement regarding the work-related effects of drug use and the unlawful possession of controlled substances on university premises. The AU policy is as follows:

- Employees are expected and required to report to work on time and in appropriate mental and physical condition for work. It is our intent and obligation to provide a drug-free, healthful, safe and secure work environment.

- The unlawful manufacture, distribution, dispensation, possession, storage or use of a controlled substance on university premises, or while conducting university business off university premises, is absolutely prohibited. Violation of this policy is a serious offense. Therefore, violations of this policy may result in disciplinary action up to and including immediate termination of employment.

- The university recognizes drug dependency as an illness and a major health problem. The university also recognizes drug usage as a potential health, safety and security problem. Employees needing help in dealing with such problems are encouraged to use the confidential services of the Faculty Staff Assistance Program (FSAP), and/or health insurance plans, as appropriate. Conscientious efforts to seek such help will not jeopardize any employee's job.

- Employees must, as a condition of employment, abide by the terms of the above policy and report any conviction under a criminal drug statue for violations occurring on or off university premises while conducting university business. Under the Drug-Free Workplace Act of 1988 a report of any such conviction must be made within five days after the conviction to the office of the executive director of Human Resources.

UNIVERSITY SANCTIONS FOR VIOLATION OF DRUG AND ALCOHOL POLICIES

Violation of the university's Alcohol and Drug Abuse Policies may result in disciplinary action, including discharge, in accordance with university policies.

In addition to any disciplinary action, the university, through its FSAP, may refer the employee to a treatment and counseling program for alcohol or drug abuse. Employees referred to such a program by the university must immediately cease any alcohol or drug abuse, and must comply with all conditions of the treatment and counseling program. The FSAP shall determine whether an employee it has referred for treatment and counseling should be temporarily reassigned to another position.

For employees working on any federal grant or contract, the university is required by federal law to notify the federal government contracting agency within ten days after learning of an employee's criminal drug statute conviction in the workplace.

Attachment II-G

Grant #: _____
Grant name: _____
PI: _____

GRANT CLOSEOUT CHECKLIST

Personnel
1. No payroll charges are pending for substitutions or additional earnings
2. All payroll charges are in the system
3. Full-time personnel hired on grants should be given:
   - 30 days written notice about position termination due to the cessation of the funding source
   - information about the accrued leave policy usage on sponsored programs
   - personnel termination paperwork should be filed with Human Resources

Consultants and Subcontracts
1. Ensure any reports or work products have been received from consultants and subcontractors
2. Verify that the reports or products are acceptable
3. Ensure that final payments have been processed for consultants and subcontractors

Purchase Orders
1. Cancel any blanket purchase orders or encumbrances
2. Verify that everything for each purchase order has been received
3. Verify that all invoices for purchase orders have been paid

Other Expenses
1. Verify that all internal expenses have been posted. (printing, telecommunications, copying, etc.)
2. Verify that all reimbursements and disbursement requests are in the system before the grant end date

Records and Reports
1. Records retention responsibility
2. Send OSP a copy of the final technical report
3. Confirm that any additional required reports have been submitted

Notes:

Attachment II-H

SPONSORED PROGRAMS CONTRACT CLOSEOUT

Contract Number: _____
Agency/Contract Title_____
AU Account Number: _____
Project Director: _____
Total Amount Awarded: _____
Contract Period: _____
Date Account Deactivated_____

1. Restricted Program Accounting

A. Final Invoice _____ (Attach Copy)

B. Final Financial Report _____ (Attach Copy)

C. Comments _____
_____
_____
_____

Prepared by: _____ Date_____

2. Office of Sponsored Programs

A. Final Technical Report (attached) ____ Submitted Date Submitted_____

B. Property Report _____Submitted _____Date Submitted _____Not Applicable

C. Patent/Copyright Forms ___ Submitted _____Date Submitted _____ Not Applicable

D. Other Sponsor Final Requirements (Please describe) _____ Not Applicable
_____
_____

E. Comments_____
_____
_____

Prepared by: _____ Date_____

Distribution: Accounting, OSP, PI, Dean/Other Executive's Office

FINANCIAL MANAGEMENT AND FORMS PROCESSING

EXPENDITURE PROCEDURES

University Object Codes

Each cost within a project budget is placed in a predetermined category, and each category is assigned object codes. (A list of expenditure object codes most commonly used at American University for use with accounts in the Datatel Colleague System appears in **Attachment III-A** or can be accessed through the web site of the Controller's Office at http://www.american.edu/finance/genacct/codes1.html). Once coded, the approved budget is entered into the University's computerized accounting system. When signing for expenditures, principal investigators (or their designees) must use the appropriate category and the assigned object codes. The Controller's Office records charges to the account numbers by object codes. If you have questions regarding the processing of internal University paperwork, please consult with your department or assigned OSP staff member.

Three screens have been developed for Principal Investigators and their departments to track expenditures on restricted accounts. These screens are:

- XEX1 – provides detail for one account number
- XEX2 – provides totals by object code for one project
- XEX3 – provides reports on all projects, one project per page

Principal Investigators are responsible for accessing and reviewing their accounts on a timely basis to ensure that expenditures are proceeding according to plan and that all costs are charged to the correct accounts and object codes. Principal Investigators must request access to their restricted account through the office of their School/College Dean. Directions regarding use of the Datatel screens for restricted accounts can be found in Attachment III-B**.**

While the Office of Sponsored Programs can use the Datatel screens to find out the remaining funds in an account, it is the responsibility of the principal investigator to validate the Datatel information. Datatel is updated on a daily basis, but, since the expenditures are entered when processed by the Controller's Office, approval of the expenditure by the department or OSP does not translate to the expenditure's appearance in the system. Therefore, the Datatel information may not include all the expenditures authorized when the Datatel screens are accessed.

Should any questions arise regarding the accounts as listed on the Datatel screens, the assigned OSP staff member can assist in working with the Controller's Office to address the concerns.

Project Expenditure Control Authority

The principal investigator approves charges to an account. The signatures of other project personnel will not be honored without prior written approval. By signing off on a project cost, the principal investigator certifies that the expenditures were appropriate, project-related, and actually incurred.

To assist Principal Investigators with their account responsibilities, OSP, the Controller's Office, and the Office of the School/College Dean jointly perform expenditure control functions designed to ensure that:

- Expenditures are allowable and allocable;
- Allotments are available;
- Proper approvals have been obtained;
- Expenditures appear consistent with the approved budget; and
- Expenditures are consistent with sponsor and university policies.

Routing of Expenditure Documents

All personnel, consultant payments, unbudgeted equipment with a value of $2,500 or more, and expenditures in excess of $5,000 total on one disbursement request or purchase order require the prior approval of OSP. The only exception is the College of Arts and Sciences, which has its own Contract Administrator who is responsible for CAS expenditure approval and is not required to have OSP concurrence on any expenditure.

Questions regarding which forms to use or who may sign for a particular expenditure should be directed to OSP. Principal Investigators and the Office of the School/College Dean should rely on their assigned OSP staff member as their primary/sole point of contact. This relieves the accounting staff of additional burdens so that they may process approved expenditures in a more expeditious fashion.

PROJECT EXPENDITURES

Personnel Costs

Rate of Pay

University regulations require that charges for work on a federal project (or for those who have a combination of federal and private funding) be made at the same rate of pay as the employee's University base salary. Salaries proposed in project budgets for each position are not guaranteed amounts. Actual salaries for faculty are subject to approval by the teaching unit, according to the faculty member's annual contract. All faculty contracts and salaries are subject to approval by the Dean of Academic Affairs, while all staff salaries are subject to approval by the Human Resources Office, which administers the classification system. Principal investigators should contact Human Resources for assistance in classifying staff positions for sponsored projects.

Payment of Salaries

Salaries are paid over the period in which they are earned; lump-sum payments are not allowed. Authorized budgets must specify not only the base salaries of project personnel, but also the time periods and percentages of effort spent. OSP, in conjunction with the University's Payroll Office, certifies at the time of approval (before the work is done) with proper wordage on the paperwork that the individual plans to do the work performed and the rate of pay is commensurate with this work.

Compensation Practices

For all faculty on federally-sponsored projects or with a combination of federal and private funding, the University follows the general practices outlined for federally-sponsored activities. Accordingly, compensation for University faculty and staff members engaged in sponsored projects is subject to the policy set forth in the Office of Management and Budget Circular A-21, Section J (8) (see Attachment III-C or http://www.whitehouse.gov/omb/circulars/a021/a021.html**). Federal policy does not allow compensation above base salary. Different compensation for private funding may be requested as an exception to policy based on a justification that is approved by the School/College Dean and the Dean of Academic Affairs and routed at the time of the proposal. This exception may only be requested when the person for whom it is being requested has no involvement with federal funding, including federal funding for a different project.**

Faculty Compensation

Subject to sponsor limitations, a faculty member on an academic year appointment may receive additional compensation for work on a sponsored project during the three summer months. The monthly summer rate may not exceed one-ninth of the academic year salary if the faculty

member is currently working on a federal grant. If the grant is from a non-federal sponsor, and the PI is not concurrently working on a federal grant, the rate may exceed the monthly one-ninth rate. The salary used to determine the summer compensation is based on that of the prior academic year.

When a faculty member teaches during a summer session in addition to fulfilling a research commitment, the compensation for both appointments during the summer period may not exceed one-third of the base salary rate for the prior year only if the faculty member is currently working on a federal grant. Otherwise, the one-third amount may be exceeded. (For further information, see Section I, "Proposal and Development Activity.")

Staff Compensation

Full-time staff positions employ individuals for 28 hours or more per week. If the position is for less than three months, it is a temporary position, and no University benefits other than Social Security are associated with it. Income taxes, however, are withheld.

Part-time staff work fewer than 28 hours per week and normally are paid hourly wages. Principal investigators should carefully monitor the total charges to projects so as not to exceed the amount provided by the grant or contract for this type of wage.

Merit increases and general adjustments to the salaries of sponsored program employees must be consistent with the University's approved policies. Pay increases take place on the University cycle.

Rates of pay for part-time staff working on sponsored projects must be consistent with similar University positions. Part-time (temporary or regular) staff receive no benefits except Social Security contributions, workers' compensation, and unemployment.

Compensation for Graduate Research Fellows and Assistants

Sponsored project graduate students who hold fellowships or assistantships are eligible for tuition remission. The principal investigator is responsible for preparing the appropriate forms and routing the forms through the teaching unit, college, and OSP. A sample Graduate Authorization for Tuition Remission form is provided in **Attachment III-D**. In addition, research fellowships and assistantships sometimes are available for the summer months.

Fringe Benefits

Full-time faculty and regular staff employed on sponsored projects are eligible for University benefits. FICA is withheld from the salaries of all employees paid through the University payroll system, including part-time staff. Exceptions are graduate students in assistantship or fellowship categories.

The employer's portion of FICA and retirement (TIAA-CREF) are charged to sponsors as direct costs. The University and the sponsored employee share coverage for other benefits according to the options available at the time of hiring. In any case, the approved fringe benefit rates (which are assigned by the University's cognizant government agency) charged to the project budget of 25.5% for full-time and 8% for part-time, students, and summer faculty apply.

Participation of Foreign Nationals on Sponsored Programs

Because of current U.S. tax code regulations and the opinions of tax advisors to the University, all foreign nationals who receive compensation and/or benefits from the University are subject to taxation. Such taxes must be withheld by payroll/accounting. The University has developed the Foreign National Taxation and Compliance Guide as a reference for university staff. A copy may be obtained from OSP or from your School/College Dean's Office. This is a reference point only and, due to changing regulations and individual circumstances, all cases should be dealt with on their individual merits. The university payroll office has a foreign national taxation specialist available. As such, if a project proposes to employ a foreign national or involves bringing foreign nationals to the university in any capacity, an appropriate visa must be held. OSP will coordinate with the Office of International Students Services at the time of the proposal to ensure that appropriate visa procedures are communicated to the Office of the School/College Dean. Based on a procedure already in place, The Washington College of Law is an exception to this policy and will be responsible for coordinating its own visa procedures. Contact your OSP assigned staff member as soon as possible if your project requires the service or participation of any foreign nationals.

Consultants

Consultants are hired to provide essential services unavailable from existing project personnel. **The principal investigator must discuss all proposed consultant agreements in advance with their OSP staff member**. In order to hire a consultant, the principal investigator should provide in writing to OSP: (1) The scope of work to be performed by the consultant; (2) the consultant's resume; (3) the consultant's address and social security number; (4) the rate of pay; and (5) the duration of the Agreement. See the checklist for consultant agreements in **Attachment III-E**.

Generally, consultant agreements are prepared by OSP in advance of the work being performed and require the consultant's signature. A Disbursement Request is utilized to effect consultant payments. When completed and approved by the principal investigator, the Disbursement Request together with the consultant invoice and a copy of the consultant agreement are then forwarded to OSP. A sample agreement form is provided in Part I of this Handbook (**Attachment I-D**); a Disbursement Request appears in **Attachment III-F**; and a sample consultant invoice appears in **Attachment III-G**.

Rate of Pay

To determine the reasonable cost of an external consultant, the principal investigator may wish to consult: (1) the range of fees of the other qualified individuals considered in the selection process; (2) the cost of consultants on other projects; and (3) University compensation levels for similar individuals. Federal agencies typically limit the maximum rate per day for consultants. The University honors any limit imposed by Federal agencies on consultant rate of pay. The OSP assigned staff member on a project can determine the actual limits set forth by the sponsor. All payments for consulting services are made directly to the consultant.

Consulting By University Employees

Faculty or staff members who serve as consultants on the sponsored projects of other faculty members receive no compensation above full-time base salary. When consultation is across teaching unit lines and the faculty or staff consultant performs the work in addition to the regular work load, compensation above base salary must be specifically provided for in the agreement with the sponsor. Individual arrangements must be approved in writing by the teaching unit head, the college dean, the Dean of Academic Affairs (for faculty), or the Director of Human Resources (for staff), and the sponsor.

Since federal regulations governing supplementary compensation are very restrictive, the principal investigator should consult the assigned OSP staff member before entering into any commitments on inter-unit consulting.

A faculty member with a full-time appointment as a principal investigator cannot function as an inter-unit consultant**.**

Personnel and Payroll Forms

Personnel recruitment and payroll forms differ between faculty and staff. Principal investigators should contact the assigned OSP staff member or the Human Resources Office for guidance on the proper payroll authorization form.

After filling out the form:

- **the principal investigator must sign as initiator;**
- **the teaching unit head must sign;**
- **the dean or dean's designee must sign; and**
- **OSP must review, sign, and send the form to Human Resources.**

Travel Policy

The full travel policy is accessible at:
http://www.american.edu/finance/rmo/policies.html#TravelPolicy

Travel Policy

The University intends that all persons traveling on behalf of and with the authorization of the University will be reimbursed for their reasonable out-of-pocket expenses incurred in connection with such travel upon presentation of a completed expenses report signed by the traveler and approved by the appropriate dean, director, department chairperson, vice president, vice provost, etc. or whomever is the supervisor of the traveler.

A. The University prefers that transportation tickets (plane, train, bus) be purchased through the official travel agencies of American University (Travel-Plus, Marathon Travel, McNair Travel or Worldtek). Provide the travel agent with your name, department, and budget account number. You can request the travel reservation to be charged directly to your account, or use the University credit card.

B. If expenses are incurred by the traveler on behalf of persons other that the traveler and reimbursements for such expense is being requested, the names of the other persons and the business purpose of the expenditures must be documented.

C. If the expense are incurred by the traveler on behalf of persons not on University business (e.g. spouse), the University portion of expenses must be clearly identified and original receipts must be submitted for the reimbursable portion. If original receipts are not available, please indicate by noting it on the expense report, or attach an explanation.

D. When travel on University business is combined with personal or non-university related, business expenses must be allocated accordingly and original receipts must be submitted for the reimbursable portion. If original receipts are not available, please indicate by noting it on the expense report, or attach an explanation.

E. Air coach accommodations should be used. Whenever possible, the use of airport shuttles rather than taxis is encouraged. Rental cars may be used when necessary and budget plans whenever possible. Use of moderately price rooms is encouraged and spousal travel is not covered except if the spouse is on university business. If frequent flyer coupons are used on university business, the traveler will not be

reimbursed for the equivalent ticket cost. ALso, frequent flyer coupons cannot be submitted as part of the accounting for a travel advance. Passenger coupons for university business must always be in the name of the traveler.

F. When a private automobile is used, the university will reimburse the traveler on a per-mile allowance basis in accordance with current university guidelines; university rates are always the same as IRS published rates.

G. A reasonable expense for valet services will be allowed if the traveler remains on university business in excess of four (4) days and appropriate receipts must be submitted.

H. Charges for telephone calls made while on university business should be claimed only if such calls are directly related to university business; personal telephone calls are not reimbursable.

I. The university will not be reimbursing the traveler for expenses incurred for personal flight insurance, alcoholic beverages, or any expense of a purely personal nature.

J Travel performed as part of a project, which is sponsored by a grant, or contract is subject to such additional travel restrictions as may be imposed by the terms of the grant or contract.

K. Travel advance may be obtained by full-time employees of the university traveling on behalf and with the authorization of the university upon presentation of a completed travel advance/expense form, signed by the traveler and approved by the appropriate supervisor.

L. Travel advance request should be submitted to the Office of the Controller at least one week prior to the date on which the advance is required. In addition to the cash advance needed for incidentals or meals, any registration fees or either items should be prepaid.

M. The university does not have a per diem allowance. All expenses must e reported on an actual-cost basis, with substantiating original receipts. If receipts are not available, this should be indicated.

N. Expenses which are prepaid by or charged directly to the university on behalf of the traveler (e.g. airline tickets, hotel accommodations) must be itemized on the travel expense form, with the notation "prepaid" in the amount column. Original receipts (if they are not available, please make a note on the travel expense form or attach an explanation), invoices, passenger coupons, etc. for expenses which were prepaid or charged directly to the university on behalf of the traveler must be submitted with the travel expense form. Amounts prepaid by or charged directly to the university on behalf of the traveler must not be reflected in the expenses claimed by the traveler.

O. Expenses for all travel activity should be charges to the travel object code, even if the expense was for food, airline tickets, or conference registration.

