

OFFICE OF RESEARCH AND PROJECT ADMINISTRATION  
Updated January 2011

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MANUAL FOR RESEARCH AND  
SPONSORED ACTIVITIES

UNIVERSITY OF ROCHESTER

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## PURPOSE

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The purpose of the Manual is to provide assistance and guidance to faculty and staff with respect to the preparation of proposals and administration of sponsored programs. Primarily, this Manual:

- defines the responsibilities of Principal Investigators and project directors for the preparation, review, management and reporting requirements of sponsored programs;
- emphasizes the necessity for uniform and consistent financial accountability and documentation in proposal budgets;
- defines the University of Rochester's criteria for acceptance of sponsored program awards;
- discusses the various regulatory compliance requirements prior to the acceptance of sponsored program funding.

Throughout the Manual, references to other University policies and procedures relevant to the academic and research conduct of investigators and faculty are cited. All faculty should be familiar with the *Faculty Handbook* and in particular, Medical Center faculty should be familiar with the School of Medicine and Dentistry's *Regulations of the Faculty*. Principal investigators and administrators of sponsored program accounts should also refer to the University *Finance Manual*, *Office of Human Resources Personnel Policies* and *Purchasing Guide*.

## REVISIONS

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As sections are updated, or new sections are added, we will announce revisions to the Manual on our list serve, ORPA-L. Suggestions for revisions and corrections may be sent to [resadmin@orpa.rochester.edu](mailto:resadmin@orpa.rochester.edu).

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## CONTACT INFORMATION

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# INTRODUCTION

## 1.1 Overview

Sponsored programs are an essential activity in support of the University of Rochester's research and academic missions. Other than hospital and faculty practice patient care revenues, the single largest revenue source for the University is from sponsored programs and its largest source of research support comes from the federal government. With this revenue stream comes ever-increasing regulatory responsibilities and accountability. The ORPA Manual attempts to consolidate University practices and cites policies vital to the stewardship of our sponsored program funding. It is critical that research investigators and administrators be aware of University policies and procedures in order to meet their individual responsibilities and permit the University to uphold its commitments.

## 1.2 Purpose of Handbook:

The purpose of the *Manual* is to provide assistance and guidance to faculty and staff with respect to the preparation of proposals and administration of sponsored program awards. Primarily, this *Manual*:

- defines the responsibilities of Principal Investigators and project directors for the preparation, review, management and reporting requirements of sponsored projects;
- emphasizes the necessity for uniform and consistent financial accountability and documentation in proposal budgets;
- defines the University of Rochester's criteria for acceptance of sponsored program awards;
- discusses the various regulatory compliance requirements prior to the acceptance of sponsored program funding.

Throughout the *Manual*, references to other University policies and procedures relevant to the academic and research conduct of investigators and faculty are cited. In particular, University faculty should be familiar with the *Faculty Handbook*; Medical Center faculty should be knowledgeable with the School of Medicine and Dentistry's *Regulations of the Faculty*. Both Principal Investigators and administrators of sponsored program accounts should have and refer to the University *Finance Manual*, *Personnel Policies and the Procedures Manual* and *Purchasing Guide*.

## 1.3 Federal Principles

University sponsored program policies and procedures are written to conform to the various federal policies that apply to federal funding at non-profit educational institutions. Cost accounting principles for higher education are established by the federal Office of Management and Budget (OMB). The OMB circulars that are most relevant to universities include:

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- *OMB Circular A-21: Cost Principles for Educational Institutions.* This circular establishes principles for determining direct and indirect costs applicable to grants, contracts and other agreements with educational institutions.
- *OMB Circular A-110: Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals and other Non-Profit Organizations.* This circular sets forth the maximum administrative requirements that educational institutions must adhere to. Individual federal agencies are required to implement OMB Circular A-110 as individual agency regulations.
- *OMB Circular A-133: Audits of Institutions of Higher Education and Other Non-Profit Institutions.* This circular establishes audit requirements and defines federal responsibilities for implementation and monitoring such requirements for institutions of higher education receiving federal awards.

In addition, the ethical standards expected of faculty participating in federally sponsored programs, are dictated by other federal funding agency policies such as financial conflict of interest regulations and misconduct policies. Copies of the OMB Circulars and other relevant federal agency policies may be obtained from the Office of Research and Project Administration (ORPA) or found at the ORPA web site.

### 1.4 Ethical Conduct and Responsibilities

In accordance with federal policy, the University of Rochester has established its own policies that govern the ethical conduct of its research faculty. These policies are found in the *Faculty Handbook* and are summarized below.

#### Policy on Research Misconduct

As accepted by the Faculty Senate on March 19, 1985, the University has established a policy that demands that those engaged in research, whether faculty, staff or students, be dedicated to the highest ethical standards. Research misconduct by any member of the University threatens the University as well as the individual. This [Policy on Research Misconduct](#) defines the procedures to be taken in response to any allegation of research misconduct.

#### Note

There is a separate policy governing procedures taken in the instance of graduate student misconduct that may be obtained from the Office of University Council of Graduate Studies..

## Policy on Conflict of Interest

The University's [Faculty Policy on Conflict of Interest](#) addresses consulting, conflict of interest and commitment, and other relationships between University personnel and external individuals and organizations. As stated in the policy, the University relies on the integrity of its faculty and staff to avoid those external activities that may lead to real or perceived conflict of interest situations. The policy provides consideration points to assist both the individual and the University in determining the appropriateness of external involvement.

The policy also mandates the disclosure practices of the University. In summary, the University:

1. requires disclosure by faculty and staff of all outside remunerative and other activities that could be considered a conflict of interest related to their teaching, research and administrative activities;
2. requires Key Personnel (defined as faculty or others named on funding proposals as key individuals) to make annual disclosure of all outside remunerative and other activities related to their teaching, research or administrative activities.

### Important

It is a Department responsibility to ensure that all research faculty complete conflict of interest disclosure forms and participate in the annual disclosure process. Failure to adhere to and comply with federal regulation and/or University of Rochester policies can result in suspension or loss of grant funds, debarment, and civil or criminal charges and penalties.

## 1.5 Consulting Activity

The University's [Faculty Policy on Conflict of Interest](#) includes a published statement on outside consulting activities. The basic tenet of the University's policy on consulting is that consulting must enhance and not reduce the faculty member's service to the University, including those activities that are performed under sponsored agreements. In general, faculty are allowed to consult on average of one day per week. Consulting activity should be indicated as part of the faculty member's annual report of activities and may be required to be disclosed as part of the annual conflict of interest disclosure if payment for consulting activity from one organization exceeds \$10,000.

## 1.6 Research Administration Structure

The primary responsibilities for the policies, procedures and administration of sponsored programs are vested in the individuals listed below. Their various roles, activities and assistance in the research function of the University are as follows:

### Provost

The Provost is the first University officer and reports to the President. As chief academic officer, his primary concern is with the nature and organization of the academic programs. Where there are special questions of proposal submission, student involvement, or research policy, the Provost is involved in the decision-making process.

### Deans

The Deans of the University oversee the research being performed in each school or college. They make decisions college-wide regarding the general scope of research performed, promotion, and budgetary recommendations when interdepartmental or intercollegiate programs are proposed or when additional space is required. The Deans (or their Associate Deans for Research) are the coordination point for research at their college or school in consultation with the Provost, Graduate Dean's Offices and the Department Chairs and Directors as requested.

### Chairs/Directors

The Department Chairs or Directors works most closely with the Principal Investigator. They are responsible for assuring that the proposal budgets are appropriate for the project involved, that there is adequate space and staffing, and that the research fits within the academic programs and strategic plan initiatives of the Department and School College.

### Research Policy Committee

As a standing committee of the Faculty Senate, the Research Policy Committee meets regularly to consider and advise the Faculty Senate, Provost and President on policy-related questions pertaining to University research. Such questions may be raised by the Senate, by University higher administration, from within the Committee itself, or by individual members of the University community.