P. The signature of the traveler is required for all advances.

Q. All travel that is funded by federal grants or other restricted grant monies, may be subject to additional restrictions as noted in the contract.

Procurement of Goods and Services

The following section contains information regarding the procurement of goods and/or services both from outside vendors and from the various units within the University, such as the Purchasing Office, University Publications, and Physical Plant. For full details, the AU Purchasing Policy and Procedures Manual should be consulted.

Purchases from Outside Vendors

Purchase Procedures

Use the Datatel Colleague system to generate an electronic Purchase Requisition when capital equipment, supplies, or services, other than those provided by AcquireX, are to be furnished by an organization outside the University. Describe the articles or services in detail, suggesting vendors if desired. Special conditions apply to the ordering of radioactive isotopes and hazardous/toxic materials.

If only one source is available, the Purchase Requisition should so indicate. The contract's or grant's restricted account number and appropriate object code should be noted in the space provided. If more than one account number will bear the cost, indicate the amount coming from each. Occasionally, teaching units share the cost of a piece of equipment, and sometimes purchase office supplies to be shared among principal investigators.

Providing detailed information expedites the procurement process. Principal investigators should attach any written price quotes obtained from outside vendors, and should be realistic about desired delivery time.

The University's computerized accounting system (Datatel) encumbers when orders are placed and then charges only when paid. The system's spending control will not allow expenditures exceeding an account's total budget allocation. Similarly, a presence control will not allow unauthorized expenditures to object codes within an account.

Only the staff of the Purchasing Office has the authority to commit the University to reimburse vendors for goods delivered and services rendered. For unauthorized purchases, the payment becomes the personal responsibility of the person placing the order, rather than the responsibility of the University.

Equipment Purchases

As of May 1, 2003, capital equipment is defined as having a unit cost of **$2,500** or more and an expected life of two years or more. OSP and the School/College Dean must approve all requisitions to purchase capital equipment.

The University policy is to capitalize all equipment, either moveable or fixed, with a unit acquisition cost of **$2,500** or greater and a useful life of two years or more. Acquisition value includes the cost of the equipment and any associated costs incurred to make the equipment usable for the purpose for which it was intended, including installation costs. Equipment purchased for Federally Sponsored Grants and Contracts must be charged to the unique object codes provided for them (54113 for computer equipment; 54114 for lab equipment). All capital equipment, whether received directly by the ordering department or via central receiving, must be identified with an American University fixed asset tag. This tag is then entered into the university's fixed asset system. Examples of equipment include computer equipment, furniture, office machines, vehicles, and

scientific equipment.

The Purchasing office must be notified when a transfer of this equipment from one location to another takes place to be able to reflect the new location on the university's records. Likewise, when a piece of equipment is purchased, the disposition of the old equipment must be handled appropriately. Purchasing must be notified to pick up the old equipment and the department disposing of the equipment must complete a fixed asset disposal form. The old equipment is the property of the university (even if there is no value) and proper disposition of the equipment is to be determined by the Vice President of Finance and Treasurer. **Departments are responsible for keeping records of all purchased capital equipment so yearly adjustments can be made to the university's accounting records**. Any unaccounted for or lost equipment will be charged to the department's operating budget.

Off-campus projects may require equipment to be delivered directly to the off-site location. On these occasions, the department receiving the equipment will provide the Fixed Asset Coordinator with the serial numbers. The Fixed Asset Coordinator will then provide the department with tags to be placed on the equipment. The Assistant Director of Purchasing (x3810) is the Fixed Asset Coordinator for the University.

Supply & Equipment Deliveries

Most suppliers deliver equipment to Central Receiving, where University personnel log the shipment and deliver the material to the location designated on the requisition. Radioactive isotopes delivered to Central Receiving must be received by the Radiation Safety Officer or Assistant. In the case of heavy or bulky equipment, gases, and live materials requiring special handling, the requisition should contain clear instructions specifying direct delivery to the proper location. In such cases, the purchase price should include freight or shipping charges to the designated building.

Purchase of Supplies from Campus Units

Campus Store

Follett provides extensive inventories of commonly used supplies, often at prices lower than outside vendors. A purchase requisition under $5,000 approved by the School/College Dean's office is required for supplies bought on campus. The principal investigator receives a copy of the requisition as confirmation of the actual cost. Charges for internally procured items and services appear on the Datatel restricted account screens.

AcquireX (Office Supplies)

Use the AcquireX system when some capital equipment or office supplies are to be furnished by a company outside the university. AcquireX is an internet-based electronic-procurement solution that streamlines the purchasing of goods and services. AU Departments may order directly with the proper ID and password supplied by the Office of the Controller. Contact the Office of your School/College Dean to access this system.

Other University Services

Various units in the University can provide services such as mailing, duplicating, and printing for use in sponsored projects. Principal investigators can request these services through Purchase Requisitions, Copy Center Requests for Reproduction Services, and Postal Charge Tickets, citing the contract or grant account number in the space provided on each form. Each expense document must be approved in advance by Department/Dean. These forms provide the best documentation of contract or grant expenses and are recommended over reimbursements to individuals for out-of-pocket expenses.

Physical Plant

A principal investigator may call on Physical Plant personnel to install equipment or provide plumbing or electrical services. The activities must be directly related to the sponsored project and their funding must be accounted for in the project budget. Ordinary "landlord" type services, such as painting, keys, and renovations, are usually unallowable and should be charged to teaching unit accounts rather than to sponsored accounts. Service requisition forms can be obtained from Physical Plant. Principal investigators, however, should call their assigned OSP staff member for information before requesting the services.

Computer Services

Many types of computing services are accessible to principal investigators and their staff. The university's network can be utilized for a variety of functions, and a full-time staff is available to provide support with statistical programs. Use of the network requires that an account be set up for each project (if new staff will be using the system). In addition, training on standard software packages, access to several microcomputer laboratories, and a hotline service for software problems are available at no charge.

Telephone Service

New telephone service for a sponsored project, including installation, must be requested through the Telecommunications Office and paid for by the contract or grant. Long distance project calls using existing University telephone lines should be charged to the contract or grant. Principal investigators should identify their calls on the teaching unit bill and sign a copy of the telephone bill; the teaching unit is responsible for sending the copy of the bill to Department/Dean with a memorandum requesting a cost transfer to the contract or grant account number. Long distance access codes may be obtained for projects with need for extensive use of long distance service. Please contact your assigned OSP staff member if you have questions.

Subagreements

The assigned OSP staff member prepares all subcontracts/consultant agreements and

submits these agreements to the Director of Procurement and Contracts for signature on behalf of the University. After this signature is obtained, the agreement is forwarded to the subcontractor or consultant for signature. Subcontracts are drafted at the request of the principal investigator, based upon information he or she provides to the assigned OSP staff member. When the subcontract has been fully executed, a copy is provided to the principal investigator for his/her records. Subcontractor invoices are submitted to the principal investigator for review and approval. A copy of the fully executed agreement is sent to the Director of Procurement and Contracts and the original is kept in the project file in OSP.

Once the principal investigator has verified that the necessary work has been completed and that the charges are accurate, he or she should complete a Disbursement Request requesting that payment be made to the subcontractor. The original invoice and a copy of the fully executed subcontract should be attached to the Disbursement Request and forwarded to OSP. Questions regarding the subcontract should be addressed to the assigned OSP staff member.

Principal Investigators may not subcontract to any corporation or company in which the Principal Investigator or members of the Principal Investigator's family have an ownership interest or to any company that any other member of the University has an ownership interest.

Facilities and Administration Allowance (Indirect Costs)

The approved facilities and administration (F&A) rate appears on the project brief. When financial reports are prepared, the F&A rate is calculated. Principal investigators can access their project accounts through an online computer linked to Datatel screens to determine the current F&A rate and charges. The University is bound by OMB Circular No. A-21 (see **Attachment III-C**).

American University has a new Negotiated Indirect Cost Rate Agreement effective May 1, 2005, and valid through April 30, 2008. The new rate assesses indirect costs on a Modified Total Direct Cost basis. The OMB Circular A-21 G.2 states that the Modified Total Direct Costs basis excludes assessment of indirect costs on tuition, capital expenditures, space rental, sub grants or subcontracts in excess of $25,000, and participant support costs. Participant support costs are defined as pass-through costs to support program participation directly attributable to an individual who is not an employee of AU or a consultant providing a service. The text of the circular may be found at http://www.whitehouse.gov/omb/circulars/a021/a021.html.

The new rate agreement may be viewed on the web page of the Office of the Controller at http://www.american.edu/finance/genacct/. This page also contains other important information about the financial administration of grants and contracts and should be checked periodically for updates.

Unallowable Expenses

Some costs cannot be charged to a sponsored project. Examples are: contingency funds or reserves; bad debts; fines and penalties; entertainment (which includes alcohol) costs; interest, fund raising, and investment management costs; losses on other research agreements, including cost overruns; costs for public information services, and alumni or public relations costs. General guidance may be found in OMB Circular A-21 Sec. J, Unallowable Expenses as part of **Attachment III-C**.

Time and Effort Certification

The University has now implemented a prospective time and effort certification system for all faculty, staff, and students compensated on external grants and contracts. Appropriate language appears on all personnel forms and e-time sheets to satisfy the federal requirement for Time and Effort certification. It is imperative that each individual signing the above mentioned forms are aware of their confirmation of proper (and auditable) time and effort upon signature. One exception to the time and effort certification is staff paid on an hourly basis. The time sheets used to log hours are sufficient to certify time and effort for these individuals. Please see **Attachment III-C** [OMB A-21 Section J (8)] for clarification of accepted time and effort methods. OSP should be contacted if you have any questions regarding Time and Effort.

The following language has been printed on the above-mentioned forms and e-time sheets: "I certify that I have first hand knowledge of (or have suitable means of verifying) work performed by this individual and the salary distribution prior to the effective date of this change is reasonable in relation to work performed." Please make sure that the documents you use have this language printed on it. If it is not, please contact OSP.

FINAL ACCOUNTING PROCEDURES

The Controller's Office prepares all final accounting reports on all sponsors' projects. The Controller's Office also prepares interim financial reports as required.

Program Income

A principal investigator must report to the sponsor any income derived from services or goods associated with a project. Such reports are processed through OSP. Income received should be deposited to the appropriate sponsored account.

In addition, any cash or checks received by the principal investigator from the sponsor must immediately be sent to Accounting. This includes money received after the project officially ends. To avoid loss, funds should be hand carried or delivered in a secure manner.

Billings/Financial Reports

The Controller's Office is responsible for the timely preparation of billings and financial reports to project sponsors. Generally, principal investigators should not prepare and send billings or provide financial reports to sponsors unless the terms of the grant specify such and it has been coordinated with OSP and the Controller's Office in advance.

Audits of Sponsored Projects

The University is subject to audit by sponsors for specific programs and is also audited annually for its administration of sponsored programs in accordance with the OMB Circular A-133. Auditors representing sponsors will periodically examine the University's records for the purposes of:

- determining whether contract or grant funds were used in accordance with applicable laws, regulations, and procedures;
- making objective appraisals of the financial accounting system and administrative controls to ensure that programs are being charged with appropriate amounts; and
- determining the accuracy of the financial reports and records.

Documentation of expenditures that include original receipts is a requirement for the audit process. The Office of the Controller, with assistance from OSP, coordinates all activities with sponsors' auditors. Principal investigators are required to be available during the audit process.

Common Audit Findings

Some of the continuous problems that Colleges and Universities encounter with sponsors are:

- cost share and matching;
- time and effort reporting; and
- payroll distribution and documentation.

ATTACHMENT III-A

American University
MOST COMMONLY USED EXPENDITURE OBJECT CODES AT AU

The object classification of expenditures identifies that which is received in return for the expenditures. Object classification has importance as a tool for internal management and as a means for reporting to external users how resources were used.

51102 FULL TIME FACULTY
Salaries paid to full-time faculty members. To be considered full-time, a faculty member must be appointed to one of the ranks specified in the Faculty Manual, and must devote full service to University duties.

51103 FULL TIME PROFESSIONAL
Salaries paid, on a monthly basis, to full-time staff members who meet the professional classification requirements specified in the Personnel Policy Manual. These individuals are EXEMPT from the Federal and State rules covering hours worked and the payment of overtime.

51104 FULL TIME BIWEEKLY STAFF

Compensation paid, on a bi-weekly basis, to full-time staff members whose job is classified as NON-Exempt from Federal and State wage and hour rules. Generally, the employee works a set amount of hours per job shift or workweek and earns an overtime rate for excess hours worked.

51203 STUDENT WAGES
Compensation to students working part-time in an administrative or academic unit. The wage is calculated at an hourly rate. For FEDERAL WORK STUDY use object code 51211.

51208 PROFESSIONAL SERVICES
Expenses associated with professional services rendered by an individual, partnership or unincorporated business (e.g. legal, management consulting, medical, etc.) and subject to the reporting requirements of IRS Form 1099. A Professional Services Agreement (PSA) is required.

51210 NON-EMPLOYEE COMPENSATION
One-time or incidental payment for honorariums, casual labor or other personal services by a non-employee and subject to the reporting requirements of IRS Form 1099.

51211 FEDERAL WORK STUDY
Student wages partially funded by U.S. Department of Education.

51513 FRINGE BENEFITS
The cost of benefits pertaining to the compensation of employees. The amount is a percentage of the total of actual salaries and wages (full- and part-time) for each center/department. The costs assigned represent a percentage of such benefits as retirement, FICA, life insurance, tuition benefits, disability, workers' compensation, health insurance and unemployment.

52101 GENERAL SUPPLIES AND EXPENSES
Charges for office supplies and consumable office goods that cost less than $2,500.00 per unit and have a service life of less than five years.

52108 CONTRACTUAL EXPENSES
Expenses associated with services provided by a corporation (not subject to IRS Form 1099) on a continuous basis and evidenced by a contract or agreement. (E.g. maintenance agreements, trash removal, etc.)

52117 MEMBERSHIP AND DUES
Charges related to membership in any organization.

52118 FOOD SERVICES
Expenses related to catered events, meals taken in restaurants, or food purchased from vendors to support office functions or needs.

52201 DOMESTIC TRAVEL
Expenses incurred while traveling on University business within the continental United States (e.g. food and lodging, transport expenses, registrations, etc.)

52301 POSTAGE AND SHIPPING
Postage and shipping charges including courier expenses (e.g. UPS, Federal Express).

52401 PRINTING AND DUPLICATING
Printing and duplication expenses paid by outside parties.

52501 TELECOMMUNICATIONS
Telephone charges associated with the procurement of telephone equipment, line, and local and long- distance services as well as internal charges from the Telecommunications Department.

54102 COMPUTER EQUIPMENT
Costs associated with the purchase of computers. Supplies for personal computers and word processors are charged to Object 52101 under Office Supplies.

54105 OFFICE FURNITURE AND EQUIPMENT
Costs related to equipment and furniture that has a unit cost of $500.00 or more and an expected service life of more than 5 years.

ATTACHMENT III-B

XEX1 and XEX2 Reference Sheet for PI's

This document reviews use of the two most useful Datatel screens for grant management:

XEX1 summarizes expenses, encumbrances, and remaining balance by object code; use for a big-picture snapshot

XEX2 details all transactions under a specific object code; use to track or identify individual expenses

Contact your departmental administrator or dean's office to arrange for Datatel access or to get more detailed information on AU's financial system, such as a list of object codes. The instructions below assume that you have the necessary software installed and that you have been given access.

LOGIN:

1. Double-click the wIntegrate logo or select wIntegrate from the Start Menu.
2. At the login: prompt, type your USERID (typically the first part of your AU e-mail address) and <enter>.
3. At the password: prompt, type your assigned password (typically birthdate in MMDDYY format) and <enter>.
4. Read the information provided and type <enter>.
5. Type the number for "Colleague live" and <enter>.
6. Read the information provided and type <enter>.
7. Type <cf><enter> for "Colleague financials." You are now at the main menu of the financial system.

XEX1 and XEX2:

1. At the main menu, type <xex1> or <xex2>.
2. At the Enter fund: prompt, type <11>.
3. At the Enter unit: prompt, type the unit number (the 6-digit number immediately following the "11" in the account number on your project brief) and <enter>.

XEX1 4. At the Enter object: prompt, type the object code (the 5-digit number beginning with "5") and <enter>.

5. At the Enter project: prompt, type the project number (the 5-digit number beginning with "34" at the end of the account number) and <enter>.

XEX1 6. At the next prompt, type <1> to see expenses to date; type <2> to see the budgeted amount for that object code.

7. After several seconds, the information should appear. If there are a lot of entries, the table will be broken into at least two screens. Hit <enter> to move on to the next screen.
8. To print the information, click the printer logo for each of the screens. Or, to get all the information on one sheet, cut and paste each successive part of the table into a Word document (you will need to choose a fixed-width font such as Courier to have all of the columns line up properly). When copying the text, use the mouse to select "copy" from the "edit" menu, rather than using <ctrl-c>.
9. When the last screen for a project is reached, it will ask "Do you want to look up another account?" If so, type <y><enter> and go to step 2. If not, type <n><enter>, which will take you back to the main menu.

LOGOUT:

1. From the main menu, type <lo><enter> for logout.
2. Type the number for "end this session" and <enter>.
3. When it says "[Connection closed from host]," click on the X in the upper right corner to close the program.

XEX3 Reference Sheet for PI's

This document reviews use of a Datatel screen for grant management:

XEX3 summarizes multiyear expenses, encumbrances, and remaining balance by object code; use for a big-picture snapshot

Your project numbers:

Fund Number: 11

Unit Number:

Project Number:

Contact your departmental administrator or dean's office to arrange for Datatel access or to get more detailed information on AU's financial system, such as a list of object codes. The instructions below assume that you have the necessary software installed and that you have been given access.

LOGIN:

1. Double-click the wIntegrate logo or select wIntegrate from the Start Menu.
2. At the login: prompt, type your USERID (typically the first part of your AU e-mail address) and <enter>.
3. At the password: prompt, type your assigned password (typically birthdate in MMDDYY format) and <enter>.
4. Read the information provided and type <enter>.
5. Type the number for "Colleague live" and <enter>.
6. Read the information provided and type <enter>.
7. Type <cf><enter> for "Colleague financials." You are now at the main menu of the financial system.

XEX3:

1. At the main menu, type <xex3>
2. Enter your login ID (USERID) again, being certain to use all upper case letters, and <enter>
3. Read the instructions. Note that you select the report month first, then which report to run.
4. At the Enter report month prompt, enter 1 for May, 2 for June, 3 for July…up through 12 for April.
5. At the Enter report number prompt, enter 1 for all projects that you have rights to, or 2 for a single project
6. If you select all projects (1), you will be prompted to enter the "as of" date for the report header. Enter the date, and <enter>. You will immediately be taken to the report screen.
7. If you select a single project (2), you will be prompted to enter your unit number. Enter your unit number and <enter>. You will then be prompted to enter your project number. . Enter your project number and <enter>. You will then be prompted to enter the "as of" date for the header. Enter the date, and <enter>. You will then be taken to the report screen.
8. To navigate around the screen use "u" for "UP," "d" for "DOWN," "l" for "LEFT," and "r" for "RIGHT."
9. To print the report, type "s" for "SPOOL." This will take you to the printer selection screen.
10. In field 1 on the printer selection screen type "P" for printer and <enter>.
11. In field 2 enter your printer's datatel queue name and <enter>.
12. Click "finish" on the button bar.
13. Your report will print, and you will be returned to the report screen.
14. Click "finish" to return to the main menu.

LOGOUT:

1. From the main menu, type <lo><enter> for logout.
2. Type the number for "end this session" and <enter>.
3. When it says "[Connection closed from host]," click on the X in the upper right corner to close the program.

ATTACHMENT III-C

OFFICE OF MANAGEMENT & BUDGET CIRCULAR A-21, SECTION J (8)

The full text of A-21 can be found at
http://www.whitehouse.gov/omb/circulars/a021/a021.html

OFFICE OF MANAGEMENT & BUDGET CIRCULAR A-21, SECTION J (8)

J. GENERAL PROVISIONS FOR SELECTED ITEMS OF COST

(8) Compensation for personal services.

a. *General*.
Compensation for personal services covers all amounts paid currently or accrued by the institution for services of employees rendered during the period of performance under sponsored agreements. Such amounts include salaries, wages, and fringe benefits (see subsection f). These costs are allowable to the extent that the total compensation to individual employees conforms to the established policies of the institution, consistently applied, and provided that the charges for work performed directly on sponsored agreements and for other work allocable as F&A costs are determined and supported as provided below. Charges to sponsored agreements may include reasonable amounts for activities contributing and intimately related to work under the agreements, such as delivering special lectures about specific aspects of the ongoing activity, writing reports and articles, participating in appropriate seminars, consulting with colleagues and graduate students, and attending meetings and conferences. Incidental work (that in excess of normal for the individual), for which supplemental compensation is paid by an institution under institutional policy, need not be included in the payroll distribution systems described below, provided such work and compensation are separately identified and documented in the financial management system of the institution.

b. *Payroll distribution*.

(1) *General Principles*:
(a) The distribution of salaries and wages, whether treated as direct or F&A costs, will be based on payrolls documented in accordance with the generally accepted practices of colleges and universities. Institutions may include in a residual category all activities that are not directly charged to sponsored agreements, and that need not be distributed to more than one activity for purposes of identifying F&A costs and the functions to which they are allocable. The components of the residual category are not required to be separately documented.
(b) The apportionment of employees' salaries and wages which are chargeable to more than one sponsored agreement or other cost objective will be accomplished by methods which will (1) be in accordance with Sections A.2 and C, (2) produce an equitable distribution of

charges for employee's activities, and (3) distinguish the employees' direct activities from their F&A activities.
(c) In the use of any methods for apportioning salaries, it is recognized that, in an academic setting, teaching, research, service, and administration are often inextricably intermingled. A precise assessment of factors that contribute to costs is not always feasible, nor is it expected. Reliance, therefore, is placed on estimates in which a degree of tolerance is appropriate.
(d) There is no single best method for documenting the distribution of charges for personal services. Methods for apportioning salaries and wages, however, must meet the criteria specified in subsection b.(2). Examples of acceptable methods are contained in subsection c. Other methods which meet the criteria specified in subsection b.(2) also shall be deemed acceptable, if a mutually satisfactory alternative agreement is reached.

(2) *Criteria for Acceptable Methods*:
(a) The payroll distribution system will (i) be incorporated into the official records of the institution, (ii) reasonably reflect the activity for which the employee is compensated by the institution, and (iii) encompass both sponsored and all other activities on an integrated basis, but may include the use of subsidiary records. (Compensation for incidental work described in Section J.8.a need not be included.)
(b) The method must recognize the principle of after-the-fact confirmation or determination so that costs distributed represent actual costs, unless a mutually satisfactory alternative agreement is reached. Direct cost activities and F&A cost activities may be confirmed by responsible persons with suitable means of verification that the work was performed. Confirmation by the employee is not a requirement for either direct or F&A cost activities if other responsible persons make appropriate confirmations.
(c) The payroll distribution system will allow confirmation of activity allocable to each sponsored agreement and each of the categories of activity needed to identify F&A costs and the functions to which they are allocable. The activities chargeable to F&A cost categories or the major functions of the institution for employees whose salaries must be apportioned (see subsection b.(1)(b)), if not initially identified as separate categories, may be subsequently distributed by any reasonable method mutually agreed to, including, but not limited to, suitably conducted surveys, statistical sampling procedures, or the application of negotiated fixed rates.
(d) Practices vary among institutions and within institutions as to the activity constituting a full workload. Therefore, the payroll distribution system may reflect categories of activities expressed as a percentage distribution of total activities.
(e) Direct and F&A charges may be made initially to sponsored agreements on the basis of estimates made before services are performed. When such estimates are used, significant changes in the corresponding work activity must be identified and entered into the payroll distribution system. Short-term (such as one or two months) fluctuation between workload categories need not be considered as long as the distribution of salaries and wages is reasonable over the longer term, such as an academic period.
(f) The system will provide for independent internal evaluations to ensure the system's effectiveness and compliance with the above standards.
(g) For systems which meet these standards, the institution will not be required to provide additional support or documentation for the effort actually performed.

c. *Examples of Acceptable Methods for Payroll Distribution*.

(1) *Plan-Confirmation*: Under this method, the distribution of salaries and wages of professorial and professional staff applicable to sponsored agreements is based on budgeted, planned, or assigned work activity, updated to reflect any significant changes in work distribution. A plan-confirmation system used for salaries and wages charged directly or indirectly to sponsored agreements will meet the following standards:
(a) A system of budgeted, planned, or assigned work activity will be incorporated into the official records of the institution and encompass both sponsored and all other activities on an integrated basis. The system may include the use of subsidiary records.
(b) The system will reasonably reflect only the activity for which the employee is compensated by the institution (compensation for incidental work described in subsection a need not be included). Practices vary among institutions and within institutions as to the activity constituting a full workload. Hence, the system will reflect categories of activities expressed as a percentage distribution of total activities. (See Section H for treatment of F&A costs under the simplified method for small institutions.)
(c) The system will reflect activity applicable to each sponsored agreement and to each category needed to identify F&A costs and the functions to which they are allocable. The system may treat F&A cost activities initially within a residual category and subsequently determine them by alternate methods as discussed in subsection b.(2)(c).
(d) The system will provide for modification of an individual's salary or salary distribution commensurate with a significant change in the employee's work activity. Short-term (such as one or two months) fluctuation between workload categories need not be considered as long as the distribution of salaries and wages is reasonable over the longer term, such as an academic period. Whenever it is apparent that a significant change in work activity which is directly or indirectly charged to sponsored agreements will occur or has occurred, the change will be documented over the signature of a responsible official and entered into the system.
(e) At least annually a statement will be signed by the employee, principal investigator, or responsible official(s) using suitable means of verification that the work was performed, stating that salaries and wages charged to sponsored agreements as direct charges, and to residual, F&A cost or other categories are reasonable in relation to work performed.
(f) The system will provide for independent internal evaluation to ensure the system's integrity and compliance with the above standards.
(g) In the use of this method, an institution shall not be required to provide additional support or documentation for the effort actually performed.

(2) *After-the-fact Activity Records*: Under this system the distribution of salaries and wages by the institution will be supported by activity reports as prescribed below.
(a) Activity reports will reflect the distribution of activity expended by employees covered by the system (compensation for incidental work as described in subsection a need not be included).
(b) These reports will reflect an after-the-fact reporting of the percentage distribution of activity of employees. Charges may be made initially on the basis of estimates made before the services are performed, provided that such charges are promptly adjusted if significant differences are indicated by activity records.
(c) Reports will reasonably reflect the activities for which employees are compensated by the institution. To confirm that the distribution of activity represents a reasonable estimate of

the work performed by the employee during the period, the reports will be signed by the employee, principal investigator, or responsible official(s) using suitable means of verification that the work was performed.
(d) The system will reflect activity applicable to each sponsored agreement and to each category needed to identify F&A costs and the functions to which they are allocable. The system may treat F&A cost activities initially within a residual category and subsequently determine them by alternate methods as discussed in subsection b.(2)(c).
(e) For professorial and professional staff, the reports will be prepared each academic term, but no less frequently than every six months. For other employees, unless alternate arrangements are agreed to, the reports will be prepared no less frequently than monthly and will coincide with one or more pay periods.
(f) Where the institution uses time cards or other forms of after-the-fact payroll documents as original documentation for payroll and payroll charges, such documents shall qualify as records for this purpose, provided that they meet the requirements in subsections (a) through (e).

(3) *Multiple Confirmation Records*: Under this system, the distribution of salaries and wages of professorial and professional staff will be supported by records which certify separately for direct and F&A cost activities as prescribed below.
(a) For employees covered by the system, there will be direct cost records to reflect the distribution of that activity expended which is to be allocable as direct cost to each sponsored agreement. There will also be F&A cost records to reflect the distribution of that activity to F&A costs. These records may be kept jointly or separately (but are to be certified separately, see below).
(b) Salary and wage charges may be made initially on the basis of estimates made before the services are performed, provided that such charges are promptly adjusted if significant differences occur.
(c) Institutional records will reasonably reflect only the activity for which employees are compensated by the institution (compensation for incidental work as described in subsection a need not be included).
(d) The system will reflect activity applicable to each sponsored agreement and to each category needed to identify F&A costs and the functions to which they are allocable.
(e) To confirm that distribution of activity represents a reasonable estimate of the work performed by the employee during the period, the record for each employee will include: (i) the signature of the employee or of a person having direct knowledge of the work, confirming that the record of activities allocable as direct costs of each sponsored agreement is appropriate; and, (ii) the record of F&A costs will include the signature of responsible person(s) who use suitable means of verification that the work was performed and is consistent with the overall distribution of the employee's compensated activities. These signatures may all be on the same document.
(f) The reports will be prepared each academic term, but no less frequently than every six months.
(g) Where the institution uses time cards or other forms of after-the-fact payroll documents as original documentation for payroll and payroll charges, such documents shall qualify as records for this purposes, provided they meet the requirements in subsections (a) through (f).

d. *Salary rates for faculty members*.

(1) *Salary rates for academic year:* Charges for work performed on sponsored agreements by faculty members during the academic year will be based on the individual faculty member's regular compensation for the continuous period which, under the policy of the institution concerned, constitutes the basis of his salary. Charges for work performed on sponsored agreements during all or any portion of such period are allowable at the base salary rate. In no event will charges to sponsored agreements, irrespective of the basis of computation, exceed the proportionate share of the base salary for that period. This principle applies to all members of the faculty at an institution. Since intra-university consulting is assumed to be undertaken as a university obligation requiring no compensation in addition to full-time base salary, the principle also applies to faculty members who function as consultants or otherwise contribute to a sponsored agreement conducted by another faculty member of the same institution. However, in unusual cases where consultation is across departmental lines or involves a separate or remote operation, and the work performed by the consultant is in addition to his regular departmental load, any charges for such work representing extra compensation above the base salary are allowable provided that such consulting arrangements are specifically provided for in the agreement or approved in writing by the sponsoring agency.

(2) *Periods outside the academic year:*
(a) Except as otherwise specified for teaching activity in subsection (b), charges for work performed by faculty members on sponsored agreements during the summer months or other period not included in the base salary period will be determined for each faculty member at a rate not in excess of the base salary divided by the period to which the base salary relates, and will be limited to charges made in accordance with other parts of this section. The base salary period used in computing charges for work performed during the summer months will be the number of months covered by the faculty member's official academic year appointment.
(b) Charges for teaching activities performed by faculty members on sponsored agreements during the summer months or other periods not included in the base salary period will be based on the normal policy of the institution governing compensation to faculty members for teaching assignments during such periods.

(3) *Part-time faculty*. Charges for work performed on sponsored agreements by faculty members having only part-time appointments will be determined at a rate not in excess of that regularly paid for the part-time assignments. For example, an institution pays $5000 to a faculty member for half-time teaching during the academic year. He devoted one-half of his remaining time to a sponsored agreement. Thus, his additional compensation, chargeable by the institution to the agreement, would be one-half of $5000, or $2500.

e. *Noninstitutional professional activities*.

Unless an arrangement is specifically authorized by a Federal sponsoring agency, an institution must follow its institution-wide policies and practices concerning the permissible extent of professional services that can be provided outside the institution for noninstitutional compensation. Where such institution-wide policies do not exist or do not adequately define the permissible extent of consulting

or other noninstitutional activities undertaken for extra outside pay, the Federal Government may require that the effort of professional staff working on sponsored agreements be allocated between (1) institutional activities, and (2) noninstitutional professional activities. If the sponsoring agency considers the extent of noninstitutional professional effort excessive, appropriate arrangements governing compensation will be negotiated on a case-by-case basis.

f. *Fringe benefits*.

(1) Fringe benefits in the form of regular compensation paid to employees during periods of authorized absences from the job, such as for annual leave, sick leave, military leave, and the like, are allowable, provided such costs are distributed to all institutional activities in proportion to the relative amount of time or effort actually devoted by the employees. See Section J.40 for treatment of sabbatical leave.

(2) Fringe benefits in the form of employer contributions or expenses for social security, employee insurance, workmen's compensation insurance, tuition or remission of tuition for individual employees are allowable, provided such benefits are granted in accordance with established educational institutional policies, and are distributed to all institutional activities on an equitable basis. Tuition benefits for family members other than the employee are unallowable for fiscal years beginning after September 30, 1998. See Section J.41.b, Scholarships and student aid costs, for treatment of tuition remission provided to students.

(3) Rules for pension plan costs are as follows:
(a) Costs of the institution's pension plan which are incurred in accordance with the established policies of the institution are allowable, provided: (i) such policies meet the test of reasonableness, (ii) the methods of cost allocation are equitable for all activities, (iii) the amount of pension cost assigned to each fiscal year is determined in accordance with subsection (b), and (iv) the cost assigned to a given fiscal year is paid or funded for all plan participants within six months after the end of that year. However, increases to normal and past service pension costs caused by a delay in funding the actuarial liability beyond 30 days after each quarter of the year to which such costs are assignable are unallowable.
(b) The amount of pension cost assigned to each fiscal year shall be determined in accordance with generally accepted accounting principles. Institutions may elect to follow the "Cost Accounting Standard for Composition and Measurement of Pension Cost" (48 Part 9904-412).
(c) Premiums paid for pension plan termination insurance pursuant to the Employee Retirement Income Security Act (ERISA) of 1974 (Pub. L. 93-406) are allowable. Late payment charges on such premiums are unallowable. Excise taxes on accumulated funding deficiencies and prohibited transactions of pension plan fiduciaries imposed under ERISA are also unallowable.

(4) Fringe benefits may be assigned to cost objectives by identifying specific benefits to specific individual employees or by allocating on the basis of institution-wide salaries and wages of the employees receiving the benefits. When the allocation method is used, separate allocations must be made to selective groupings of employees, unless the institution demonstrates that costs in relationship to salaries and wages do not differ significantly for different groups of employees. Fringe benefits shall be treated in the same manner as the

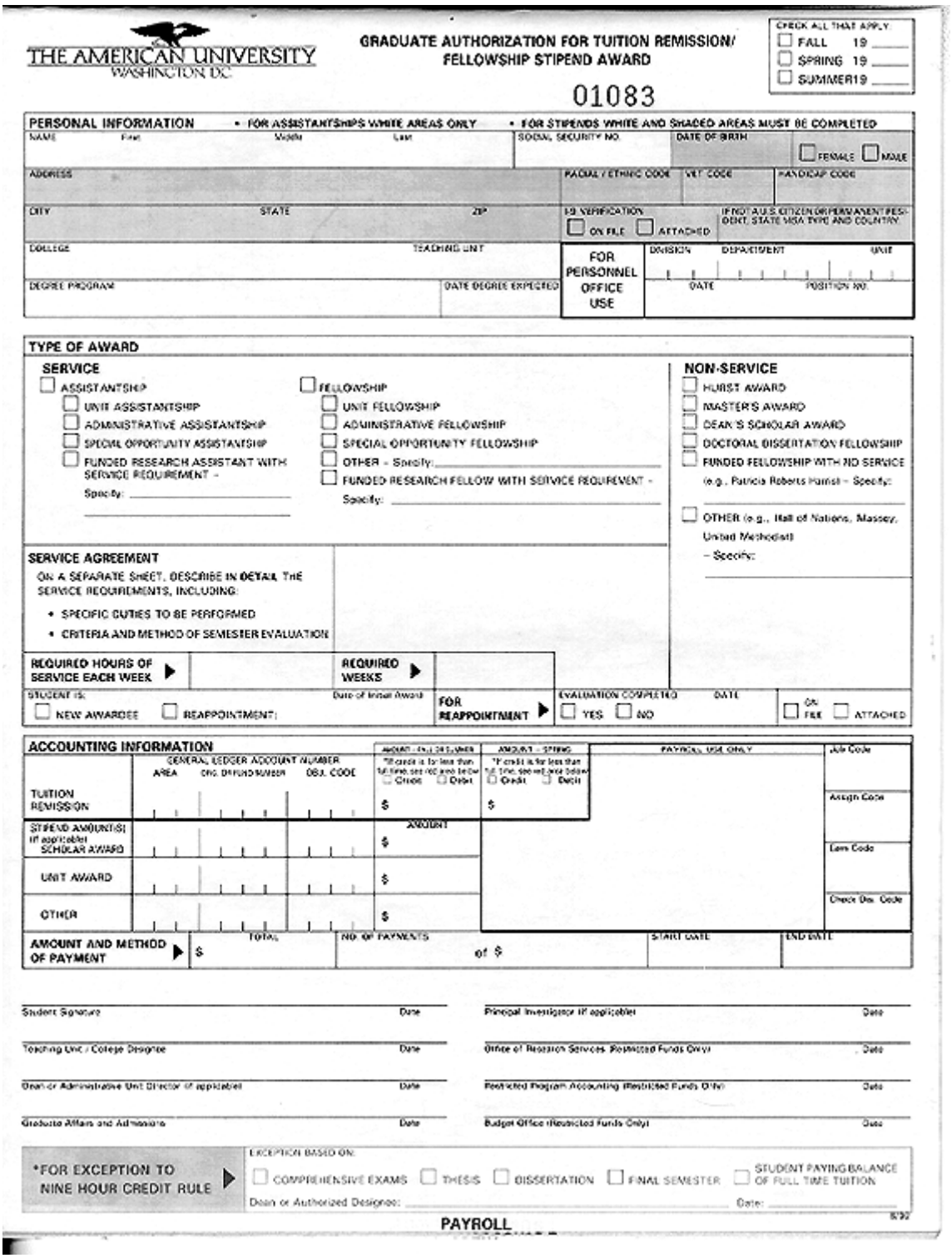
salaries and wages of the employees receiving the benefits. The benefits related to salaries and wages treated as direct costs shall also be treated as direct costs; the benefits related to salaries and wages treated as F&A costs shall be treated as F&A costs.

g. *Institution-furnished automobiles*.