### UR Ventures

The office of UR Ventures works with faculty to coordinate all aspects of commercializing University technology emerging from basic research. Specifically,

1. works with faculty to identify and patent new inventions and register copyright in software and multimedia;
2. advises companies of new inventions at the University;

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3. negotiates and authorizes license agreements;
4. advises venture capital groups of new inventions and facilitate start-up of new companies;
5. provides feedback for faculty on intellectual property and relevant laws and regulations; and
6. reviews and authorize Material Transfer Agreements for shipment of biological materials between institutions.

### Office of Research and Project Administration

The Office of Research and Project Administration (ORPA) is the office delegated by the Board of Trustees for the administration of sponsored programs at the University. Discussion of the specific responsibilities and services that ORPA provides is stated in Section 1.7.

### Office of Research Accounting and Costing Standards

The Office of Research Accounting and Costing Standards (ORACS) is responsible for the post-award financial activities of sponsored programs accounts, which includes financial reporting, billing, letter of credit draws, cash management and financial close-out.

#### Note

Principal Investigators retain the final responsibility for financial management of individual projects and programs.

### Indirect Cost Accounting

The Office of Indirect Cost Accounting (ICA) is responsible for the calculation and negotiation of the University's Facilities and Administrative (indirect) cost rate, as well as the fringe benefit rates. The ICA interfaces closely with the University's federal cognizant audit agency (DHHS) to ensure the acceptance of these rates. ICA reviews all University cost center rates, develops the Central Administration and River Campus cost allocations, and provides guidance in the development of service center cost rates. ICA is responsible for the submission of any changes to the University's cost accounting standards disclosure statement (DS-2) which may occur due to changes in either University policies and procedures or Federal regulations. The Office works closely with the Finance Department and SPA on cost accounting matters.

### Office of University Audit

The Office of University Audit is responsible for performing independent appraisals to examine and evaluate the business, financial, and administrative operations of the University as a service to management. For sponsored research, University Audit evaluates the level of compliance with federal regulations, sponsor specific requirements, and established University policies and procedures. Generally, sponsored programs are reviewed during routine departmental reviews or by management request. Recommendations will be made as needed to strengthen internal controls and improve operating procedures to ensure consistent

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application of cost accounting principles and compliance to regulations for sponsored funds. Management's detailed plans for addressing audit findings are incorporated into the final audit report that is distributed to senior management.

### Principal Investigator

The terms Principal Investigator, Investigator, Project Director are used interchangeably in this Manual. They refer to that single individual, normally a full-time faculty member, who has the full and final responsibility to ensure that a sponsored program is carried out as proposed. The Principal Investigator (PI) shall use all reasonable and best efforts to comply with the terms, conditions, and policies of both the sponsor and the University. More discussion on the responsibilities of the PI is found in Chapters 6 and 8 and throughout this Manual.

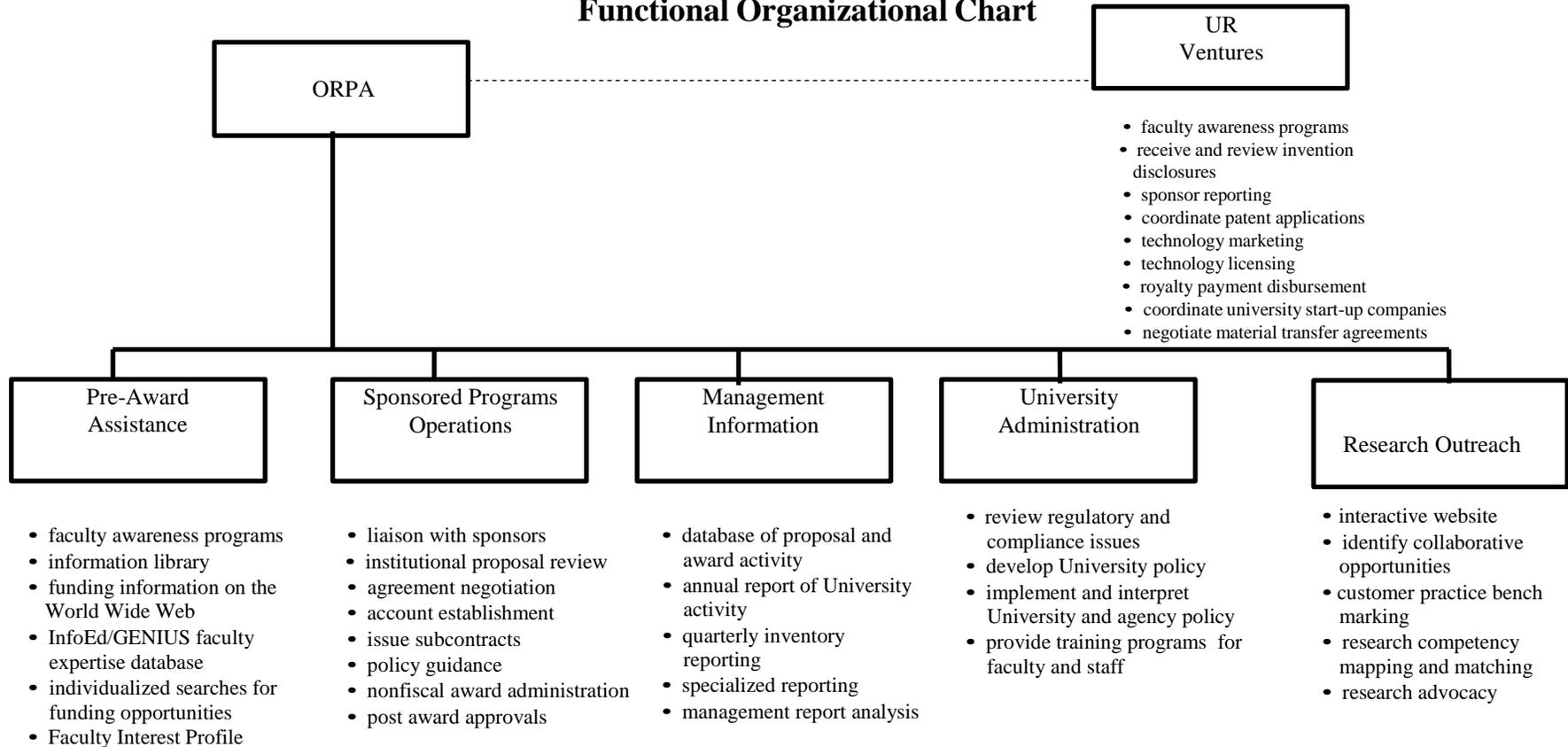
## 1.7 ORPA Responsibilities and Services

A chart of the various functions of ORPA follows (Illustration 1-1). In general, ORPA:

1. assists in identifying potential sponsors via University-licensed databases;
2. maintains a web-site that contains information on funding sponsors and research policy located at <http://www.rochester.edu/orpa>;
3. reviews and endorses proposals and awards on behalf of the institution to ensure that all University and sponsor requirements have been met;
4. negotiates appropriate terms and conditions of agreements;
5. provides an educational function with respect to sponsored program opportunities, policies, regulations and procedures for faculty and administrators via workshops, seminars and meetings.
6. receives awards on behalf of the University;
7. serves as liaison with sponsors on behalf of PIs and the University, working in concert with University departments;
8. recommends and administers policies and procedures with respect to sponsored activity. ORPA interacts closely with all the offices affiliated with the research process previously mentioned, in addition to University Counsel, the Research Subjects Review Board and other regulatory compliance offices, and the Development Offices across the University.

Illustration 1-1

**University of Rochester  
Office of Research & Project Administration  
UR Ventures  
Functional Organizational Chart**



## GENERAL CONSIDERATIONS

### 2.1 Definition of a Sponsored Program

A sponsored program is identified when any of the following conditions apply. Excluded from this classification are: a) contracts entered into by faculty for scholarly writing and artistic creation or b) a subset of service agreements administered by the School of Medicine and Dentistry in ledger 3 accounts (e.g., some clinical service agreements and professional service agreements):

1. The proposed work binds the University or the investigator to a specific line of inquiry;
2. Funding is contingent upon the University's acceptance of a specific commitment, such as the stated level of personnel effort, stated deliverables (i.e., a report, patient case report, device or prototype), or the achievement of specific performance targets or milestones;
3. There is a line-item budget detailing or limiting expenses by activity function, or project period or by limiting the University's freedom to transfer funds among expenditure categories;
4. A detailed financial status report or external audit is required;
5. Any unexpended funds must be returned to the sponsor at the end of the budget period;
6. The proposed activity involves the use of human subjects, laboratory animals, radioactive materials or isotopes, biological hazards or recombinant DNA;
7. The proposed agreement with the sponsor provides for the disposition of intangible property (e.g., rights in data, copyrights, patents, licenses, inventions, etc.), which may result from the sponsored activity or for the disposition of tangible property acquired during the project (e.g., equipment, supplies, drugs, materials, etc.).

If none of the described characteristics of a sponsored project are described, such awards may be treated as gifts as noted at the end of this chapter.

### 2.2 General Categories of Sponsored Projects

Sponsored projects at the University of Rochester are categorized under the following general headings:

1. Organized Research, including Sponsored Research and University Research;
2. Sponsored Instruction (Fellowship, Training);
3. Other Sponsored Activities (Clinical Trials, Service).

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Classification of a sponsored project into one of these categories determines the appropriate indirect rate to be charged (see also Chapter 4). Definitions and examples of these categories follow.

### Organized Research

The University's definition of research is stated below. Research activities may be funded by both external sponsors (Sponsored Research) or by the University of Rochester (University Research). Together these categories comprise the Organized Research distribution base, used to calculate the research indirect cost rate. OMB Circular A-21, states that organized research means **all** research and developmental activities that are **separately budgeted and accounted for**.

**Sponsored Research** – Research activities are properly classified as sponsored research if the activity is funded by an external organization, e.g., a federal, state or private organization or agency.

**University Research** – Research activity is properly classified as University Research only if the activity is supported by either of the following:

1. Cost sharing expenditures which are committed to be borne by the University rather than by the sponsor, or
2. Funding that is derived from University institutional funds (e.g., gifts, endowment income, operating budget) through a competitive application and award process, and where the research activity has any of the defining characteristics of a sponsored project. An example of University Research is an award made under research stabilization funding at the Medical Center.

#### Accounting for Organized Research

Expenditures for all activities that qualify as Organized Research are coded as research in the University's accounting system. Space used in the conduct of Organized Research is also coded to research in the University's space inventory system. All other research activity not defined as either Sponsored Research or University Research is considered Departmental Research. Expenditures for Departmental Research are coded to Instruction in the accounting system and Departmental Research (DR) in the space inventory system.

### Sponsored Instruction

Sponsored Instruction is defined as teaching and training activities at the University funded by grants and contracts from federal and non-federal sponsors. Sponsored Instruction includes research training grants and agreements (defined below), projects involving University students in community service activities and activities funded by awards to departments or schools for the support of students.

#### Accounting for Sponsored Instruction

The expenditures for training are coded as Instruction while Fellowships are considered Student Aid in the accounting system. The space for these awards is included in Other Sponsored Programs (OSP) in the space inventory system.

### Other Sponsored Activities

Other sponsored activities are defined as academic projects funded by sponsors in which project activities involve the performance of work other than Sponsored Instruction or Sponsored Research. Since most projects in this category do not directly involve students and gain little, if any benefit from libraries, the indirect cost rate applicable to Other Sponsored Activities is usually less than the rate for Organized Research. Other sponsored activities may include clinical trials, support for conferences or seminars, support for programs to enhance institutional resources and some service agreements.

#### Accounting for Other Sponsored Activities

Expenditures related to OSA may NOT be coded to research in the University accounting system. These expenditures are coded as Other Sponsored Programs (OSP) in the space inventory system and a variety of appropriate classifications in the accounting system.

## 2.3 Types of Sponsored Program Awards

A sponsored program award may be made for several purposes and will be classified in the University's accounting system in the appropriate classification noted previously, and on the space system in two (2) different categories (note that there are different categories for unsponsored activity, such as departmental research). While the majority of sponsored awards fund research, other types of awards are made to the University in the form of fellowships, training grants, clinical trials or service contracts. A brief definition of each type of award follows.

### Research

Research is broadly defined as a systematic investigation designed to develop or contribute to generalizable knowledge (DHHS) or any experiment that involves a test article and one or more human subjects (FDA). A research award funds scientific inquiry with the work scope normally defined by the University Principal Investigator. (Generally classified as Sponsored Research in the accounting system.)

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### Training

A training grant provides specific support for training of students or postdoctoral fellows in defined research fields. (Generally classified as Instruction in the accounting system.)

### Fellowship

Fellowships are generally individual awards providing support for a student or postdoctoral fellow. Normally, fellowships provide payment of a stipend and/or tuition support. ORPA administers fellowships from outside sponsors, such as NIH National Research Service Awards, NSF Graduate Fellowships and Jacob Javits Fellowships. Other types of fellowships are administered by other University offices, such as the University Sproull Fellowships that are administered by the Office of Graduate Studies. (Generally classified as Student Aid in the accounting system.)

### Clinical Trials

The University defines a clinical trial as the testing of a drug, biologic or device on human subjects. The protocol for a clinical trial is either developed by the agency or pharmaceutical company sponsoring the study, or by the University Principal Investigator. (Generally classified as Clinical Trials in the accounting system.)

### Service

Service agreements fund work performed at the University or other facility in support of an external request. The work scope is generally defined by the sponsoring agency or company. Clinical services are a subset of service agreements where specific tests/assays are completed or patient services rendered. Depending on the nature of the agreement, the contract will be administered either as a sponsored project (ledger 5) or organized activity (ledger 3). The determination of the account type will be made at the contract review stage by the Dean's office and ORPA. Refer to the University policy on "[\*Service Agreements\*](#)". (Generally classified as Other Sponsored Activities in the accounting system.)

### Other Types of Sponsored Funding

Other activities that are supported by external sponsors and fall under the definition of a sponsored program are awards for curriculum development, travel and conferences, construction, and equipment. (Generally classified as Other Sponsored Activities in the accounting system.)

Types of sponsored projects summarized by the Accounting and Space classifications are noted below:

## Types of Sponsored Projects

	Accounting Classification	Space Classification
Research	Sponsored Research (normally)	Organized Research
Training	Instruction	Other Sponsored Programs
Fellowship	Student Aid or Instruction	Other Sponsored Programs
Clinical Trials	Clinical Trials	Other Sponsored Programs
Service	Other Sponsored Activities	Other Sponsored Programs

## 2.4 Principal Investigator Eligibility

The Principal Investigator of a sponsored program assumes full responsibility for the scientific and intellectual direction of the project, as well as financial management in accordance with University and sponsor regulations. The delegation of the title of “Principal Investigator” and “Co-Investigator” are normally available only to full-time faculty positions, or full-time positions enjoying similar rights and privileges. Exceptions may be made with the approval of the appropriate Chair and Dean, in accordance with the University’s [Principal Investigator Eligibility Policy](#).

## 2.5 Types of Award Mechanisms

Sponsored program award mechanisms can take several forms, the most common being a grant or a contract. The federal government distinguishes between grants and contracts on the basis of whether the award is considered assistance or procurement.