That portion of the cost of institution-furnished automobiles that relates to personal use by employees (including transportation to and from work) is unallowable regardless of whether the cost is reported as taxable income to the employees.

ATTACHMENT III-D

Sample Graduate Authorization and Tuition Remission Form



THE AMERICAN UNIVERSITY
WASHINGTON, DC

GRADUATE AUTHORIZATION FOR TUITION REMISSION/ FELLOWSHIP STIPEND AWARD

01083

CHECK ALL THAT APPLY:
☐ FALL 19 ____
☐ SPRING 19 ____
☐ SUMMER19 ____

PERSONAL INFORMATION • FOR ASSISTANTSHIPS WHITE AREAS ONLY • FOR STIPENDS WHITE AND SHADED AREAS MUST BE COMPLETED

NAME First Middle Last | SOCIAL SECURITY NO. | DATE OF BIRTH | ☐ FEMALE ☐ MALE

ADDRESS | RACIAL / ETHNIC CODE | VET. CODE | HANDICAP CODE

CITY STATE ZIP | I-9 VERIFICATION ☐ ON FILE ☐ ATTACHED | IF NOT A U.S. CITIZEN OR PERMANENT RESIDENT, STATE VISA TYPE AND COUNTRY

COLLEGE TEACHING UNIT | FOR PERSONNEL OFFICE USE: DIVISION DEPARTMENT UNIT

DEGREE PROGRAM DATE DEGREE EXPECTED | DATE POSITION NO.

TYPE OF AWARD

SERVICE

☐ ASSISTANTSHIP
- ☐ UNIT ASSISTANTSHIP
- ☐ ADMINISTRATIVE ASSISTANTSHIP
- ☐ SPECIAL OPPORTUNITY ASSISTANTSHIP
- ☐ FUNDED RESEARCH ASSISTANT WITH SERVICE REQUIREMENT – Specify: _____

☐ FELLOWSHIP
- ☐ UNIT FELLOWSHIP
- ☐ ADMINISTRATIVE FELLOWSHIP
- ☐ SPECIAL OPPORTUNITY FELLOWSHIP
- ☐ OTHER – Specify: _____
- ☐ FUNDED RESEARCH FELLOW WITH SERVICE REQUIREMENT – Specify: _____

NON-SERVICE
- ☐ HURST AWARD
- ☐ MASTER'S AWARD
- ☐ DEAN'S SCHOLAR AWARD
- ☐ DOCTORAL DISSERTATION FELLOWSHIP
- ☐ FUNDED FELLOWSHIP WITH NO SERVICE (e.g., Patricia Roberts Harris) – Specify: _____
- ☐ OTHER (e.g., Hall of Nations, Massey, United Methodist) – Specify: _____

SERVICE AGREEMENT
ON A SEPARATE SHEET, DESCRIBE IN DETAIL THE SERVICE REQUIREMENTS, INCLUDING:
- SPECIFIC DUTIES TO BE PERFORMED
- CRITERIA AND METHOD OF SEMESTER EVALUATION

REQUIRED HOURS OF SERVICE EACH WEEK ▶ | REQUIRED WEEKS ▶

STUDENT IS: ☐ NEW AWARDEE ☐ REAPPOINTMENT; Date of Initial Award | FOR REAPPOINTMENT ▶ EVALUATION COMPLETED ☐ YES ☐ NO DATE | ☐ ON FILE ☐ ATTACHED

ACCOUNTING INFORMATION

	GENERAL LEDGER ACCOUNT NUMBER: AREA	ORG. DIV/SUB NUMBER	OBJ. CODE	AMOUNT – Fall / 1st Summer (If credit is for less than full time, see reverse side) ☐ Credit ☐ Debit	AMOUNT – Spring (If credit is for less than full time, see reverse side) ☐ Credit ☐ Debit	PAYROLL USE ONLY: Job Code / Assign Code / Earn Code / Check Dist. Code
TUITION REMISSION				$	$	
STIPEND AMOUNT(S) (If applicable) SCHOLAR AWARD				AMOUNT $		
UNIT AWARD				$		
OTHER				$		

AMOUNT AND METHOD OF PAYMENT ▶ $ Total | NO. OF PAYMENTS of $ | START DATE | END DATE

Student Signature Date | Principal Investigator (If applicable) Date

Teaching Unit / College Designee Date | Office of Research Services (Restricted Funds Only) Date

Dean or Administrative Unit Director (If applicable) Date | Restricted Program Accounting (Restricted Funds Only) Date

Graduate Affairs and Admissions Date | Budget Office (Restricted Funds Only) Date

*FOR EXCEPTION TO NINE HOUR CREDIT RULE ▶ EXCEPTION BASED ON: ☐ COMPREHENSIVE EXAMS ☐ THESIS ☐ DISSERTATION ☐ FINAL SEMESTER ☐ STUDENT PAYING BALANCE OF FULL TIME TUITION

Dean or Authorized Designee: _____ Date: _____

PAYROLL

8/92

ATTACHMENT III-E

CONSULTANT /SUBCONTRACT REQUEST FORM

Date:

Principal Investigator Name and Telephone Number:

Name and Telephone Number of Person to Whom Questions Should be directed if Other than the Principal Investigator:

Type of Contract:

Article I. Consultant (individual) _____

Subcontract (organization) _____

Grant or Contract Number to Which Agreement Applies:

Period of Performance:

Statement of Work (should be detailed enough to measure progress):

Compensation Terms (should include performance milestones if compensation is significant):

Any Special Clauses Necessary:

Is this a "Work Made For Hire" or are there copyright or intellectual property issues:

Name of Individual or Organization:

Individual Organization or Address:

Telephone Number:

Social Security Number for Individual:

Address to which agreement should be sent (if different from above):

ATTACHMENT III-F

AMERICAN UNIVERSITY
WASHINGTON, DC

OFFICE OF THE CONTROLLER

DISBURSEMENT REQUEST

PAYEE INFORMATION	
NAME OF PAYEE	AU EMPLOYEE (CHECK ONE) ☐ YES ☐ NO
ADDRESS OF PAYEE (Campus address if AU employee)	
STREET	
CITY STATE ZIP CODE	
REQUESTING DEPARTMENT	DEPT. PHONE #
SOCIAL SECURITY NO. / FEDERAL I.D. NO.	(CHECK ONE) ☐ Individual ☐ Corporation ☐ Sole Proprietorship/Partnership
U.S. CITIZEN? (please confirm) ☐ YES ☐ NO	☐ PERMANENT RESIDENT Please attach form 1078 and copy of Alien Reg Card

For Use by the Office of the Controller Only	
0074448	
☐ CXR ☐ PRE	
AMOUNT $	
AUDITED BY	DATE

DATE	DESCRIPTION	AMOUNT
	TOTAL	$

CHECK ONLY ONE FOR DISTRIBUTION		
☐ HOLD FOR PICKUP AND CALL EXT. _____	A.U. EMPLOYEE SIGNATURE (for personal reimbursements only) I certify that the above charges, incurred by me, are correct and proper.	DATE
☐ SEND CAMPUS MAIL	AUTHORIZED APPROVAL SIGNATURE	DATE
☐ SEND U.S. MAIL	BUDGET ACCOUNT NUMBER	$
	RESTRICTED APPROVAL	DATE

Rev. 5/97

ATTACHMENT III-G: Sample Consultant Invoice

Jane Doe, Ph.D.
2000 Georgia Ave NW
Washington, DC 20009
(202) 555-1212

a. INVOICE

Date: November 11, 1997
To: Mary Jones
American University

i. **From:** Dr. Jane Doe

Task	**Fee**
Analyze data and interpret meaning from 14 training sessions with AU graduate students on study habits.	$1,000.00

ATTACHMENT III-H: Sample

Report of travel for Dr. Mary Jones
Dates: 10/1/94 - 10/3/94

10/1/94

$12.00 - Taxi from Airport to Hotel - receipt attached

$8.50 - Lunch - no receipt - paid cash

$21.00 - Dinner - receipt attached - MasterCard

10/2/94

$4.50 - Breakfast - no receipt - paid cash

$34.00 - Lunch w/ conference coordinator - receipt attached - MasterCard

$14.00 - Dinner - Room Service - on Hotel bill

$3.50 - Long Distance Calls - check voice mail at University and return a call - on Hotel bill

10/3/94

$4.50 - Breakfast - receipt attached - paid cash

$12.50 - Taxi from Hotel to Airport - receipt attached

$14.00 - Parking for Car at National Airport - receipt attached

Other Costs

$242.27 - Two Nights stay at hotel (plus tax) - receipt attached - MasterCard

$312.00 - Airfare To/From Conference to National Airport - receipt attached - pre-paid on Purchase order #N123456R

TOTAL COSTS = $648.27
COSTS ALREADY PAID = $312.00
ADVANCE MADE TO DR. JONES = $250.00
TOTAL DUE TO DR. JONES = $86.72

ATTACHMENT III-I

CONTACT	DEPT. EXT.

AMERICAN UNIVERSITY
WASHINGTON, DC

0020522 ADV

ADVANCE / EXPENSE FORM

A PAYEE INFORMATION

NAME OF PAYEE	A.U. EMPLOYEE ☐ YES ☐ NO
ADDRESS (Campus Address if A.U. Employee)	
SOCIAL SECURITY NO.	☐ U.S. CITIZEN ☐ PERMANENT RESIDENT (Attach Form 1078 and Alien Reg. Card) ☐ FOREIGN NATIONAL

B TRIP / EVENT INFORMATION

LOCATION / DESTINATION	DEPARTURE DATE	RETURN DATE
PURPOSE		
AMOUNT OF CASH REQUESTED	NEEDED BY (Date)	

C VENDOR INFORMATION (Complete only for checks requested in addition to cash advance.)

LODGING	VENDOR NAME					AMOUNT NEEDED
	VENDOR ADDRESS	CITY	STATE	ZIP CODE		CHECK NEEDED BY (Date)
REGISTRATION	VENDOR NAME					AMOUNT NEEDED
	VENDOR ADDRESS	CITY	STATE	ZIP CODE		CHECK NEEDED BY (Date)
TRANSPORTATION	VENDOR NAME					AMOUNT NEEDED
	VENDOR ADDRESS	CITY	STATE	ZIP CODE		CHECK NEEDED BY (Date)

TO BE COMPLETED BY THE OFFICE OF THE CONTROLLER

EXPENSE	AREA ORG. OBJ.	$
EXPENSE	AREA ORG. OBJ.	$
EXPENSE	FUND B/S ACCT.	$
AUDITED BY	DATE	

SUMMARY	AMOUNT
TOTAL CASH REQUESTED	
TOTAL VENDOR CHECKS REQUESTED	
TOTAL ADVANCE ➡	$

☐ HOLD FOR PICKUP EXT. _____

☐ CAMPUS MAIL

☐ U.S. MAIL

INSTRUCTIONS FOR COMPLETING THIS FORM

- Use ballpoint pen only.
- Complete all unshaded sections. (Section C should be completed only for checks requested in addition to cash advance.)
- White copy for Controller's Office.
- Yellow copy should be retained by traveler for reconciliation.

D AUTHORIZATION

TRAVELER SIGNATURE:
I hereby authorize all delinquent monies to be deducted from my paycheck.

X _____ Date _____
AUTHORIZED SIGNATURE DATE

PRINTED NAME

BUDGET ACCOUNT NO. $

BUDGET ACCOUNT NO. $

RESTRICTED AUTHORIZATION

COMPLIANCE POLICIES

The Compliance Administrator at OSP serves as the administrator for committees established to ensure compliance in three areas of research: human subjects, animal care and use, and radiation safety. AU compliance policies in these areas and committee procedures and memberships are given below. Hazardous materials and controlled substances are also addressed.

The information in this handbook details policies and procedures for the AU compliance committees for which the Office of Sponsored Programs provides coordination services. For general information about the university's risk management and safety services for hazardous materials and chemical hygiene go the website http://american.edu/finance/rmo/ehands.html."

HUMAN SUBJECTS

Protection of human subjects in research at American University is overseen by the Institutional Review Board for the Protection of Human Subjects (IRB). AU adheres to 45 CFR 46, *Protection of Human Subjects*, as amended (made more stringent) by the IRB and approved by the Provost (see **Attachment IV-A**), for all federally-funded research. For this research, AU operates under the terms of its Federalwide Assurance (FWA) on file with the Department of Health and Human Services' Office for Human Research Protections (OHRP) (see **Attachment IV-B**).

All research involving human subjects must receive prior approval from the IRB or appropriate Unit Designee. Review of all externally funded or high-risk research is done by the IRB, which meets monthly during the academic year and once during the summer. Non-funded and minimal risk studies are approved by the Unit Designees. For a decision tree chart regarding human subjects research at AU, see **Attachment IV-C**. Researchers should submit the Research Proposal Review form (**Attachment IV-D**), with all of the required documentation, to the IRB Administrator or the Unit Designee. Researchers may file a Claim of IRB Exemption (**Attachment IV-E**) if they believe that the project falls under one or more of the regulatory exemptions, but the determination of exemption can only be made by the IRB or Unit Designee.

A new condition for IRB approval, effective in the fall of 2002, is completion by all researchers involved in a project of an on-line educational training module at http://www.cc.nih.gov/researchers/training/crt.shtml or the completion of comparable documented training.

Questions and Answers about Human Subjects Protection at American University (**Attachment IV-F**) covers the basic policies and procedures. Further questions should be referred to the IRB Administrator or Unit Designee. Additional guidance is available at http://www.hhs.gov/ohrp/policy/index.html.

IRB members, 2005-6

Chair:	Peter Jaszi, Washington College of Law
Members:	Karen Froslid-Jones, Institutional Research and Assessment

James Gray, Psychology
Dolores Koenig, Anthropology
Renee Marlin-Bennett, School of International Service
Ruth Cernea, community member

Alternates: Joseph Eldridge, University Chaplain
Brian Yates, Psychology

Administrator: Catherine Kirby, OSP (x3440, ckirby@american.edu)

ANIMAL CARE AND USE

Research involving animals at American University is overseen by the Institutional Animal Care and Use Committee (IACUC). AU adheres to legislation such as the Animal Welfare Act of 1966 and the Health Research Extension Act of 1985, as well as the Public Health Service Policy on Humane Care and Use of Laboratory Animals and other relevant guidelines. Applicable regulations are available at the web site of the Office of Laboratory Animal Welfare (OLAW): http://grants.nih.gov/grants/olaw/olaw.htm. AU operates under the terms of its Animal Welfare Assurance with OLAW.

AU's policies on animal care and use are described in detail at the IACUC web site (http://www.american.edu/academic.depts/provost/osp/iacuc/index.cfm). The site is password-protected; for a password, contact the IACUC Administrator.

All research involving animals must receive prior approval from the IACUC. The IACUC meets twice a year but proposals can be reviewed at any time. Proposals should be submitted to the IACUC Administrator using the *Protocol for the Use of Live Vertebrates for Research, Teaching, or Demonstration* form (**Attachment IV-G**).

IACUC procedures include monthly inspections (announced and unannounced) by AU's consulting veterinarian. The IACUC prepares semi-annual reports for the Provost.

Since 1995 AU has not been engaged in research using any animals whose use would require a license and annual inspection from the U.S. Department of Agriculture. Introduction of certain animals other than mice, rats, pigeons, and fish could trigger these new requirements.

IACUC members, 2005-6

Chair: Anthony Riley, Psychology

Members: Lynne Arneson, Biology
Bernard M. Flynn, consulting veterinarian
Michael Gross, community member
Craig Gruber, community member

Administrator: Catherine Kirby, OSP (x3440, ckirby@american.edu)

RADIATION SAFETY

AU is licensed by the Nuclear Regulatory Commission (NRC) and the District of Columbia to use specific radioactive isotopes for teaching, research, and training. NRC inspectors can and do conduct unannounced inspections to determine the University's compliance with licensing requirements. Use of radioactive isotopes is overseen by the Radiation Safety Committee.

A researcher who proposes to use radioactive isotopes must:

- have current training in radiation safety;
- request inclusion on AU's NRC license;
- ensure that AU is licensed for the isotopes to be used; and
- strictly follow all the requirements for ordering, use, and disposal of the isotopes (see **Attachment IV-H** for further information on ordering and receiving radioactive materials).

The names of all persons approved to use radioactive isotopes at AU must appear on the license, and their training in this area must be current. All isotopes and their locations must appear on AU's inventory, and warning signs must be posted in each location. In addition, all orders for isotopes for use at AU must be signed by the teaching unit head and the Radiation Safety Officer. All isotopes that are ordered must include an approved plan for disposal.