### Grant

As noted above, grants are considered “assistance”. Congress has defined assistance as the transfer of money, property or intellectual services for the public’s benefit, which is of national interest (Public Law 95-224). The sponsor of a grant, whether the government or a private organization, has no substantial involvement in the work. A grant is given without the expectation of delivery of a specific product or service other than a written technical report. Most applications for grant support originate with an individual investigator who develops a proposed plan for research within a sponsor’s area of interest. Grants normally fund basic research, fellowships and training.

### Contract

A contract is a written agreement and is enforceable by law. The principal purpose of a contract is support of a project for the direct benefit of the sponsor. The University is subject to certain

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standards of performance and is normally responsible to produce a tangible product or service, such as a technical report or patient case report forms. Generally, there is substantial involvement by the sponsor, particularly in defining the statement of work. Contracts normally fund applied research, clinical trials and service by the University.

Administrative requirements for federal contracts are governed by the Federal Acquisition Regulations (FAR). ORPA will review the contract solicitation or contract to ensure that it is appropriate and that the University is able to comply with the stated FAR's.

Commercial contracts are also reviewed and negotiated by ORPA, to ensure that contract clauses are not in conflict with University policies and procedures (see Chapter 3).

Contract types are grouped into two broad categories, namely cost-reimbursable and fixed price.

### Cost-Reimbursable Contracts

Cost-reimbursable contracts provide for sponsor payment of the allowable, allocable and reasonable costs of the project. As defined by the FAR, cost-reimbursable contracts are designed to estimate total project costs in order that funds may be obligated for the work, and to set a ceiling that the investigator may not exceed without the approval of the sponsor. Normally, the University will attempt to negotiate cost-reimbursable contracts as these provide for some cost adjustment and present the least amount of risk to the University.

### Firm Fixed-Price Contracts

Firm fixed-price contracts establish an agreed-upon price for performing the work. Payment is generally made upon the completion of certain milestones or delivery of prescribed items. These contracts do not provide for any cost adjustment, and place the University at maximum risk for assuming full responsibility for total project costs. Investigators should ensure that proposal budgets are accurate and funding will sufficiently cover all project expenses. Fixed-price contracts may be used when the risk involved is minimal or can be predicted with an acceptable degree of certainty.

Examples of fixed price contracts from commercial organizations are clinical trial agreements, where the University is reimbursed on a preset per-patient amount, or assay agreements.

### Cooperative Agreements

Cooperative agreements are similar to grants in that they are also defined as assistance, but differ in the extent of the sponsor's involvement. In cooperative agreements, the sponsor may become substantially involved in the project by giving technical and programmatic advice. Cooperative agreements are normally awarded in support of basic research.

## 2.6 Definition and Administration of Gifts

Gifts or donations may be funds or tangible property that are given to the University with no expectation of benefit to the donor. Gifts may stipulate that the contribution be used in a certain way, such as to benefit a specific division of the University or for a specific broad area of research.

Gifts are not subject to any of the restrictions that are stated in Section 2.1 above, are not viewed as sponsored projects, and are not processed through ORPA; gifts are processed through the University Gift Office upon receipt. Gifts are subject to Chair, Dean and/or Development Office approval prior to solicitation by a proposal or acceptance through the University's customary gift acquisition process. Gift solicitations are to be coordinated with the appropriate Development Office, which typically transmit the proposals to the funding entities (both individual and organizational). Such coordination will assure that the appropriate sponsor is being contacted and that past and present relationships will be maintained. Some organizational donors limit the number of proposals that may be submitted by the University.

On occasion, a gift will be awarded with unforeseen restrictions or obligations. If the gift contains any of the restrictions of a sponsored program, these will be referred to ORPA for processing.

## POLICY CONSIDERATIONS

### 3.1 Consistency with University Mission

It is the policy of the University that all sponsored programs should capitalize on existing strengths or provide the means for the development of new strengths. In addition, acceptance of any sponsored program is based on the premise that any award furthers one or more of the University missions of education, research or clinical service.

### 3.2 Criteria for Acceptability of Sponsored Research

The University transmits knowledge to future generations and extends the frontiers of knowledge in basic liberal and scientific studies. Therefore, it is expected that research programs undertaken should relate to the discovery of the type of knowledge that enhances and contributes to the research priorities of the University's faculty and students. Research that is aimed at short-run utilitarian goals or which is intended primarily to solve only the problems of a particular sponsor should be avoided. There are several other criteria that are considered when accepting sponsored funding, the most significant being:

- open academic environment;
- freedom to publish;
- ownership of intellectual property resulting from basic research;
- availability of space and resources;
- acceptance of the protocol by the compliance and regulatory committees of the University.

These considerations are described below. Further considerations for industry, clinical trial and other agreements are discussed in Chapter 9.

#### Open Academic Environment

The University academic administration is responsible for assuring that an open academic environment exists throughout the University. It is the responsibility of the administration, faculty and the Faculty Senate to establish appropriate norms and to assure the existence of an open academic environment.

#### Freedom to Publish

University policy prohibits the acceptance of any award that prohibits or restricts publication or dissemination of research results. The University will accept a reasonable delay on publication for the purposes of sponsor review and protecting patentable information, as long as this delay does not impact a student thesis. The recommended period of delay is thirty (30) days; this period of sponsor review will normally not exceed ninety (90) days.

## Ownership of Intellectual Property

Generally, title to patents and copyrights developed under sponsored programs remains with the University. The University is prohibited from assigning title to intellectual property developed from research performed under federal awards as prescribed by 37 CFR Part 401. Acceptance of a federal award obligates the University to provide the government with a paid-up, non-exclusive license to any intellectual property generated under the funded project. License rights to inventions developed under non-federal research sponsors are governed by the terms of the contract. Under research contracts with industrial sponsors, the first right to negotiate for license rights is normally granted to the sponsor; such license rights may be further dictated by provisions of the University's tax-exempt bond financing. A full discussion of intellectual property considerations is found in the University's [\*Policy on Intellectual Property and Technology Transfer\*](#).

## Availability of Space, Facilities and Personnel

For any sponsored project to succeed, it is important that all personnel involved support the project and understand their roles. In addition, it is necessary that the Department Chair and Dean fully support the commitment of space, facilities and personnel required by the project. This review and consideration is accomplished through the University Sign-Off Process that is described in Chapter 6.

## Research Involving Humans, Animals or Recombinant DNA

Special legal requirements are imposed on any program involving investigation on human subjects, use of laboratory animals, use of specific carcinogens or other toxic substances, or research into DNA recombination. Clearances by established regulatory review committees are generally required prior to submission of the proposal to any funding agency. For a description of the University's regulatory review committees refer to Chapter 10 of this Manual.

## Classified Research

Classified research and secrecy are incompatible with the free exchange of information required in education. Therefore, such restrictions are not accepted for University research projects. However, this does not prohibit the individual faculty and staff member from entering into personal consulting arrangements that may involve classified or proprietary matters. Faculty are warned that every precaution should be taken to ensure that their consulting work does not overlap with University research or other University commitments.

## Proprietary Information Furnished by Sponsors

Information and data that cannot be freely discussed limit the interactions of faculty, students, and staff. However, if the University considers it necessary for the conduct of a highly desirable sponsored project to obtain or accept confidential or proprietary information belonging to a sponsor, the information may be received only if certain conditions are completely met, the freedom to publish is assured, and with the understanding that the University will use its reasonable efforts

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to maintain such confidentiality. The information may be disclosed to those with the University who are engaged in the conduct of the related research. Any sponsor proprietary information should be marked and designated as confidential and the investigator must reserve the right to refuse the information.

### Initiation of New Programs, Centers or Institutes Within A Department

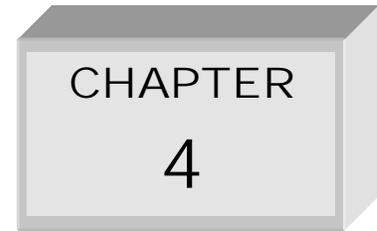
There are subtle but essential differences between developing a research project and initiating a program. Individually-initiated or interdepartmental research programs generally operate within the existing organizational structure. Creating programs, centers, institutes and similar research-related efforts requires that researchers and administrators work especially close to create an effective administrative support structure and system for the new venture. From the beginning of the proposal development, the department Chair, Dean and other University administrators should be consulted and their guidance relied upon.

### Initiation of an Interdepartmental or Interdisciplinary Program

When an interdepartmental or intercollegiate proposal or other multidisciplinary is being developed, the Principal investigator will inform the Department Chair and Dean of his/her intention to apply for such a program. The Dean of the College/School in which the majority of the funds of the grant or contract will be expended will normally assign its Associate Dean to take responsibility for assuring that agreement is obtained among all the contributing units. It will usually be necessary to develop an estimated budget and list of anticipated researchers long before the technical details of the project are written. Negotiations between Schools/Colleges may well take several weeks in order to resolve any questions and sufficiently plan for a strong research program. The rule (to which exceptions may be made only in extraordinary circumstances) is that the University (whether it be through ORPA, the Development Office, or the Provost's Office) will not submit proposals unless the procedure described in this paragraph have been followed.

### Collaborative Research Between Different Institutions

Principal Investigators should assure that appropriate review has been made within the home institution of any outside collaborating investigator. ORPA is available to assist with negotiations leading to the proposal, as well as any resultant subcontracts. Agreement in writing must be obtained for items such as the scope of work, budget, and subcontractual arrangements prior to the submission of a funding proposal.



# PROPOSAL DEVELOPMENT AND COSTING

## 4.1 Types of Proposals

### What is a Proposal?

A proposal may be a request for financial assistance, payment for services rendered, or loan of research equipment. Proposals generally contain a technical description of the work or activity to be performed and a request for financial assistance.

### Preliminary Proposals

Preliminary proposals or “white papers” are abbreviated descriptions of the proposed project. Preliminary proposals are often requested by sponsor for large programs and result in fewer invited proposals. Preliminary proposals usually include an estimated budget.

#### Note

The estimated budget often becomes the basis for the financial limits of a formal proposal; therefore, consideration should be given to making this preliminary budget as realistic as possible.

Preliminary proposals are not formal commitments by the University. In general, a University Proposal Sign-Off Form (as described in the following section) is not required. However, a copy of a preliminary proposal should be furnished to the appropriate Department Chair or Dean’s Office. If the preliminary proposal contains substantial cost-sharing contributions and/or commitments, the appropriate Chair and Dean should be consulted. If the sponsor requests a formal proposal, refer to Chapter 6 for processing procedures.

### Formal Proposals

Formal proposals, all of which require review and endorsement by the University, can be any of the following:

- *Solicited Proposal:* Submitted to a specific program and responds to sponsor requirements and guidelines.

- *Unsolicited Proposal:* Developed independently by the Principal Investigator (PI) in accordance with his/her field of research and submitted to an appropriate funding sponsor.
- *Response to a Request for Proposals (RFP):* Submitted in response to a specific work statement developed by the sponsor. RFP's generally have a firm response time, contain proposed contract provisions, and require lengthy certifications to be completed.

#### Note

ORPA should be notified as soon as possible when intending to submit a response to an RFP. ORPA will need to review proposed contract provisions since exceptions can normally be stated only at the time of proposal submission. In addition, ORPA will require time to complete any necessary certifications.

- *Competing Renewal Proposal:* A competing renewal proposal is a formal request for continued funding of a project where the funding period is ending. These proposals are normally subject to the same sponsor review criteria as new proposals. Competing renewals must be routed through the standard University sign-off process.
- *Non-competing Continuation Proposal:* Requests the next year's funding within a multi-year grant or approved project period. Continuation proposals are brief. They usually consist of a progress report and perhaps a budget and other relevant materials. Non competing continuations may require institutional endorsement by ORPA, as specified by the sponsor.

#### Note

Sign-Off requirements for non-competing continuations vary with each School or College, and the appropriate Dean's office should be consulted, along with the ORPA Guide entitled [\*Guidance for the Submission of Sponsored Project Proposals\*](#).

## 4.2 General Format

Many sponsors provide standard application forms and prescribe rigid rules for proposal format, which indicate that the designated format/forms must be used or the proposal could be returned without review. For sponsors that do not require a prescribed format, the following items comprise a standard proposal format:

### Transmittal Letter

If a transmittal letter by an authorized University Official is required, ORPA will prepare the letter using information provided on the Sign-Off Form. Alternatively, the PI may elect to write the transmittal letter, which will be reviewed by ORPA.

## Cover Page

The cover page should contain enough information to clearly identify the proposed project and relevant parties/contracts. A sample cover page is located at Appendix A.

## Abstract

Most sponsors require an abstract of approximately 200 words that outlines the proposed scope of work, methods, and significance of the project.

## Statement of Work

The statement of work is a complete and detailed explanation of the proposed project, including general background, proposed methodology, goals and objectives, significance and any other items relevant to presenting a detailed plan of the proposed work.

## Personnel

Project personnel and their responsibilities must be identified.

## Biographical Sketch

Current vita for key personnel and consultants should be included.

## Current and Pending Support

Some sponsors require a listing of the key personnel's current proposals and awards. This information should include the percentage of effort devoted to these other projects and explanation of any relevant scientific or budgetary overlap.

## Facilities and Equipment

This section describes equipment or other relevant University community resources that will be available to the project and that offer unique advantages to the proposed research.

## Budget and Budget Justification

Developing an accurate budget acceptable to the sponsor is critical. Budget development and costing guidelines are discussed fully in the next section.

## Appendices

Appendices may include letters of endorsement or cooperation, previous publications, or other materials that are relevant and would enhance the proposal.

## 4.3 Budget Development

### Overview

The University adheres to OMB Circular A-21, [\*Cost Principles for Educational Institutions\*](#). As such, the following principles must be applied when requesting funding from any sponsor. A cost is allowable if it is:

- reasonable;
- allocable;
- consistent;
- and conforms to any limitations or exclusions as set forth in A-21.

ORPA will provide guidance as to what costs are not reimbursable. Examples of unallowable costs under federal sponsors are:

- alcoholic beverages;
- alumni activities;
- commencement and convocation costs;
- donations and contributions;
- memberships;
- entertainment costs.

In addition, A-21 limits reimbursement for administrative and clerical staff, postage costs, telephone costs and routine office supplies. Requests for these items must be specifically justified as outlined in the University of Rochester [\*Implementation of Revisions to OMB Circular A-21\*](#) dated December 27, 1993. Requests for these items are only appropriate if the costs are proven to be for the sole direct benefit of the project.

### Cost Categories

There are three important categories of costs associated with a proposal budget. These are *direct cost*, *modified total direct costs* and *facilities and administrative costs*.

#### Direct Costs

Direct costs are those expenses that can be directly identified with a particular project. Categories of direct costs may include salaries and wages, benefits, consultants, subcontracts, equipment, supplies and travel. Other allowable direct costs are described in OMB Circular A-21, Section J, or in the sponsor's own application guidelines.

#### Modified Total Direct Costs (MTDC)

MTDC is a subset of direct costs and is the base to which facilities and administrative costs are applied in most funding proposals. (Note there are exceptions!) MTDC is equal to total

costs less tuition and fees, capital equipment, renovation, patient care expenses, rental costs of off-site facilities, and subcontract expenditures in excess of \$25,000. An example of the application of MTDC is described in Example 4-4.