For further information on federal and AU procedures regarding research with radioactive isotopes or specific licensing requirements, contact either the Radiation Safety Officer or the Compliance Administrator.

Radiation Safety Committee members, 2005-6

Chair:	Albert Cheh, Chemistry (Radiation Safety Officer)
Members:	Anthony Newman, Contract and Risk Management
	Catherine Schaeff, Biology
Administrator:	Catherine Kirby, OSP (x3440, ckirby@american.edu)

HAZARDOUS MATERIALS

American University conducts research and other activities that involve the use of hazardous materials. These materials, if not properly used, stored, transported, or disposed of, may pose a risk to persons or the environment. AU's policy is to provide an environment free from recognized, significant hazards and comply with local and federal regulations regarding environmental and occupational safety and health, such as those promulgated by the Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA).

Accordingly, all projects involving the use of hazardous chemical or biological materials must adhere to the University's Chemical Hygiene Plan, available from the Office of Contract and Risk Management. This policy serves as a guide for laboratory researchers, professors, students, and other AU personnel who generate hazardous waste.

Management questions should be addressed to:
Anthony Newman, Director of Risk Management, x2706, anewman@american.edu

CONTROLLED SUBSTANCES

Researchers cannot use controlled substances in research unless they have registered with the Drug Enforcement Agency (DEA). 21 CFR 1301 (and in particular 21 CFR 1301.18) covers requirements that must be met by any researcher anticipating the use of controlled substances listed under schedules one through five. The application (DEA form 225 or 225a) requires the submission of the research protocol, a description of the quantity and type of controlled substance proposed for use; and an explicit description of the safe, location of the safe, and controlled access to the safe in which the substances will be stored.

Since the researcher registers directly with the DEA for a license to obtain controlled substances, AU has no standing committee for this purpose. However, faculty members considering research that involved controlled substances may wish to contact OSP for guidance in contacting the proper authorities.

Attachment IV-A

American University Regulations on the Protection of Human Subjects

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

American University regulations on the protection of human subjects follow 45 CFR 46 with the exception of articles 46.101(b)(3) and (4), which have been modified (made more stringent).

CODE OF FEDERAL REGULATIONS
TITLE 45
PUBLIC WELFARE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
OFFICE FOR PROTECTION FROM RESEARCH RISKS
PART 46
PROTECTION OF HUMAN SUBJECTS
*** * ***
Revised November 13, 2001
Effective December 13, 2001
*** * ***

Subpart A -- Federal Policy for the Protection of Human Subjects (Basic DHHS Policy for Protection of Human Research Subjects)

Sec.

Authority: 5 U.S.C. 301; Sec. 474(a), 88 Stat. 352 (42 U.S.C. 2891-3(a)).

Note: As revised, Subpart A of the DHHS regulations incorporates the Common Rule (Federal Policy) for the Protection of Human Subjects (56 FR 28003). Subpart D of the HHS regulations has been amended at Section 46.401(b) to reference the revised Subpart A.

The Common Rule (Federal Policy) is also codified at

7 CFR Part 1c	**Department of Agriculture**
10 CFR Part 745	**Department of Energy**
14 CFR Part 1230	**National Aeronautics and Space Administration**
15 CFR Part 27	**Department of Commerce**
16 CFR Part 1028	**Consumer Product Safety Commission**
22 CFR Part 225	**International Development Cooperation Agency, Agency for International Development**
24 CFR Part 60	**Department of Housing and Urban Development**
28 CFR Part 46	**Department of Justice**
32 CFR Part 219	**Department of Defense**
34 CFR Part 97	**Department of Education**
38 CFR Part 16	**Department of Veterans Affairs**
40 CFR Part 26	**Environmental Protection Agency**

45 CFR Part 690	**National Science Foundation**
49 CFR Part 11	**Department of Transportation**

TITLE 45
CODE OF FEDERAL REGULATIONS
PART 46
PROTECTION OF HUMAN SUBJECTS

* * *

Revised June 18, 1991
Effective August 19, 1991

* * *

Subpart A	Federal Policy for the Protection of Human Subjects (Basic DHHS Policy for Protection of Human Research Subjects)
	Source: 56 FR 28003, June 18, 1991.

§46.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any Federal Department or Agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each Department or Agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States.

(1) Research that is conducted or supported by a Federal Department or Agency, whether or not it is regulated as defined in §46.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a Federal Department or Agency but is subject to regulation as defined in §46.102(e) must be reviewed and approved, in compliance with §46.101, §46.102, and §46.107 through §46.117 of this policy, by an Institutional Review Board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:[1]

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

*(3) Research involving survey or interview procedures, except where responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, and (i) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, or (ii) the research deals with sensitive aspects of the subject's own behavior, attitudes or opinions.

*(4) Research involving the observation (including observations by participants) of public behavior, except where responses are recorded in such a manner that the human subjects can be identified, directly or through

* As modified (made more stringent) by American University.

identifiers linked to the subjects, and (i) the observations about the individual, if they become known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, or (ii) the research deals with sensitive aspects of the subject's own behavior, attitudes or opinions.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or Agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or Agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the Department or Agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent Federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any State or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a Department or Agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the Department or Agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the Department or Agency head, notices of these actions as they occur will be published in the **Federal Register** or will be otherwise published as provided in Department or Agency procedures.

(i) Unless otherwise required by law, Department or Agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes or research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the Department or Agency head shall forward advance notices of these actions to the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services (DHHS), and shall also publish them in the **Federal Register** or in such other manner as provided in Department or Agency procedures.[1]

[1] Institutions with DHHS-approved assurances on file will abide by provisions of Title 45 CFR Part 46 Subparts A-D. Some of the other departments and agencies have incorporated all provisions of Title 45 CFR Part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, Subparts B and C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, Subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

§46.102 Definitions.

(a) *Department or Agency* head means the head of any Federal Department or Agency and any other officer or employee of any Department or Agency to whom authority has been delegated.

(b) *Institution* means any public or private entity or Agency (including Federal, State, and other agencies).

(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a Federal Department or Agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentallyregulated by a Federal Department or Agency solely as part of the Department's or Agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) data through intervention or interaction with the individual, or
(2) identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) *IRB* means an Institutional Review Board established in accord with and for the purposes expressed in this policy.

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) *Certification* means the official notification by the institution to the supporting Department or Agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

§46.103 Assuring compliance with this policy -- research conducted or supported by any Federal Department or Agency.

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a Federal Department or Agency shall providewritten assurance satisfactory to the Department or Agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual Department or Agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Protection from Research Risks, National Institutes Health, DHHS, and approved for Federalwide use by that office. When the existence of an DHHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to Department and Agency heads shall also be made to the Office for Protection from Research Risks, National Institutes of Health, DHHS.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the Department or Agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of

whether the research is subject to Federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to Department- or Agency-supported or regulated research and need not be applicable to any research exempted or waived under §46.101 (b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the Department or Agency head, unless in accord with §46.103(a) of this policy, the existence of a DHHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Protection from Research Risks, National Institutes of Health, DHHS.

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the Department or Agency head prescribes.

(d) The Department or Agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the Department or Agency and such experts or consultants engaged for this purpose as the Department or Agency head determines to be appropriate. The Department or Agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the Department or Agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The Department or Agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a Federal Department or Agency and not otherwise exempted or waived under §46.101 (b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by §46.103 of this policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the Department or Agency to which the application or proposal is submitted. Under no condition shall research covered by §46.103 of the policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the Department or Agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution. (Approved by the Office of Management and Budget under Control Number 9999-0020.)

§§46.104--46.106 [Reserved]

§46.107 IRB membership.
(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.
(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB

§46.108 IRB functions and operations.
In order to fulfill the requirements of this policy each IRB shall:
(a) Follow written procedures in the same detail as described in §46.103(b)(4) and to the extent required by §46.103(b)(5).
(b) Except when an expedited review procedure is used (see §46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting

§46.109 IRB review of research.
(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.
(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.
(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117.
(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.
(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
(a) The Secretary, HHS, has established, and published as a Notice in the **Federal Register**, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the Federal Register. A copy of the list is available from the Office for Protection from Research Risks, National Institutes of Health, DHHS, Bethesda, Maryland 20892.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).
(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.
(d) The Department or Agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

§46.111 Criteria for IRB approval of research.
(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§46.112 Review by institution.
Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§46.113 Suspension or termination of IRB approval of research.
An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination or approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Department or Agency head. (Approved by the Office of Management and Budget under Control Number 9999-0020.)

§46.114 Cooperative research.
Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the Department or Agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

§46.115 IRB records.
(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in §46.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in §46.103(b)(4) and §46.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by §46.116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the Department or Agency at reasonable times and in a reasonable manner.
(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§46.116 General requirements for informed consent.
Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) a description of any reasonably foreseeable risks or discomforts to the subject;

(3) a description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) any additional costs to the subject that may result from participation in the research;

(4) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) the approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) the research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) the research involves no more than minimal risk to the subjects;

(2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) the research could not practicably be carried out without the waiver or alteration; and

(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.
(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.
(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§46.117 Documentation of informed consent.
(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.
(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.
(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§46.118 Applications and proposals lacking definite plans for involvement of human subjects.
Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under §46.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the Department or Agency.

§46.119 Research undertaken without the intention of involving human subjects.
In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a

certification submitted, by the institution, to the Department or Agency, and final approval given to the proposed change by the Department or Agency.

§46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
(a) The Department or Agency head will evaluate all applications and proposals involving human subjects submitted to the Department or Agency through such officers and employees of the Department or Agency and such experts and consultants as the Department or Agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.
(b) On the basis of this evaluation, the Department or Agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§46.121 [Reserved]

§46.122 Use of Federal funds.
Federal funds administered by a Department or Agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§46.123 Early termination of research support: Evaluation of applications and proposals.
(a) The Department or Agency head may require that Department or Agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the Department or Agency head finds an institution has materially failed to comply with the terms of this policy.
(b) In making decisions about supporting or approving applications or proposals covered by this policy the Department or Agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the Department or Agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to Federal regulation).

§46.124 Conditions.
With respect to any research project or any class of research projects the Department or Agency head may impose additional conditions prior to or at the time of approval when in the judgment of the Department or Agency head additional conditions are necessary for the protection of human subjects.

Subpart B	**Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research**
	Source: Federal Register: November 13, 2001 (Volume 66, Number 219), Rules and Regulations, Page 56775-56780, from the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr13no01-9].

§46.201 To what do these regulations apply?
(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving pregnant women, human fetuses, neonates of uncertain viability, or nonviable neonates conducted or supported by the Department of Health and Human Services (DHHS). This includes all research conducted in DHHS facilities by any person and all research conducted in any facility by DHHS employees.
(b) The exemptions at Sec. 46.101(b)(1) through (6) are applicable to this subpart.
(c) The provisions of Sec. 46.101(c) through (i) are applicable to this subpart. Reference to State or local laws in this subpart and in Sec. 46.101(f) is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.
(d) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§46.202 Definitions.
The definitions in Sec. 46.102 shall be applicable to this subpart as well. In addition, as used in this subpart:
(a) Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

(b) Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.
(c) Fetus means the product of conception from implantation until delivery.
(d) Neonate means a newborn.
(e) Nonviable neonate means a neonate after delivery that, although living, is not viable.
(f) Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.
(g) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.
(h) Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the Federal Register guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of this part.

§46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.
In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart and the other subparts of this part.

§46.204 Research involving pregnant women or fetuses.
Pregnant women or fetuses may be involved in research if all of the following conditions are met:
(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
(c) Any risk is the least possible for achieving the objectives of the research;
(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;
(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
(g) For children as defined in Sec. 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;
(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
(j) Individuals engaged in the research will have no part in determining the viability of a neonate

§46.205 Research involving neonates.
(a) Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

(1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

(2) Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

(3) Individuals engaged in the research will have no part in determining the viability of a neonate.

(4) The requirements of paragraph (b) or (c) of this section have been met as applicable.

(b)Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met:

(1) The IRB determines that:

(i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or

(ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and

(2) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

(c) Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:

(1) Vital functions of the neonate will not be artificially maintained;

(2) The research will not terminate the heartbeat or respiration of the neonate;

(3) There will be no added risk to the neonate resulting from the research;

(4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

(5) The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of Sec. 46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

(d) Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

§46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

(a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.

(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

§46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

The Secretary will conduct or fund research that the IRB does not believe meets the requirements of Sec. 46.204 or Sec. 46.205 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined either:

(1) That the research in fact satisfies the conditions of Sec. 46.204, as applicable; or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;

(ii) The research will be conducted in accord with sound ethical principles; and

(iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

Subpart C	**Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects**
	Source: 43 FR 53655, Nov. 16, 1978.

§46.301 Applicability.
(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.
(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.
(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§46.302 Purpose.
Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§46.303 Definitions.
As used in this subpart:
(a) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.
(b) "DHHS" means the Department of Health and Human Services.
(c) "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which providealternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.
(d) "Minimal risk" is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

§46.304 Composition of Institutional Review Boards where prisoners are involved.
In addition to satisfying the requirements in §46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:
(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.
(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

§46.305 Additional duties of the Institutional Review Boards where prisoners are involved.
(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

(1) the research under review represents one of the categories of research permissible under §46.306(a)(2);

(2) any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) the information is presented in language which is understandable to the subject population;

(6) adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.
(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§46.306 Permitted research involving prisoners.
(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) the institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under §46.305 of this subpart; and

(2) in the judgment of the Secretary the proposed research involves solely the following:

(A) study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(B) study of prisons as institutional structures or of prisoners asincarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(C) research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the **Federal Register**, of his intent to approve such research; or

(D) research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the

Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the **Federal Register**, of the intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

Subpart D	Additional DHHS Protections for Children Involved as Subjects in Research
	Source: 48 FR 9818, March 8, 1983; 56 FR 28032, June 18, 1991.

§46.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (i) of §46.101 of Subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions at §46.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at §46.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at §46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of §46.101 of Subpart A are applicable to this subpart.

§46.402 Definitions.

The definitions in §46.102 of Subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) "Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) "Parent" means a child's biological or adoptive parent.

(e) "Guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

§46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§46.404 Research not involving greater than minimal risk.

DHHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in §46.408.

§46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

DHHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

(a) the risk is justified by the anticipated benefit to the subjects;

(b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
(c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.

§46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
DHHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:
(a) the risk represents a minor increase over minimal risk;
(b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
(c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
(d) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408.

§46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.
DHHS will conduct or fund research that the IRB does not believe meets the requirements of §46.404, §46.405, or §46.406 only if:
(a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
(b) the Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

(1) that the research in fact satisfies the conditions of §46.404, §46.405, or §46.406, as applicable, or (2) the following:

(i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) the research will be conducted in accordance with sound ethical principles;

(iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408.

§46.408 Requirements for permission by parents or guardians and for assent by children.
(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with §46.116 of Subpart A.
(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by §46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is covered by §46.406 and §46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in §46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.
(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by §46.117 of Subpart A.
(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§46.409 Wards.
(a) Children who are wards of the State or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is:

(1) related to their status as wards; or

(2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Attachment IV-B Version Date 03/20/2002

U. S. Department of Health and Human Services (DHHS)
Office for Human Research Protections (OHRP)

FEDERALWIDE ASSURANCE OF PROTECTION FOR HUMAN SUBJECTS

A. TERMS OF THE FEDERALWIDE ASSURANCE FOR INSTITUTIONS WITHIN THE UNITED STATES

1. Human Subject Research Must be Guided by Ethical Principles

All of the Institution's human subject activities and all activities of the Institutional Review Boards (IRBs) designated under the Assurance, regardless of funding source, will be guided by the ethical principles in: (a) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, or (b) other appropriate ethical standards recognized by Federal Departments and Agencies that have adopted the Federal Policy for the Protection of Human Subjects.

2. Applicability

These terms apply whenever the Institution becomes engaged in federally-supported* (i.e., conducted or supported) human subject research, which is not otherwise exempt from the Federal Policy for the Protection of Human Subjects. The Institution becomes so engaged whenever (a) the Institution's employees or agents intervene or interact with human subjects for purposes of federally-supported research; (b) the Institution's employees or agents obtain individually identifiable private information about human subjects for purposes of federally-supported research; or (c) the Institution receives a direct federal award to conduct human subject research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

[*Federally-supported is defined throughout the FWA and the Terms of Assurance as the U.S. Government providing any funding or other support (including, but not limited to, providing supplies, products, drugs, and identifiable private information collected for research purposes) and/or the conduct of the research involves U.S. Government employees.]

3. Compliance with the Federal Policy for the Protection of Human Subjects

Institutions conducting federally-supported human subject research and the IRB(s) designated under the Institution's Assurance will comply with the Federal Policy for the Protection of Human Subjects, known as the Common Rule. All federally-supported human

subject research will also comply with any additional human subject regulations and policies of the supporting Department or Agency. All human subject research conducted or supported by the Department of Health and Human Services (DHHS) will comply with all Subparts of DHHS regulations at Title 45 Code of Federal Regulations Part 46 (45 CFR 46 and its Subparts A, B, C, and D).

The reference in the Code of Federal Regulations is shown below for each Agency which has adopted the Common Rule:

7CFR 1c	Department of Agriculture
10 CFR 745	Department of Energy
14 CFR 123	National Aeronautics and Space Administration
15 CFR 27	Department of Commerce
16 CFR 1028	Consumer Product Safety Commission
22 CFR 225	Agency for International Development
24 CFR 60	Department of Housing and Urban Development
28 CFR 46	Department of Justice
32 CFR 219	Department of Defense
34 CFR 97	Department of Education
38 CFR 16	Department of Veterans Affairs
40 CFR 26	Environmental Protection Agency
45 CFR 46	Department of Health & Human Services
45 CFR 690	National Science Foundation
49 CFR 11	Department of Energy
By Executive Order	Central Intelligence Agency
By Statue	Social Security Administration

4. **Written Procedures**

a) The Institution should establish, and should provide a copy to OHRP upon request, written procedures for:
1) ensuring prompt reporting to the IRB, appropriate institutional officials, the relevant Department or Agency Head, any applicable regulatory body, and OHRP of any: (i) unanticipated problems involving risks to subjects or others, (ii) serious or continuing noncompliance with the Federal Regulations or IRB requirements, and (iii) suspension or termination of IRB approval.