## Facilities & Administrative (F&A) Costs

Facilities & Administrative costs (indirect cost) are those costs not easily identified with a particular project and include such categories as utility costs, depreciation of building and equipment, operations and maintenance expenses, general administrative expenses and library expenses. F&A costs must be requested at the University's current negotiated rate and at the appropriate on- or off-campus rate, unless restricted by agency regulations. Further discussion of F&A costs begins on page 4-16.

### Note

The appropriate Dean's Office must approve (in advance) requests for a waiver to the negotiated F&A rate.

## 4.4 Budget and Cost Guidelines

The following is a guideline of how to develop proposal budgets and how to calculate University costs. In addition, a [Proposal Budgeting Information Table](#) is available on ORPA's website. This table contains current rates and costs for proposal preparation as well as other useful information often required in sponsor applications. In addition, the [Proposal Budgeting Information Table](#) contains current escalation factors that are recommended for developing costs for out years.

The proposal budget should reflect an accurate assessment of the necessary project costs that are allowable and reasonable for the proposed research, unless other instructions have been provided by the sponsor (e.g., NIH Modular Grants or Just In Time Submissions). NIH Modular Grants instructions and guidelines are found at ORPA's web site. Current and complete cost estimates and documentation used in estimating those costs must be kept by the department to support the reasonableness of the request to the sponsor. This is especially important if the proposal undergoes a pre-award audit (generally done only for very large federal awards). Sponsor requests for additional budget information or pre-award audits are usually coordinated through ORPA. Most scientific and administrative reviewers will be able to ascertain whether sufficient funds have been requested or whether costs are reasonable in order to complete the statement of work.

The salary section of the proposed budget should indicate the personnel working on the project, role on project, an estimate of the percentage of effort to be devoted to the project and the salary anticipated to be charged to the project. The percentage of effort proposed will normally correlate to the salary requested; uncompensated salary is considered cost sharing and treated in accordance with the University's policy (see Section 4.5). Unless otherwise stated, all salaries should be budgeted at current institutional base salary levels plus projected increases consistent with escalation factors cited in the [Proposal Budgeting Information Table](#). If a promotion is planned during the project period, the planned salary increase should be projected in the appropriate year and fully justified.

Normally, all key personnel (Principal Investigators, scientists, and researchers) should be named. Specific salary guidelines for faculty and professional staff follow.

## Faculty Salary

Medical School faculty are generally appointed on a twelve-month or calendar year basis. Guidelines on faculty appointments for the Medical Center are found in the School of Medicine & Dentistry's *Regulations of the Faculty*. In addition, some Dean's Offices have their own policies on academic year and summer salary.

The base salary for other University faculty is generally on a nine-month basis or academic year. Faculty may charge a portion of their academic year salaries directly to sponsored projects. Normally, salary recovery from sponsored programs during the academic year may not exceed a 50% level of effort, unless the faculty member has a special appointment. Faculty appointed on an academic-year basis may receive additional salary for work performed on sponsored projects during the summer period (June 1 through August 30) up to a maximum of 2.5 months of the budgeted academic-year salary. Faculty academic and summer effort should be listed separately on the proposal budget page. Faculty members must be working on the project while receiving summer salary; vacations during this period are unallowable. Note that NSF has a two-month limitation on summer salary. NSF will not award, nor can the individual be paid, more than two months of summer salary support from NSF funds per year.

### IMPORTANT

Compensation on sponsored projects must not exceed the authorized base rate of pay from the University; salary proposed on a sponsored project is not normally considered extra compensation.

Some sponsors, such as NIH, impose a salary cap limitation. It is generally the University's policy to request salary up to the level of the mandatory cap.

## Visiting Academic Appointments

Visiting appointments are temporary appointments. Some sponsored programs allow for the charging of visiting faculty salary; these salaries should be requested at levels recommended by the Chair and Dean.

## Sabbatical Leaves

Salary support for faculty while on sabbatical leave may be allowed by the funding sponsor at a rate consistent with the level of effort performed. Sponsor regulations should be consulted if requesting sabbatical support.

## Emeritus Faculty Salary

Retired faculty holding the rank of Emeritus Faculty may request salary support from sponsored programs. Salaries should be requested at the level agreed upon by the Chair and Dean.

## Calculating Salaries and Person Months

The following examples have been provided to illustrate how to calculate salaries and/or person months on proposal budgets.

### Example 4-1 Salary

Assistant Professor Jones is currently earning \$60,000 for an academic appointment. She will expend 10% effort during the academic year and 100% effort for two (2) summer months on a proposed twelve-month NIH project. Assistant Professor Jones' salary is calculated as follows:

Step 1) Determine Professor Jones' salary for the start date of the project. In this case, the project is proposed to start in the next fiscal year and an escalation factor of 4% is used.

Step 2) Multiply the projected academic year salary of \$62,400 by 10% effort

$$\$62,400 \times .10 = \$6,240$$

Step 3) Professor Jones will be working on this project for two (2) summer months. Summer salary is calculated by dividing the annual salary by 9 months = \$6,933 per month; then multiplying the monthly amount, which represents 100% effort, by 2 months

$$\$6,933 \times 2.0 = \$13,866$$

Step 4) Total Salary Requested for Professor Jones

$$\text{Step 2} + \text{Step 3} = \$20,106$$

Note that benefits have not yet been calculated and the salary has been calculated for the first year only. Subsequent years should be calculated at the University's suggested escalation factor, taking into account projected adjustments for promotion.

### Example 4-2 NIH Salary Cap

Dr. Smith has a twelve-month (calendar) appointment in the School of Medicine and Dentistry, with a projected base salary of \$170,000. He will expend 33% effort on a NIH project for the year.

Step 1) Because NIH has a salary cap of \$166,700 (example as of 01/01/02); you would multiply the salary cap by 33% to determine the total salary request for the calendar year.

$$\$166,700 \times .33 = \$55,011 \text{ (total salary request)}$$

Step 2) If Dr. Smith were to expend 33% effort for anything less than the full 12 months, you would first need to determine his monthly salary based on the salary cap:

$$\$166,700 \div 12 = \$13,892 \text{ (monthly salary)}$$

Step 3) Multiply the monthly salary by the number of months Dr. Smith works (in this case, 7 months):

$$\$13,892 \times 7 \text{ months} = \$32,091$$

Step 4) Determine the 33% effort:

$$\$97,244 \times .33 = \$32,091 \text{ (total salary request)}$$

#### Note

The fringe benefit rate applied to the salary request would be the rate associated with the actual institutional salary (e.g., \$170,000), not the salary cap.

#### Example 4-3 Person Months

The National Science Foundation (NSF) is one sponsor that asks for a calculation of person months on the project, versus percentage of effort. To calculate person months, multiply the percentage of effort by the number of months of support requested.

Assistant Professor Wind has an academic appointment (nine months). She will expend 10% of her effort on a National Science Foundation project for the academic year and 50% effort in the summer. Person months are calculated as follows:

$$\text{Academic Year} = 10\% \text{ effort} \times 9 \text{ months} = 0.9 \text{ months}$$

$$\text{Summer} = 50\% \text{ effort} \times 2.5 \text{ months} = 1.25 \text{ months}$$

$$\text{Total person months} = 2.15 \text{ months}$$

If Professor Wind had a twelve-month (calendar) appointment and expended 10% effort for the year, her person months on the project would be calculated by multiplying 0.10 by 12 months to arrive at 1.2 months.

## Postdoctoral Salary

Postdoctoral appointments are typically made to individuals conducting research whose primary goals are to extend their own education and experience. Postdocs work primarily under the direction of faculty and are not considered independent researchers. Benefits should be charged at the postdoctoral rate.

### Note

Postdoctoral trainees applying for individual fellowships or training grants should request a stipend and health coverage in accordance with the guidelines provided by the sponsoring agency. These are considered to be “not for service” or trainee appointments. The post-doctoral employee benefit rate is not applied for postdoctoral trainees.