2) Verifying, by a qualified person or persons other than the investigator or research team, whether proposed human subject research activities qualify for exemption from the requirements of the Common Rule;

b) The designated IRB(s) has established, and will provide a copy to OHRP upon request, written procedures for:
1) Conducting IRB initial and continuing review (not less than once per year), approving research, and reporting IRB findings to the investigator and the Institution;

2) Determining which projects require review more often than annually and which projects

need verification from sources other than the investigator that no material changes have occurred since the previous IRB review;

3) Ensuring that changes in approved research protocols are reported promptly and are not initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject.

5. Responsibilities and Scope of IRB(s)

Except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the Common Rule, all human subject research will be reviewed, prospectively approved, and subject to continuing oversight and review at least annually by the designated IRB(s). The IRB(s) will have authority to approve, require modifications in, or disapprove the covered human subject research.

6. Informed Consent Requirements

Except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the Common Rule, informed consent will be:

a) sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Section 116 of the Common Rule;

b) appropriately documented, in accordance with, and to the extent required by Section 117 of the Common Rule.

7. Requirement for Assurances for Collaborating Institutions/Investigators

The Institution is responsible for ensuring that all institutions and investigators engaged in its U.S. federally-supported human subject research operate under an appropriate OHRP or other federally-approved Assurance for the protection of human subjects. In some cases, one institution may operate under an Assurance issued to another institution with the approval of the supporting Department or Agency and the institution holding the Assurance.

8. Written Agreements with Non-Affiliated Investigators

The engagement in human research activities of each independent investigators who is not an employee or agent of the Institution may be covered under the FWA only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and IRB oversight. OHRP's sample Unaffiliated Investigator Agreement may be used or adapted for this purpose, or the Institution may develop its own commitment agreement. Institutions must maintain commitment agreements on file and provide copies to OHRP upon request.

9. Institutional Support for the IRB(s)

The Institution will provide the IRB(s) that it operates with resources and professional and support staff sufficient to carry out their responsibilities under the Assurance effectively.

10. Compliance with the Terms of Assurance

The Institution accepts and will follow items 1-9 above and is responsible for ensuring that (a) the IRB(s) designated under the Assurance agree to comply with these terms; and (b) the IRB(s) possesses appropriate knowledge of the local research context for all research covered under the Assurance (please refer to the OHRP guidance on IRB Knowledge of Local Research Context on the OHRP website).

Any designation under this Assurance of another Institution's IRB or an independent IRB must be documented by a written agreement between the Institution and the IRB organization outlining their relationship and include a commitment that the designated IRB will adhere to the requirements of this Assurance. OHRP's sample IRB Authorization Agreement may be used for such purpose or the two organizations may develop their own agreement. This agreement should be kept on file at both organizations and made available to OHRP upon request.

11. Assurance Training

The OHRP Assurance Training Modules describe the major responsibilities of the Institutional Signatory Official, the Human Protection Administrator, and the IRB Chair(s) that must be fulfilled under the Assurance. OHRP strongly recommends that the Institutional Signatory Official, the Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person), and the IRB Chair(s) personally complete the relevant OHRP Assurance Training Modules, or comparable training that includes the content of these modules, prior to submitting the Assurance.

12. Educational Training

OHRP strongly recommends that the Institution and the designated IRB(s) establish educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, relevant ethical principles, relevant Federal Regulations, OHRP guidance, other applicable guidance, state and local laws, and institutional policies for the protection of human subjects. Furthermore, OHRP recommends that a) IRB members and staff complete relevant educational training before reviewing human subject research; and b) research investigators complete appropriate institutional educational training before conducting human subject research.

13. **Renewal of Assurance**

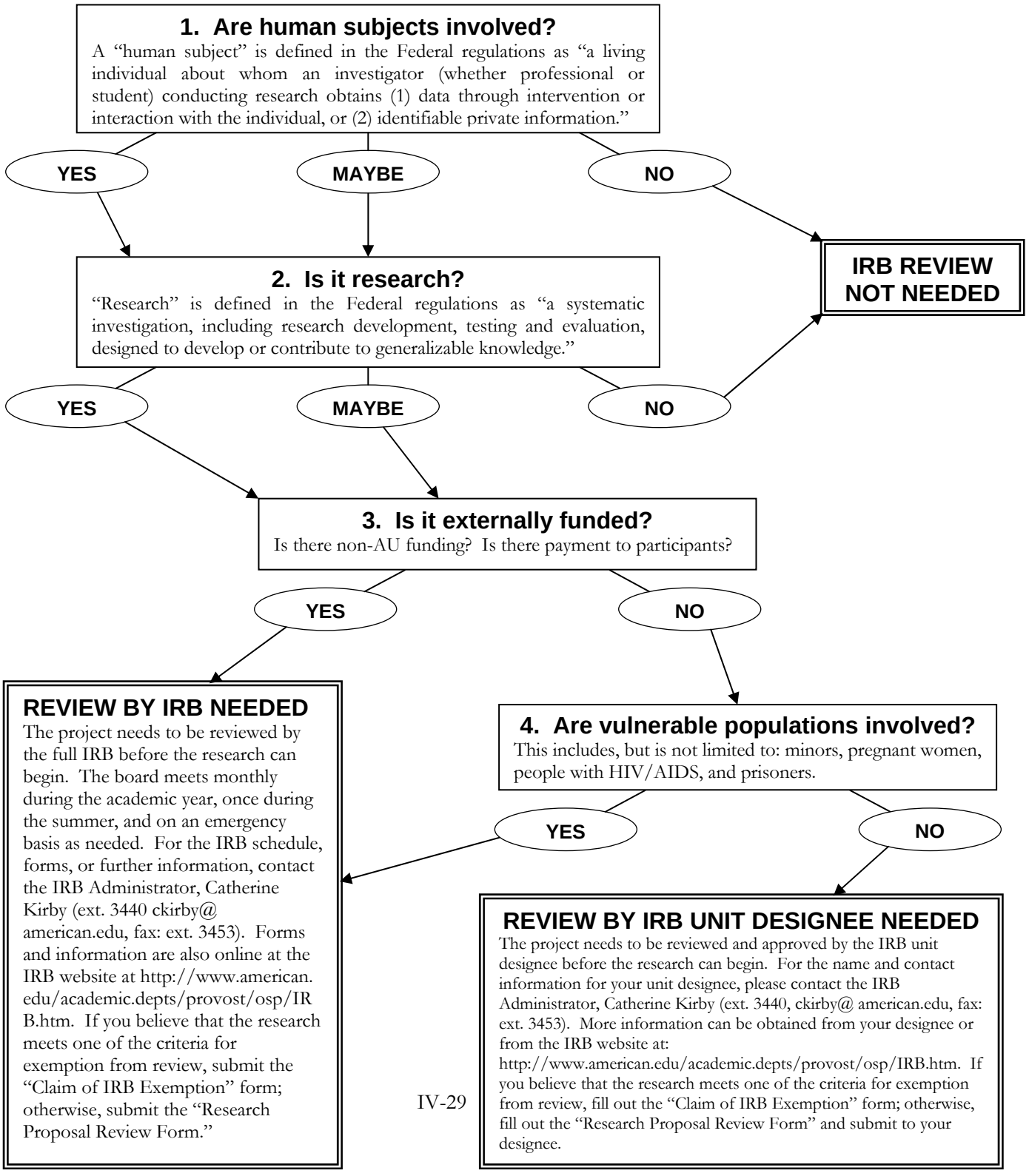
All information provided under this Assurance must be updated at least every 36 months (3 years), even if no changes have occurred, in order to maintain an active Assurance. Failure to update this information may result in restriction, suspension, or termination of the Institution's FWA for the protection of human subjects.

Attachment IV-C

prepared by the Institutional Review Board, August 2002

Human Subjects Research at AU

All research on human subjects, as defined below, must receive prior approval by AU's Institutional Review Board for the Protection of Human Subjects (IRB) or its designee. Research that might need review includes: survey research, interviews, questionnaires, focus groups, and observation projects. This chart helps to identify the steps needed to secure IRB approval.



Attachment IV-D

Date Submitted: _____ Date(s) of IRB Review: _____

INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS
Research Proposal Review

IRB approval must be obtained for all projects involving human subjects. It is the responsibility of the Investigator to initiate this form, and return it to the Unit Designee, or to the University Compliance Adminstrator, Office of Sponsored Programs.

Title of Proposal: _____

Investigator: _____ Teaching Unit/College: _____ Tel. _____
(Last name, first)

Faculty ☐ Staff ☐ Student ☐ Faculty Supervisor (if applicable): _____
(Last name, first)

Short Description of project

How are human subjects involved ?

Identify category(ies) of risks and describe details.

Physical ☐ Psychological ☐ Social, Economic, and/or Environmental ☐

What plans do you have to minimize these risks ?

Supporting documents attached (check all that apply):

Informed consent(s) ☐ Survey Instrument(s) ☐

Research methodology ☐ Other ☐ Describe: _____

Final Action/Recommendation (IRB use only):

Approved ☐ Disapproved ☐ Exempt ☐ Basis: _____

Approved with the following conditions: _____

Signature of IRB Unit Designee or Chair: _____ Date: _____

This form, when executed and signed, indicates approval to proceed. Copies to: University IRB, Teaching Unit/College, and Investigator

Attachment IV-E

Claim of IRB Exemption

Many research projects involve studying people but are exempt from IRB review. In some cases, these projects are exempt because the interview subjects – as human beings – are not the subject of the inquiry. Instead, the project deals with the public role of these individuals. In other cases, the questions being asked are simply not sensitive, and we can reasonably claim that the research does not pose a risk of harm to subjects. If you believe that your research project is exempt from IRB review, please elaborate on your claim below.

In submitting this form, you asking the appropriate IRB representative to grant your project an exemption from IRB review. The researcher can not make the determination herself or himself.

Principal Investigator: _____
Title of Project: _____
Brief Summary of Project Research Question:

Brief Summary of Research Design:

Justification for Exemption. Federal law lists the following forms of research as exempt from IRB review (indicate all that apply):

Research is on educational methods or evaluation in a normal educational setting.	Research involves tests, surveys, or observations of public behavior without collecting any information to identify the subjects.
Research involves no sensitive information (i.e., no physical, psychological, or social harm would come to the subject if he or she were identified with the information collected).	Research involves public (elected or appointed) officials in their public roles.
Research involves publicly available information or documents.	Research involves the collection or study of existing data, documents, records AND the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.
Research or demonstration projects evaluate, or otherwise examine public benefit or service programs.	Research involves taste and food quality consumer acceptance studies of wholesome food.

All the human subjects components of the research design fall into at least one of the above exempt categories. Yes _____ No _____

Unit Designee, IRB Chair, or other IRB representative:
The proposed research is/is not exempt from IRB review.

Signature: _____

Name: _____

Date: _____

Examples:

Research is on educational methods or evaluation in a normal educational setting.

You might introduce a "pre-test" teaching methodology in one section and compare the final exam test scores of students in and not in the pre-test section.

Research involves no sensitive information (i.e., no physical, psychological, or social harm would come to the subject if he or she were identified with the information collected).

You can ask people which brand of toothpaste they prefer and why.

Research involves publicly available information or documents.

You can use Washington Post reports of leaks from the Kenneth Starr investigation.

Research or demonstration projects evaluate, or otherwise examine public benefit or service programs.

You can accept a contract from the USDA to set up a demonstration project to test a new model for delivering WIC benefits.

Research involves tests, surveys, or observations of public behavior without collecting any information to identify the subjects.

You can observe and record how people passing a homeless person on a Washington street react to him or her.

Research involves public (elected or appointed) officials in their public roles.

You can ask President Clinton how the Lewinsky issue is affecting his ability to govern.

Research involves the collection or study of existing data, documents, records AND the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.

You have access to data someone else has collected, and all demographics that would provide unique identifiers have been stripped.

Research involves taste and food quality consumer acceptance studies of wholesome food.

You can have people take the "Pepsi Challenge."

Attachment IV-F

Questions and Answers

About

Human Subject Protection

At

American University

The Institutional Review Board
for the
Protection of Human Subjects
American University

Revised 1991

TABLE OF CONTENTS

TABLE OF CONTENTS (Continued)

Questions and Answers About Human Subject Protection at American University was compiled by the AU IRB. This publication is based on 45 CFR 46, "Protection of Human Subjects" and American University revisions to 45 CFR 46.

August 1991 revision

INTRODUCTION

All research involving human subjects that is done at American University or on behalf of the University is subject to review. The review of this research is based on 45 CFR 46,
Protection of Human Subjects, as amended by American University. Each teaching unit and pertinent administrative unit has copies of this regulation, as amended. In general, proposals for funded research involving human subjects, for university research questionnaires, and for all research involving a "fee for service" component is reviewed by the University Institutional Review Board. Proposals for unfunded research are reviewed at the teaching or administrative unit level.

This booklet is designed to help faculty and staff comply with the human subject research regulations and, in particular, to assist personnel at the teaching unit or administrative unit level who will be taking responsibility for human subject review for nonfunded research. The information in the booklet will help answer the following basic questions:

What is the University Institutional Review Board; who serves on the Board?

How is "Research with Human Subjects" defined?

When are research proposals involving human subjects reviewed by the University Institutional Review Board, and when are they reviewed by the Unit Designee?

What is an exemption from IRB review; who decides?

How can the Unit IRB Designee function effectively?

Where can the Unit IRB Designee get assistance?

Do classroom projects involving human subjects need to be reviewed; under what conditions?

Who reviews questionnaires which will use a campus-wide population as subjects; who reviews research in which there is a "fee for service" component?

How can I help researchers determine what constitutes risks and safeguard?

What is an informed consent; when is it needed; and what type of information should be in an informed consent?

How can I assure maximum confidentiality of sensitive data involving human subjects?

In the age of computerization, how can I be sure that research data entered about human subjects can be protected?

BASIC QUESTIONS ABOUT THE INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS

1. WHAT IS THE IRB?

The Institutional Review Board (IRB) has the responsibility within our University to carry out the regulations (45 CFR 46) which the Department of Health and Human Services (HHS) has developed to protect human subjects involved in research conducted by persons affiliated with American University (staff, students, or faculty), but apply to all research done under the auspices of any federal agency. In addition, American University has adopted 45 CFR 46, with amendments, for use in assisting human subject protection in all research done under the auspices of the University. In doing this, AU is among approximately 70% of the U.S. colleges and universities which use these regulations as amended as a guide to AU review of research involving human subjects.

2. OBJECTIVES?

In general, the IRB:

* Reviews proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas.
* In order for the research to be approved, it must be accepted by a majority of those members present at the meeting.
* Reviews and has the authority to approve, require modifications in, or disapprove all research activities covered by regulations on Protection of Human Subjects.
* Requires that information given subjects as part of the informed consent is in compliance with the regulations and may require that additional information be included in order to assure the protection of subjects.
* Notifies investigators and the institutions/agencies in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. In the case of disapproval, reasons for this disapproval must be given to the investigator in writing and the investigator must be given an opportunity to respond in writing or in person.
* Conducts continuing reviews (not less than once per year), and has the authority to observe or have a third party observe the consent process and the research.
* Is responsible for reporting to institutional officials and sponsoring agencies any serious or continuing noncompliance by investigators with the requirements and determinations made by the IRB.

3. WHO ARE THE MEMBERS OF THE IRB? HOW IS IT CONSTITUTED?

* IRB membership is specified in 45 CFR 46, Protection of Human Subjects.

* Each IRB must have at least five members with varying backgrounds to promote complete and adequate review of research activities conducted by the institution.

* No IRB may be composed entirely of men or entirely of women, or entirely of members of one profession.

* Each IRB must have one member whose primary concerns are nonscientific; for example, lawyers, members of the clergy, ethicist.

* Each IRB must include at least one member who is not affiliated with the institution (a community member). This member cannot be related to a person who is affiliated with the institution. The presence of the community member is a prerequisite for certain Board actions.

* An IRB may invite individuals with specific expertise to assist in the review of complex proposals which require special knowledge beyond that represented on the Board; however, this person(s) cannot participate in the voting.

* The IRB operates within the Office of Sponsored Programs (OSP), Nebraska Hall, Room 105, x3440. A list of current IRB members and a list of Unit Designees can be obtained by contacting the University Compliance Administrator in OSP. Information can also be obtained through the department chairs or directors of the various units.

* All members are appointed by the University Provost. Members of the University faculty who have interest in serving on the IRB should notify the Provost.

4. HOW OFTEN DOES THE IRB MEET?

The University IRB meets at least once per month and often twice monthly during the academic year. In addition, if there are unexpected proposal deadlines, the IRB tries to accommodate the research with emergency meetings.

DEFINITIONS

1. HOW IS "RESEARCH WITH HUMAN SUBJECTS" DEFINED?

Two definitions contained in the regulations, augmented by some examples, should help answer this question.

RESEARCH means a systematic investigation designed to develop or contribute to generalized knowledge. Activities that meet this definition constitute "research" for the purpose of these regulations, whether or not they are supported or funded under a program which is considered research for other purposes. The definition in the regulations is a very broad definition and includes, for example, classical experiments, work involving questionnaires and field observations, and classroom demonstrations and experiments where students are used as subjects. In the case of surveys in classroom teaching, whether informal or formal, coverage can depend on the degree of sensitivity of the question(s) and whether responding is optional. For example, a professor might ask a question such as, "How many of you are Republicans?" Students can abstain from answering. However, if the professor asks each student individually about his/her political affiliation in the class setting, each student might feel pressure to respond. This type of survey might be used in teaching statistics' students how to construct frequency tables.

HUMAN SUBJECT means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. "Intervention" includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occur in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Examples of human subjects include the classic subject who receives a fee or services for participation, the person to whom a questionnaire is administered, the living person about whom historical research is undertaken, and the student in the classroom where experiments with new technology are taking place.

2. DO THE HHS REGULATIONS DEFINE ADDITIONAL PROTECTIONS? DO THEY APPLY TO OUR UNIVERSITY?

* Yes, there are additional protections defined and explained in the January 26, 1981 and the March 8, 1983 revisions of the regulations. They are as follows:

* Subpart B concerns additional protection for research, development and related activities involving fetuses, pregnant women, and human in vitro fertilization.

* Subpart C concerns additional protections applicable to biomedical and behavioral research involving prisoners as subjects.

* Subpart D concerns additional protections for children involved as subjects of research.

Any research proposed by person affiliated with American University involving pregnant women, fetuses, prisoners, and minor children must comply with these regulations in order to receive IRB approval.

GENERAL PROCEDURES

1. WHEN DO RESEARCH PROPOSALS HAVE TO BE REVIEWED BY THE UNIVERSITY IRB; WHEN DO THEY HAVE TO BE REVIEWED BY THE DEPARTMENTAL OR SCHOOL IRB?

All research involving human subjects must be reviewed at the departmental or university level. Proposals for funded research, including "fee for service" research, involving human subjects are reviewed by the University Institutional Review Board. Proposals for nonfunded research are reviewed at the unit level. If the departmental reviewer and/or committee have questions about the protection of human subjects in a specific proposal or, if for any reason, the departmental designee feels he/she cannot handle a specific research project, that person can consult with the IRB or refer the proposal to the IRB.

2. WHAT IS THE PROCESS FOR AN EXEMPTION? DO INDIVIDUAL RESEARCHERS DECIDE? OR, MUST THE DECISION COME FROM THE DEPARTMENTAL DESIGNEE OR THE UNIVERSITY IRB?

The most important fact to remember in this series of questions is that the decision is not made by the individual researcher. Research proposals must be evaluated by either the unit process or the University IRB in order to reach a decision as to whether the research can be categorized as exempt. If the research is categorized as exempt, it may not have to go through a detailed review and may not be subject to the use of consent forms.

3. HOW DO THE UNIVERSITY'S REGULATIONS VARY FROM 45 CFR 46? WHY DID THE UNIVERSITY DECIDE TO USE MORE STRINGENT REGULATIONS?

The difference is in section 46.101(b)(3) and 46.101(b)(4) and American University's amendments are somewhat more stringent. Copies of 45 CFR 46 distributed by the IRB contain these revisions.

The University administration determined that although the 1981 regulations were generally an improvement, they went too far in providing large-scale exemptions from human subject protection and review. Therefore, the above revisions in those regulations were adopted to govern American University research. Over 75 percent of U.S. universities and colleges also adopted the more

stringent regulations. These revisions are particularly pertinent for survey and participant observer studies.

4. WHAT ABOUT QUESTIONNAIRES WHICH GO OUT FROM THE UNIVERSITY (OR WITHIN THE UNIVERSITY)? HOW ARE THEY REVIEWED? SHOULD THEY BE REVIEWED? ARE THEY COVERED UNDER THE UNIVERSITY'S REGULATIONS ON HUMAN SUBJECTS RESEARCH?

All research within the University is reviewable. This includes survey research such as questionnaires sent to faculty and staff, as well as questionnaires eliciting information from enrolled students, accepted students who chose not to attend the University, alumni, and the like. The University IRB should review these questionnaires. It is expected that some survey research will be exempt from detailed review under the regulations adopted by the University in 1983; however, in order to determine whether a particular proposal for survey research can be classified as exempt, the IRB or the Unit Designee must consider the characteristics of that research. The exemption decision is not made by the researcher.

Surveys which involve students of the University are also provided to the Office of the Student Services for review.

5. CAN THE IRB OR THE DEPARTMENTAL DESIGNEE SUSPEND OR TERMINATE APPROVAL OF RESEARCH?

Yes, that is one of their main functions. Section 46.108© states that the IRB shall "be responsible for reporting to the appropriate institutional officials and the Secretary any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB."

Furthermore, section 46.113, "Suspension or Termination of IRB Approval of Research," states, "An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the Investigator, appropriate institutional officials, and the Secretary."

The IRB has a procedure for follow-up on research projects, and it is suggested the departmental designees also have some type of system to follow research in order to determine whether the conditions of the review are being met. One way of accomplishing this is to ask that the researcher submit a brief report in writing during the process of research.

6. HOW CAN THE HUMAN SUBJECTS DESIGNEE OR THE IRB REQUIRE AN INFORMED CONSENT IF THE RESEARCH PLAN IS NOT SPECIFIC AT THE TIME OF THE PROPOSAL SUBMISSION? DOES THE RESEARCHER HAVE TO PRESENT HIS/HER PROPOSAL FOR INFORMED CONSENT AT A LATER DATE?

The IRB or its unit counterpart can (1) require that the research plan be more fully developed to the extent that approval can be granted, or (2) a "first-phase" approval can be given with the condition that no research which involves human subjects be started until the research plan (including the experimental design) is completed, questionnaires and informed consent are developed, and specific terms of informed consent and any other information needed is submitted to the Board or designee.

If Option 2 is used, the researcher should be informed, in writing, that no research with human subjects can proceed until full approval is granted.

7. IF THE RESEARCHER IS WORKING THROUGH ANOTHER INSTITUTION (FOR EXAMPLE, THE D.C. SCHOOLS), IS THAT RESEARCHER STILL REQUIRED TO SUBMIT RESEARCH PROPOSALS TO THE APPROPRIATE PERSON OR COMMITTEE AT THE UNIVERSITY?

Yes, however, there can be different arrangements. For example:

(1) Cooperative research. "Cooperative research projects involve institutions in addition to the grantee or prime contractor. In such instances, the grantee or prime contractor remains responsible for safeguarding the rights and welfare of human subjects. Also, when cooperating institutions conduct some or all of the research involving some or all of these subjects, each cooperating institution shall comply with these regulations ... In complying with these regulations institutions may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort."

(2) Research where the investigator is using subjects within another institutional setting; e.g., a doctoral student is doing a survey with students in the District of Columbia Public Schools, or a researcher is working with subjects who are employed by the Montgomery County government. Each of these institutions usually has a procedure for research approval and informed consent. This approval should be obtained and submitted to the IRB or the unit designee.

8. WHAT ARE THE PROCEDURES FOR GETTING APPROVAL FOR USING HUMAN SUBJECTS IN RESEARCH INVOLVING MEDIA, PHOTOGRAPHY, AND THE LIKE?

The procedure is the same as in studies involving other types of research tools. If there is something about the nature of what is being photographed, for example, which is potentially controversial and if the subjects are identifiable, then there is a problem and there ought to be consent obtained if any intention exists to make use of the material. The mere taking of photographs in connection with a public activity is not a matter of concern so long as those photographs are being taken in public places. Of concern, however are the various uses to which those photographs may be put and where they may be published or publicized. In cases where photographs or other media records are to be redisseminated, potential human subjects problems may arise. The designee should review the project to see if the subject might be put at risk. If so,

the informed consent procedure should be used. It is a good idea to think ahead when using photography or other forms of media; if publication is a possibility, then it would be a good idea to get an informed consent at the time for the photography. Of course, if a researcher is using photography or other media in a private setting, then the situation calls for review.

9. WHAT HUMAN SUBJECTS' STANDARDS DO WE USE FOR RESEARCH WHICH IS BEING DONE OVERSEAS - OUR STANDARDS, THE COUNTRYS' STANDARDS, OR BOTH?

The Department of Defense in 32 CPR Part 219, "Protection of Human Subjects in Department of Defense Supported Research," states in 219.4(1) (4) (1), "In research conducted outside the United States involving non-U.S. citizens as human subjects, the laws, customs, and the practices of the country in which the research is conducted, or those required by this rule, whichever is more stringent, shall take precedence. The research shall meet the same standards of ethics and safety that apply to research conducted within the Untied States involving U.S. citizens." It is the position of the IRB that this regulation should be used at American University. One implication of this procedure for anyone who is anticipating doing research overseas, especially in non-western cultural settings, is that the researcher has to ascertain whether members of that culture have any group sensitivities in respect to the proposed research activities. These should be discussed in the human subjects section of this proposal.

DEPARTMENTAL HUMAN SUBJECTS PROCEDURES

1. HOW DO YOU SUGGEST THAT I FUNCTION AS A DEPARTMENTAL HUMAN SUBJECTS' DESIGNEE? HOW DO I DETERMINE COMPLIANCE WITH THE REGUIATIONS; I.E., WHAT SHOULD I DO IF KNOW THAT SOMEONE IS DOING RESEARCH INVOLVING HUMAN SUBJECTS, BUT THE PROPOSAL HAS NOT BEEN REVIEWED? ARE THERE UNIVERSITY RESOURCES TO HELP ME WITH THIS TASK? WHEN SHOULD I REFER PROPOSALS TO THE UNIVERSITY IRB?

* You may find that you can be more effective as a Unit Human Subject's designee by using some of the following suggestions:

* Be sure that it is officially announced, in writing, that you are the human subjects designee for your unit.

* Explain your function at your department/school/unit's next meeting.

* Use handouts to further explain the responsibilities which researchers whose studies involve human subjects have for review of their research proposals.

* Have handouts available that further explain specifics, such as the contents and informed consent, etc.

* Routinely inform persons in your unit who supervise graduate student theses/dissertations about the requirements for human subjects review.

What do I do if I know that someone is doing research involving human subjects, but the proposal has not been reviewed? The University has a policy which states that all research involving human subjects must be reviewed at either the departmental or University level. With that in mind, probably the first step is discussing this policy with the person doing the research and hoping that the person will then go through the human subjects procedure. Secondly, if this does not work, discussing next steps with the unit chairperson, or with the University IRB would be advisable.

Are there University resources to help me with this task? Yes, human and material. The Compliance Administrator in OSP has the forms which are needed to review research. In addition, copies of the regulation, 45 CFR 46, are also available from OSP. Members of the University IRB and the Compliance Administrator are also willing to help unit designees with problems or interpretations of parts of the 45CFR 46 regulations.

In addition, periodic training sessions are provided for new unit designees and experienced designees who would like to review their responsibilities.

When should I refer proposals to the University IRB? When the funding for the research is from a source external to the University, or, if the project is of such a complex nature that the unit designee feels that an additional opinion is necessary.

2. ARE THERE CLASSROOM PROJECTS WHICH MIGHT REQUIRE REVIEW BY THE DEPARTMENTAL DESIGNEE? INTERN PROJECTS?

Classroom Projects: The issue is whether students are at risk. Routine experiments with new forms of classroom teaching are usually exempt, but there may be other situations where students could be at risk in connection with classroom activities. Some examples are:

* When demonstration experiments are performed in the classroom using students as subjects.

* When survey information is collected from students in a classroom setting.

* When students are subjected to any form of non-educational testing in the classroom such as psychological testing or blood testing.

If these activities are occurring in your area, it would be appropriate for the unit designee to conduct a review to determine whether and to what extent students will be at risk.

Intern or Cooperative Education Projects: These projects are subject to review if they involve student-initiated research involving human subjects. Student involvement in these projects is usually in one

of the following two situations. One would be when the student is placed in a setting where there is basically no ongoing research, but the student performs research of his/her own, for example, survey research. That type of research, if it involves human subjects, is reviewable at the student's department. The other situation is where a student is an intern or a cooperating student and is placed in an agency where there is ongoing research. That type of research should be reviewed by the institution employing the student. The department interacting with that institution should determine whether a proper review has taken place. For example, one inquiry per year to ascertain whether there is adequate human subject protection ought to be enough when a department has continuing relationship with an institution or agency. This is especially important when a student is working under a college credit arrangement.

3. WHAT ABOUT GRADUATE STUDENT RESEARCH OR DISSERTATION RESEARCH? IS THERE A PROCESS THROUGH WHICH EACH STUDENT GOES TO DETERMINE WHETHER OR NOT THAT STUDENT HAS SATISFIED THE HUMAN SUBJECT REVIEW PROCESS?

The University catalog and the graduate student guide both contain sections about review requirements for research involving human subjects. Any graduate research involving human subjects must be reviewed by the departmental/school unit designee and approved before there can be any involvement with human subjects.

4. IS THERE A STANDARD UNIVERSITY FORM FOR USE IN REVIEWING RESEARCH INVOLVING HUMAN SUBJECTS?

Yes, The IRB "Research Proposal Review" form. Some departments have developed their own human subjects' review form. If you have a large quantity of research involving human subjects, your unit might want to do this also.

5. TO WHOM DOES THE UNIT DESIGNEE REPORT RESEARCH WHICH HAS BEEN REVIEWED AND THE ACTIONS TAKEN ON IT?

The person who will be doing the research with human subjects should complete the form and submit it to the IRB or the unit designee with a copy of the proposed research. When the proposal is approved by the unit designee, copies should be provided to the IRB office in OSP, Nebraska Hall; the researcher; and the unit's administrative office; and one should be retained by the unit designee's office.

INFORMED CONSENT

1. WHAT IS INFORMED CONSENT?

Informed consent means the "knowing" consent of an individual or that individual's legally authorized representative. Informed consent embodies the following concepts:

* This consent must be sought only under circumstances where the individual has sufficient opportunity to consider participation.

* There should be no undue coercion, force, or influence.

* The informed consent must be in language that can be understood by the subject.

* The informed consent can contain no language through which the subject is made to waive or appears to waive any legal rights and no language that releases the investigator, sponsor, or institution from liability for negligence.

Additional information regarding the informed consent process can be obtained from the University Compliance Administrator or the unit designees.

2. WHERE IS INFORMED CONSENT NEEDED? ARE THERE EXCEPTIONS?

Informed consent is needed in all research with human subjects unless there is a waiver by the IRB or the unit designee under 46.117 © (1) (2). The situations under which informed consent may be waive able are (1) when the risk is minimal, and (2) when the informed consent would do more harm than good. Although most of the time the informed consent is in written form, there is also a possibility of oral informed consent in some research studies. See sections 46.116 and 46.117 for additional information.

Minimal risk means that the "risks of harm anticipated in the proposed research are not greater... than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

3. WHAT SHOULD BE CONTAINED IN AN INFORMED CONSENT?

Some basic components of an informed consent follow; additional information can be obtained by reading section 46.116 of the 45 CFR 46 Regulation, Protection of Human Subjects.

1. A statement that the study involves research, an explanation of the purposes of the research, length of the subject's participation, description of the procedures to be followed, and identification of any procedures which are experimental.

2. A description of any reasonable foreseeable risks or discomforts to the subject.

3. A description of any benefits to the subject or to others as a result of this research.

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. (This is particularly relevant for biomedical research)

5. A statement describing the safeguards which will be used to minimize risks disclosed, including, where relevant, a statement describing the extent to which confidentiality or records which have the potential for subject identification will be maintained.

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs, and, if so, what they consist of, or where further information may be obtained. (Again, this is especially appropriate for biomedical research.)

7. Names, addresses, telephone numbers of persons who the subject may contact for answers to pertinent questions about the research and the research subject's rights, and whom to contact in the event of a research-related injury. This could be to departmental or unit chairperson, the departmental human subjects designee, the IRB chairperson, or, in the case of a graduate student, his/her thesis advisor.

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

4. ARE THERE EXAMPLES OF INFORMED CONSENT THAT I COULD USE?

Yes, the University Compliance Administrator and the unit designees have examples.

5. WHAT PROCEDURES SHOULD RESEARCHERS USE FOR INFORMED CONSENT FOR MINORS?

The March 8, 1983, revisions of 45 CFR 46, Protection of Human Subjects, add to the requirement of permission by parents and guardians, the requirement of assent by the child who will be involved in the research. "The IRB shall determine that adequate provisions are made for soliciting the assent to the child (children) when in the judgment of the IRB the children are capable of providing assent." The IRB shall take into account the children's:

`

* Ages
* Maturity
* Psychological state

RISKS AND SAFEGUARDS

1. HOW IS RISK DEFINED? WHAT ARE THE CLASSIFICATIONS OF RISK? HOW CAN WE BEST DEAL WITH THESE RISKS?

There are three major kinds of risk: (1) the risk of physical harm, (2) the risk of psychological harm in connection with either the process of the experiment or the results of the experiment, and (3) the possibility of various types of environmental harm ranging from economics, such as loss of job or job prospects, to social, such as ostracism from a group, as well as other harms which are peculiar to the subject's particular situation. The subject of risk must be defined broadly rather than in a narrow fashion. Even if the probability of risk occurring is low, it does not mean that it can be excluded from consideration and hence from human subject's review.

The best way to deal with risk is by carefully defining each risk and developing appropriate safeguards to minimize them.

2. HOW DOES ONE BEST GO ABOUT ASSURING ANONYMITY?

An example of a possible risk which is often noted in research reviewed at American University is the potential for breach of confidentiality. Therefore, it is important to be able to develop safeguards that minimize this risk. One of the best ways of minimizing this risk is by developing safeguards that will help anonymity.

The assurance of anonymity can be handled in three ways, (1) by gathering as little identifying information as possible, consistent with the research methodology, (2) by keeping the information secure, and (3) by destroying the raw data which includes the information traceable to individuals, at the earliest possible time consistent with the methodology. If for any reason it is necessary to store the raw data for any longer period of time, then it will be necessary to use a form of maximum security for the data such as a safe or safety deposit box. In assuring security of data, the researcher should keep the number of persons handling the information to a minimum, code data to the greatest degree possible, and keep coding keys and master lists under lock and key.

It is important to remember that anonymity is not just a concern when one is collecting names. Anonymity is an obvious problem in any situation where the names of subjects are known and the information being collected about them is sensitive. However, anonymity can also be a problem in a study where no names are collected if the demographic data being collected is significantly detailed and the group from whom it is being collected is relatively small.

3. CAN CASE STUDY RESEARCH BE USED AND STILL HAVE ANONYMITY ASSURED?

It is important to note that the regulations do not rule out any type of methodology. If sufficient numbers of transformations are performed with the nonsignificant demographic indicators relating

to the subjects, case study research can probably be used. This always involves judgment on the part of the researcher in determining what degree of transformation is required. Of course the name of the subject should never be used. In addition, the more sensitive the information, the more one may wish to make such transformations; e.g., change the geographic area, change the economic level, change the physical description, etc.

4. WHAT SAFEGUARDS SHOULD BE USED FOR RESPONDENT CONFIDENTIALITY WHEN SOME TYPE OF FOLLOW-UP MAY BE NECESSARY OR IN THE REALM OF POSSIBILITY?

The essential data and the codes must be kept in a highly secure place. This would not be just a locked file cabinet; it would require a safety deposit box or safe. In cases of extremely sensitive data that must be retained for longitudinal study purposes, the IRB can petition to use secure storage in the Bender University Archives.