## Graduate Student Salary

A graduate student may be appointed as a research assistant and charged to a sponsored program. The Graduate Dean’s Offices for the various schools/colleges establish minimum salary rates for graduate research assistants and these offices should be consulted prior to proposing graduate salary. Tuition expenses may be requested for graduate students working on sponsored projects; however, these are requested as a separate cost and not included in the student’s salary compensation (see “Tuition Costs” below). Fringe benefits are not normally applied to graduate student salary, except at the River Campus during the summer months when the student is not registered for full-time study. This benefit rate can be obtained from the [Proposal Budgeting Information Table](#).

### Note

Graduate student stipends on institutional training grants should be proposed in accordance with the guidelines provided by the sponsoring agency. These are considered to be “not for service” or trainee appointments. However, costs reimbursed directly to the student in excess of stipend, fees and tuition may be considered taxable. The Office of Human Resources and University Controller can provide guidance in this matter.

## Administrative and Clerical Staff Salary

Staff members responsible for providing administrative coordination and support of a sponsored program are considered administrative/clerical staff. As mentioned earlier, OMB Circular A-21 limits reimbursement for administrative and clerical staff, and such costs are appropriate only when these individuals and their related effort can be specifically identified with the project or activity. Administrative and clerical salaries must be separately listed, justified and specifically assignable to the project with a high degree of accuracy. Examples provided by OMB to illustrate when direct charging may be appropriate are as follows:

*“Individual projects requiring project-specific database management; individualized graphics or manuscript preparation; human or animal protocol, IRB preparations and/or other project-specific regulatory protocols; and multiple project-related investigator coordination and communications.”*

## Undergraduate Student Salary

Undergraduate student salary is proposed on an hourly rate basis consistent with the student’s level of expertise and prior experience. The Career & Internship Center establish these wages and the number of hours a student is allowed to work. Student salary is excluded from the employee fringe benefit calculation, unless the salary is being charged during the summer months when the student is not registered for full-time study. The summer rate can be obtained from the [Proposal Budgeting Information Table](#).

## Fringe Benefits

Fringe benefits or employee benefits are treated as direct costs and should not be combined with salaries. Fringe benefits may include medical and dental insurance, retirement benefits, social security, worker’s compensation, life insurance, vacation benefits, tuition benefits and other miscellaneous costs. Employee benefits are calculated as a percentage of salaries. There are different rates for various categories of employees; the differing benefit rates can be obtained from the fringe benefit summary chart disseminated by the Budget Office or on ORPA’s [Proposal Budgeting Information Table](#). The fringe benefits are negotiated each year with the University’s cognizant federal audit agency; new rates are effective on July 1. Rates should be proposed at the most recently approved rates for the proposed project period.

## Capital Equipment

Capital equipment is defined at the University of Rochester as any unit item with a life expectancy of more than one year and an acquisition cost of \$1,000 or more. Shipping, taxes, in-transit insurance, and installation charges should be included under this category for new purchases, provided these costs are included on the original purchase order. If an item falls outside this definition, it is considered “expendable materials and supplies.” Equipment rental or lease, for instance, is not included in the capital equipment definition.

The equipment budget should contain an estimate and justification for all equipment needed to perform the scope of work. All equipment purchases should be listed by type of equipment, manufacturer’s name or identifying mark, quantity, estimated cost and the basis for the estimate. Estimates should be based upon catalog quotes, telephone quotes, historical cost, engineering estimates or experience. Purchasing Services can help to obtain vendor quotes. It is very important to document the basis for the cost estimate, as this is often requested by sponsoring agencies or must be produced in the event of a pre-award audit.

#### Note

Software is generally not defined as equipment unless it meets the equipment definition, is purchased as a package with the initial equipment order, or is classified as operating software essential to operate the computing equipment. Application software is not considered equipment and should be budgeted in expendable materials and supplies.

On occasion, the sponsor may request certification as to the non-availability or non-existence of the proposed equipment on the University campus. ORPA will provide this certification if necessary.

### Special Purpose vs. General Purpose Equipment

Equipment is subdivided into two classifications in OMB Circular A-21, *special purpose* and *general purpose*. Special purpose equipment is equipment that is used primarily for “research, medical, scientific, or other technical activities.” As a rule, only special purpose equipment is funded in sponsored programs since it can be proven that it is necessary for the goals of the project. General purpose equipment is not limited to these activities and includes equipment such as office furniture, printing and copying equipment, pagers, typewriters, copiers, and word processing equipment. General purpose equipment is unallowable as a direct charge, except where it is used primarily or exclusively for the actual conduct of the project. Therefore, any general purpose equipment should be fully justified.

### Fabricated Equipment

Fabricated equipment is special purpose equipment, which is engineered, designed or constructed in order to accomplish a unique purpose in the performance of the project. Fabricated equipment is further discussed in the University’s [Policy on Fabrication of Special Purpose Capital Equipment](#). In summary, the criteria for fabricated equipment are as follows:

1. the non-salary cost of the fabrication must equal or exceed \$1,000 (Note that the University does not capitalize on in-house labor used for fabrication, unless the fabrication is done by a University fully-costed shop and captured in the shop rate);
2. the useful life of the fabricated item must be more than one year;
3. the item must have a nature allowing for accountability, must be identified as a discrete item and be tagged with the standard University equipment tag.

### Materials and Supplies

Generally, this category refers to consumable materials or supplies that will be used during the project period. Supplies may consist of items such as:

1. items that cost under \$1,000 or have a useful life of less than two years;
2. computer supplies;
3. project-related consumable such as glassware and chemicals;

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4. project-related items such as books, periodicals and tapes;
5. software packages;
6. laboratory animals.

Note

The Vivarium (x5-2651) should be contacted for current animal prices, service charges, box charges, per diem rates and shipping costs. Inflation factors for these rates should also be obtained from the Vivarium.

7. radioactive isotopes.

Note

Radiation Safety (x5-3781) should be contact to obtain the current fee schedule for radioactive isotopes.

Supplies should be listed in the budget by type (e.g., chemicals, computer supplies, and glassware) and by estimated costs. Again, some sponsors will require that the basis for cost estimates is included in the budget justification and some sponsors have restrictions on office supply purchases.

General office supplies are normally treated as F&A costs and are only appropriate to request as a direct cost if the cost can be justified as a sole direct technical benefit of the project. Again, please refer to the [OMB Circular A-21](#).

## Consultant Costs

Consultant costs are for personnel who provide a professional service for a fixed period of time and are not University employees. When budgeting for consultants, it should first be determined whether the person meets the Internal Revenue Service's criteria for consultants as opposed to a University employee. Please refer to University Personnel Policy No. 122 entitled *Employee/Employer Relationships vs. Independent Contractors* and the *Purchasing Guide*. Note that consultants should be budgeted only when on-campus expertise does not exist or is not readily available.

A consultant should be proposed describing the individual's name, services to be rendered, number of days charged, justification for selection, and daily rate proposed. The daily rate may include fees and travel expenses, or related travel expenses should be itemized. Costs should be based on actual quotes from the consultant. Sponsoring agencies normally require curriculum vitae.

Note

Some sponsors, such as NSF, limit the daily rate charged to Federal funds to the daily rate for Federal employees in the GS-18 salary classification. This rate can be obtained by calling ORPA or referring to, [Proposal Budgeting Information Table](#). Some sponsors prohibit the use of consultants. Additional information is found in the ORPA reference entitled [Faculty Guidance on Consulting](#)

## Subcontracts

A subcontract is an agreement with a separate organizational entity outside of the University of Rochester to perform a significant portion of the proposed statement of work. Distinguishing characteristics of a subrecipient or subcontractor include performance measured against meeting the objectives of the program and responsibility for programmatic decision making. The subcontractor directs and takes full responsibility for its portion of the project.