5. ARE THERE ADDITIONAL RISKS WHEN RESPONSES AND/OR DATA FROM HUMAN SUBJECTS ARE COMPUTERIZED? SHOULD ADDITIONAL SAFEGUARDS BE EMPLOYED?

The use of computerized data banks to store data and the use of computer programs to analyze data gathered about human subjects pose some special risks, but also present some special opportunities for creating new safeguards. The risks exist mainly because the computer can be used not only to store data, but also to recover information about the demographic characteristics of the individual respondents and the sensitive information that the individual respondents may have provided the researcher. There may be a risk of unauthorized person gaining access to these files unless precautions are carefully followed.

The following can help to minimize the risks:

Under no circumstances should any master code list which contains names of subjects be entered into the computers.

Researchers should be careful not to collect irrelevant demographic information which could be sensitive and could be retrieved.

Researchers should check out the possibility of use of a random number generator which can serve to provide further assurance of anonymity, and they should always use a password which is known only to them and is changed regularly.

Other suggestions for safeguards can be obtained from specialists at American University's computer center.

Attachment IV-G

PROTOCOL FORM
for use at
The American University

INSTRUCTIONS FOR COMPLETING "PROTOCOL FOR USE OF LIVE VERTEBRATES"

(Submit completed Protocol Form to the Office of Sponsored Programs, Nebraska Hall - Room 105, x3440)

Federal regulations require that all uses of living vertebrates within the university be reviewed for their appropriateness by the Institutional Animal Care and Use Committee (IACUC).

An additional application of these protocols is to permit identification of each individual animal with its proper protocol at the request of an inspector. Similar procedures conducted on different species associated with the same study may be listed on one protocol provided all animal species are documented; however, if completely different procedures are to be conducted on groups of animals in a related study, then a separate explanation should be submitted for each procedure. These separate explanations can be paragraphs attached to the original protocol.

The information provided via this Protocol Form will be reviewed by the IACUC, including a non-scientist; every attempt should be made to use terminology understandable to a lay person. The completed Protocol Form will be held on file as a current protocol until the project is terminated, the course is discontinued, or the use is revised and new approval is obtained. The effective time period is for the ensuing twelve months.

> ***Protocols must stand on their own merit. Protocols once submitted are public documents and available through the Freedom of Information Act. In order to project an image of competence and knowledge, it is essential the document be well written from both a scientific and grammatical standpoint. Many items are taken out of context by the media. It is wise to carefully read and edit the document to remove or replace verbiage that may be confusing, contradicting, or troublesome when read by the nonscientific general public.***

Experiments Involving Pain and/or Distress

A major concern of the reviewers of these protocols is the degree of pain and/or distress imposed on the animals in the studies, and the methods the investigators will use to prevent, relieve, or minimize any suffering.

The American Physiology Society ("Animal Pain: Perception and Alleviation." Kitchell, R.L., Erickson, H.H., Carstens, E. and Davis, L.E., editors. Am. Physiol. Soc., 1983, Williams and Wilkins, Baltimore) has defined stimuli as painful to animals if those stimuli:

a) are detected as pain in humans,
b) approach or exceed tissue damaging proportions, or
c) produce escape behavior in animals.

Following is a partial list of procedures known possibly to involve significant pain and/or distress:

1. Surgery, including biopsy and gonadectomy
2. Burning, freezing, branding
3. Fracturing bones
4. Electrical shocks, including shock reinforcement
5. Injection of any agent which induces excessive inflammation or neurosis, e.g.: Bradykinin, Freund's complete adjuvant, certain infectious agents
6. LD-50 Determinations
7. Neurophysiological preparations
8. Chair or stock restraint of unadapted animals, or restraint of any animal for more than 12 hours
9. Skin or corneal corrosivity testing
10. Drug or radiation toxicity testing
11. Intracerebral or intracardiac inoculations
12. Intracardiac or periorbital blood collection
13. Application of noxious stimuli without escape
14. Induction of psychotic behavior
15. Natural or experimental diseases
16. Moderate to severe malnutrition
17. Procedures that result in chronic function deficit
18. Cage restraint of wild-caught animals
19. Imposition of abnormal environmental conditions

If you plan to conduct studies which employ one or more of these procedures, or another procedure which in your estimation also involves significant pain and/or distress, the animal must be given appropriate anesthetics or analgesics to prevent or alleviate pain (tranquilizers for distress) and Box 14b on page 3 of the Protocol Form must be checked.

If the nature of the study prohibits the use of pain- and/or stress-relieving drugs, or if unavoidable and unalleviable pain or distress will be produced, you are requested to check Box 14c on page 3 of the Protocol Form, and provide a written justification in Section C3 on page 4. The justification must include factual data and not be limited to statements of "belief."

In the event that a procedure will be employed which may eventually cause death preceded by pain and/or distress (e.g., studies of disease, hybridoma studies), the investigator must state the methods to be

Please note that procedures associated with minor pain and/or distress (e.g., administration of anesthetics, analgesics, fluids, immunizations, oral medications, short-term catheterization, gastric lavages, venipunctures) do not necessitate a written justification; just check Box 14a on page 3 of the Protocol Form.

Experiments Involving Major Survival Surgery

"Major surgery" is defined here as any surgical intervention that penetrates and exposes a body cavity, or any procedure which produces permanent impairment of physical or physiological functions. "Survival surgery" means that the animal will awaken from the anesthesia (in non-survival surgery, euthanasia is done before recovery from anesthesia). Aseptic technique should be used on all animals that undergo major survival surgery.

If you are doing major survival surgery in your studies, please indicate in Section B7 and 8 on page 2 of the Protocol Form all of the following information:

1. The procedures to be undertaken (describe fully);
2. The surgeon/anesthetist's name and qualifications;
3. The location of the facility (building, room number) where surgery will be done;
4. Drugs to be used for pre-anesthesia and anesthesia, and their dose rates;
5. Provisions for post-surgical care of the animals; and
6. Drugs to be used to alleviate post-surgical pain or distress, and their dose rates.

Justify any chronic functional deficit and ensuing distress that may result from the surgery in Section C3 on page 4 of the Protocol Form. Indicate how any such distress will be minimized in Section C4.

Please note that the IACUC discourages the use of multiple major survival surgical procedures on a single animal except in special circumstances (cost alone is not an adequate reason for performing multiple major survival surgical procedures). If you need to use a single animal for multiple major survival surgical procedures, please explain and justify in Section C3 on page 4 of the Protocol Form.

If non-survival surgery is the goal of the project, please describe in Section B7 and 8 on page 2 of the Protocol Form the procedure to be done and the drugs to be used, and the personnel responsible for surgery and anesthesia.

Experiments Involving Physical Restraint

Physical restraint of animals may cause distress and/or pain. To minimize any suffering, the period of restraint should be the minimum required to accomplish the research objectives, and the animals to be placed in restraint equipment should be conditioned to such equipment prior to initiation of the studies.

If a restraint device is to be used for continuous periods of more than 12 hours, Box 14C on page 3 of the Protocol Form should be checked and the procedures fully explained in Section B6 on page 2 and justified in Section C3 on page 4. Include the methods whereby you will monitor and evaluate each animal to minimize the degree of distress in Section C4 on page 4.

Experiments Involving Nutritional Distress

Nutritional distress is defined here as a level of malnutrition that significantly interferes with the normal physiology of the animal.

Fasting for up to 24 hours in most animals (48 hours for ruminants) is not considered to be significant nutritional stress, except in the case of neonates. Starvation for more than this period, or feeding a diet with nutrients or a nutrient below the recommended levels, may cause a degree of nutritional stress that varies widely with the extent of deprivation and the species involved.

It is the Committee's understanding that NO drug can abrogate the distress associated with fasting, replenishment of the diet being the only method of alleviation of the stress.

If significant nutritional restriction or nutritional distress is induced in your studies, please check Box 14c on page 3 of the Protocol Form, explain your study in Section B9 on page 3 and justify its rationale in Section C3 on page 4. Include the methods whereby you will monitor and evaluate each animal to minimize the degree of distress in Section C4 on page 4.

Experiments Involving Abnormal Environmental Conditions and/or Physical Facilities

Recommended ranges for environmental factors such as illumination, temperature, humidity and ventilation for common laboratory animals are given in the "Guide for the Care and Use of Laboratory Animals" (Revised Edition, 1985).

If your study makes it necessary to vary from these recommended environmental conditions, please indicate degree and duration of variations from normal for each factor in Sections B4 and 5 on page 2 of the Protocol Form, justify the rationale in Section C3 on page 4, and give methods by which distress will be minimized in Section C4 on page 4.

Experiments Involving Euthanasia

Please refer to the Report of the AVMA Panel on Euthanasia (J.A.V.M.A., 188 (3): 252-268, 1986) when selecting the actual method employed. (Each teaching unit and researcher has a copy of the AVMA Report.) Describe fully the method of euthanasia to be used in Section B12 on page 3 of the Protocol Form, and any drugs to be used in Section B8 on page 2. Euthanasia methods which deviate from those recommended by the AVMA must be justified in Section C3 on page 4.

PROTOCOL FOR USE OF LIVE VERTEBRATES FOR RESEARCH, TEACHING, OR DEMONSTRATION

American University

(Submit completed Protocol Form to the Office of Sponsored Programs, x3440)

IACUC PROTOCOL ID NUMBER: _____

A. Principal Investigator/Instructor

Title_____Campus Phone_____Home Phone

Department/Section_____College/Division

Area/Building where animals will be held_____

Principal person performing the work (if different from above)

Title_____Campus Phone_____Home Phone_____

Individual in charge of animal management_____

Project Funding Agency (if applicable)_____Course No._____

Specific Experiment, Project, or Course Name

Check one:

_____Initial Review
_____Continuation, no change* --> Sign and date here
_____Continuation with revisions

*Submit this sheet only; no need to rewrite abstract or rationale.

Study, Objectives, and Rationale: Briefly describe in non-technical language the objectives of the study, and the rationale for animal use. Use additional sheets if necessary.

Describe the experimental design in general terms as it relates to the number of animals indicated in Part B. Specify all animal procedures to be used. Include inoculation (sites, substances, dosages, and schedules),

blood withdrawal (volume, frequency, and withdrawal sites), radiation (dosages and schedule), and methods of restraint. State what resultant effects, if any, the animals are expected to experience. Experimental endpoint criteria (i.e., tumor size, percentage body weight gain or loss, inability to eat or drink, clinical symptomatology, or signs of toxicity) must be specified when the administration of tumor cells, biologic, infectious agents, radiation, or toxic chemicals are expected to cause significant symptomatology or are potentially lethal. Use additional sheets if necessary.

B. Describe here the experimental animals and the nature of their use. (No justification for the use of animals is necessary in this section.)

1. Animal Data:

	Species	Sex	Age/Weight	Number*
a.				
b.				
c.				

*Number = Total number to be in residence at any one time

2. Source (e.g., purchased [give name of vendor], institutional bred, transferred from another study, donated, captured from wild):

3. Housing conditions (cage or tank size, room, facility, etc.):

4. Duration of the study, specifically the period during which animals may suffer any pain and/or distress:

5. Any abnormal environmental conditions that may be imposed (see instructions):

6. Any restraint devices that may be employed (see instructions):

7. Any surgical procedures to be carried out (see instructions):

   Is this survival surgery? Yes___ No

8. Any drugs or controlled substances to be used and their dose rates:

9. Any studies that may result in nutritional restriction or distress (see instructions):

10. Will transplantable tumors or hybridoma cells be injected into animals? Yes___ No
If so, have they been tested for inadvertent contamination by viruses?

11. Will any human or animal pathogens be used in these studies? Yes___ No
If so, describe how these agents will be contained.

12. Methods of euthanasia (see instructions):

13. Final disposition of animal if other than euthanasia (e.g., transfer to another study, kept for natural life span):

14. Degree of pain and/or distress imposed. Check one or more as appropriate (see instructions):

    a. ___The experiments involve minor or no pain and/or distress.

    b. ___Appropriate drugs will be administered, or other methods will be used, to prevent or relieve any significant pain and/or distress.

    c. ___These experiments involve significant pain and/or distress; either no method is available for avoiding or alleviating the pain and/or distress, or else appropriate drugs will interfere with the study.

    If animals are listed in 14c, a written scientific justification is required to explain why the pain or distress is unavoidable (justify in part C3).

15. Describe any other procedures to be undertaken in your studies not already mentioned above:

16. Does this project or procedure have as its sole purpose the instructing or training of inexperienced personnel? Yes___ No
If so, please explain.

C. Justification for use of living vertebrates (provide sufficient information to enable an informed review)

1. State briefly why living animals are required for this study, rather than some alternative model. Provide a description of the methods and sources (e.g., the Animal Welfare Information Center) used to determine that alternatives are not available:

2. Justify the number of animals relative to intended use (e.g., individual instruction of students, extent of between-animal variation, etc.):

3. Justify use of any specific procedures or conditions as indicated in Section B5 through 15. Label (B5, B9, etc.), and use the reverse side if necessary:

4. Describe any steps to be taken to monitor potential or overt pain and/or distress during the course of this study, and how it will be alleviated:

D. Potential hazards to humans from animal studies

1. If radioisotopes are to be used, researcher has received University Radiation Safety Subcommittee approval on:

   Yes___ No___ If yes, date:

2. If carcinogens, mutagens, infectious agents, toxins, radioisotopes, tumor cells, etc., are used, has the university's Hazardous Materials Safety Committee or Radiation Safety Subcommittee been notified?

   Yes___ No___ If yes, date:

3. If controlled substances are used, do you have a DEA license? Yes___ No

4. List all TAU employees (including graduate assistants and other students) who are responsible for daily animal care on this project:

Name	Training? Yes	No	Needed	Date Last Physical Examination
a.				
b.				
c.				

I hereby certify that:

- the activities described herein do not unnecessarily duplicate previous experiments;
- I have attended an approved investigator-training course;
- the individuals working on the above project have received training in the appropriate techniques;
- I will inform the IACUC of any significant changes occurring in this project;
- I have considered the rationale for using animals, and the species and number is appropriate and necessary to accomplish this work;
- alternatives to animal use have been considered, that the standard data bases have been searched, and that no suitable alternatives exist;
- and that all information provided is true and correct to the best of my knowledge and belief.

Signature_____Date_____
(Faculty Member or other approved Principal Investigator)

DO NOT WRITE IN THIS SPACE (IACUC use only)

Date Received_____Action_____Date

/s/_____ /s/
Chair, IACUC Consulting Veterinarian

cc: College/Division
Principal Investigator and Professor in Charge
IACUC

THIS REVIEW IS MANDATED FOR THE PURPOSE OF DETERMINING COMPLIANCE WITH EXISTING GUIDELINES AND/OR REGULATIONS FOR REASONABLE AND PROPER USE OF LIVING ANIMALS

Attachment IV-H

PROCEDURES FOR ORDERING AND RECEIVING
RADIOACTIVE MATERIALS AT AMERICAN UNIVERSITY

Overview

All requirements for radioactive material for any activity at American University must be approved by the University Radiation Safety Officer and ordered through the Purchasing Office. Inbound shipments must be received by the Radiation Safety Officer, the Deputy Radiation Safety Officer, the Hazardous Materials Coordinator, or other authorized receiver, and will be released for delivery to the end user only after inspection by one of these authorized receivers. This procedure is intended to provide protection to those persons handling the material as well as to comply with other requirements of federal regulations on radioactive materials.

Requisitioning of Radioactive Material

All radioactive material will be ordered on a Special University Purchase Requisition marked with the Radioactive Material Trefoil (at right). The Purchase Requisition must be approved by the University Radiation Safety Officer before it is taken to Purchasing.

Ordering of Radioactive Material by Purchasing Department

Ordering will be accomplished in such a manner as to minimize risk of contamination to University personnel or facilities as well as to reduce liability. Buyers must adhere to the following guidelines.

- Orders must be placed on a Purchase Order basis.
- Vendors will be informed about University terms and conditions concerning proper packaging, marking, and shipping. Vendors will also be informed of the University policy on liability for damages if items are improperly packaged, marked, or shipped.
- Vendors will also be advised that orders require 24 hours advance notice for delivery, and must be made between 9:00 A.M. and 4:30 P.M. Monday through Friday.
- FOB terms will be DESTINATION.
- Radioactive material must be marked with the Radioactive Material Trefoil.
- The mail will not be used as a mode of transportation. Vendors will be directed to use package delivery services (e.g., UPS, Federal Express, etc.) or express air freight.
- Delivery location specified will be Central Receiving, and delivery will proceed as follows.
    - Deliverer must check in with Central Receiving.
    - Central Receiving will contact one of the following authorized receivers:
        -Radiation Safety Officer, or
        -Hazardous Materials Coordinator, or
        -For Hydrogen 3, Carbon 14, Phosphorus 32, or Sulfur 35, the investigator who is authorized to use the material
- Deliverer will redeliver to the authorized receiver who has been contacted.

Receipt of Radioactive Material
Upon delivery, the authorized receiver will inspect the package before signing any papers. If the package appears intact, the authorized receiver will sign for the item and accept delivery. Only the authorized receiver may remove radioactive material from the receiving area.

If there is moisture on the package, discoloration of the wrapping, or damage to any of the outer wrapping, the receiver will take the following steps:

- Do not sign, or take receipt of the item.
- Do not allow the deliverer to leave the premises.
- Follow the procedures outlined for emergency spills of the material in question.

Data Base Inventory Control
The College and University Financial System (CUFS) enables the Radiation Safety Officer to monitor all radioactive purchases and deliveries.

Additional Information

- Every user of radioactive materials must keep a ledger indicating their complete inventory, when it was used, and how and where it was disposed.
- If radioactive material is picked up by a researcher outside the laboratory, the laboratory must issue documentation. A copy of this documentation must be forwarded to the University Compliance Administrator in the Office of Sponsored Programs.
- Gifts of radioactive material are prohibited.

Authorized Receiver
Radiation Safety Officer
Professor Albert Cheh
Department of Chemistry
Beeghly 304
x1772 or x1750 (office)
Home: (301) 652 – 3299

Additional Numbers
Department of Biology x2194
Department of Chemistry x1750
Department of Physics x2745

Compliance Administrator
Office of Sponsored Programs
Nebraska Hall - Room 105
x3440