The following items are required in the proposal if it has a subcontract component:

1. justification of the need for the subcontract in the proposal narrative, along with the defined tasks of the subcontractor or a work statement;
2. a budget, done in the same level of detail that is being proposed by the University of Rochester. Guidance for subcontractors in preparing their budgets may be found in the [ORPA Subcontracting Guide](#). Note that commercial subcontractors may include costs such as labor overhead, general and administrative expense, cost of money and profit or fee. Some federal agencies limit or disallow profit or fee; agency guidelines may be obtained from ORPA. The PI is responsible for reviewing the subcontract budget to ensure that it is reasonable;

Note

Subcontract budgets submitted in response to a solicitation for a Federal contract must also include a Certification of Cost or Pricing Data. This form may be obtained from ORPA.

3. a letter of commitment or intent must be submitted with the proposal. Proposals from other organizations must include a signature of an official authorized to legally commit that organization or institution to the portion of work described and corresponding budget;
4. a copy of the subcontractor's F&A rate negotiation agreement (e.g., obtained from the Sponsored Program Office).

Determination of whether someone is a consultant or a subcontractor, or whether a subcontract should be issued versus a vendor purchase order, can be obtained either from ORPA or Purchasing Services. Also refer to the ORPA Guide entitled [ORPA Guide for Subcontracting](#)".

#### Note

The total cost of the subcontract (including any indirect costs or fees charged by the subcontractor) is listed as a direct cost of the University of Rochester. The University's F&A costs are applied to the first \$25,000 of each subcontract for the entire project period. The amount of the subcontract that exceeds \$25,000 will be excluded from F&A costs. Note that the F&A rate applied on the subcontract will be the rate that is assessed on the University's award.

## Travel

Separate detail should be provided in the budget for foreign and domestic travel. Foreign travel is any trip outside the United States, its territories, possessions, and Canada. Foreign travel usually requires special authorization from the sponsor.

The University of Rochester's *Travel and Conference Handbook* should be consulted when proposing travel costs. The University will reimburse the traveler for reasonable, actual costs; it will not reimburse travelers for costs in excess of coach fares. Generally, it should be anticipated, however, that Federal sponsors will compare travel costs to current government approved rates. These rates may be obtained from ORPA or by accessing the Federal Acquisition Regulations website, at <http://www.acquisition.gov/far/>.

Each trip proposed in the budget should be listed separately and should include the following detail:

- names and number of travelers;
- point of origin and destination;
- cost of transportation (e.g., airfare, cost per mile);
- per diem costs for lodging and meals, incidental expenses such as ground transportation and conference or registration fees.

It is important that the relevance of the trip to the proposed project be described in the budget justification. Expenses are reimbursed for the period of travel only and must be reasonable to the project. Entertainment expenses (e.g., movies, alcohol, and payment of guest meal expenses) are generally unallowable.

## Other Direct Costs

Other direct costs proposed for sponsored funding may include the following:

### Communications

These costs include charges for postage and telephones. On federally funded projects, postage costs for routine correspondence and local telephone costs (e.g., equipment,

installation, maintenance, line charges, and fax lines) are normally treated as F&A (indirect) costs and are only appropriate to budget as direct costs if the purpose of such is for the sole direct benefit of the project. Network expenses are allowed if appropriate to the project and justified; these costs must be explicitly budgeted and specifically identified. Examples of allowable communication expenses include shipment of project materials and deliverables, generally by express services, express mail charges, long distance telephone charges, and fax transmission charges. A listing of such items and the estimated cost is required.

## Repair and Maintenance

These costs include charges for maintenance, repair or upkeep of property utilized in the performance of the sponsored project. Budgeting should be based upon actual experience or from the actual maintenance agreements. Proposal detail should include a listing of the type of equipment to be maintained and the estimated costs.

## Other Services

Other services include professional services by University departments and outside firms. Internal services include those performed by the department of Biostatistics, Media Services, Computer Services, Academic Computing, Copy Centers, and University Shops. For internal services, budgets should reflect actual quotes received from those departments based upon the current fee structure. Budgets should list the types of services required and the estimated fee. Some sponsors require that computing services be listed on a separate budget line; the budget detail may include charges for connect time or CPU.

### Note

Services provided by fully costs University shops are not assessed F&A costs. The fully costed shops include NSRL, SW Barnes Research Lab, The College Shop, Optical Fabrication Shop, LLE/COI Electronics, SEM/TEM Lab, and Thin Films Tech Shop.

## Student Tuition

Tuition charges for graduate research assistants may be requested in proportion to the percentage of effort the student is devoting to the project. For example, if the student is devoting 50% effort on a project, tuition should be prorated to 50% of the tuition expense. Departments should consult their College or School for guidance on proposing tuition costs. Current tuition rates and fees may be obtained from the Deans' Offices or from the [Proposal Budgeting Information Table](#).

### Note

Some sponsors limit the total amount of compensation (salary, benefits and tuition) to graduate students. NIH, for instance, limits the amount of graduate student compensation paid from research grants to the amount paid to a first-year postdoctoral employee. Information on agency limitations is available from ORPA. Tuition, scholarships, and fellowships are excluded from F&A costs.

## Publication Costs

Publication costs consist of the documenting, preparing, publishing, and sharing of project findings and supporting material. Budgets should indicate the name of the journal, page charges, number of pages and the estimated costs. If color reproductions are required (to accurately depict a photograph) it should be explicitly justified.

## Human Subject Fees

Human subjects sometimes receive financial compensation for their participation in research projects or clinical trials. The number of subjects and related fee should be stated in the budget. Guidance on appropriate fees for human subjects can be obtained from the Office for Human Subject Protection (x3-4127).

## Patient Care Costs

Patient care costs may include the following: inpatient room charges; use of outpatient space; ancillary tests (e.g., laboratory, radiology); supplies used directly with patients (e.g., IV bags, syringes, drugs, disposables); food provided to patients as part of special research diets. Expenses such as separately identifiable nursing and dietary salaries, equipment and non-patient supplies are charged to other expense categories. Patient care expenses are excluded from F&A costs.

## Rental Space

Lease and rental expenses for non-university buildings, offices and storage areas are included in this category. Budgeting should be based upon actual experience or upon the actual lease agreements. PI's requesting reimbursement for rental property should contact the appropriate Dean's Office and make sure that all such proposals are approved in advance. Proposals should list the type of lease or rental and the estimated costs. PI's proposing at the off-campus rate may include the costs of space rental, in addition to building maintenance and upkeep, if appropriate. Rental costs of off-site facilities are excluded from F&A costs.

## Alterations/Renovations or Construction

Costs of alterations or construction to a sponsored project are rare and must be fully justified and supported. PI's should discuss any proposed renovation charges with the

sponsor's scientific liaison in advance. Proposals directly in response to a RFP for a facilities construction grant are generally limited per institution. All such proposals are coordinated with the Department and Dean's Offices, and approved proposals coordinated with University Facilities.

#### Note

Capital expenditures for construction, alterations and/or renovation are excluded from F&A costs.

## What are Facilities and Administrative Costs?

As previously mentioned, Facilities and Administrative (F&A) costs (or indirect costs) are real costs that cannot be separately identified or measured for a specific project, but are shared costs with other activities. At the University of Rochester, the F&A cost rate is comprised of the following components:

### Facility Components

- *Building Depreciation:* Depreciation on all University buildings less any federal funds;
- *Equipment Depreciation:* Depreciation on all University owned equipment not purchased with federal funds;
- *Operations and Maintenance Expense:* Utilities, maintenance and repair of University buildings;
- *Library:* Library operations including the purchase of books, journals and serials, less any applicable credits.

### Administrative Components

- *General Administration:* Administrative salaries and expenses of offices such as the President, Provost, Human Resources and Purchasing Services;
- *Department Administration:* Administrative salaries and expenses of Department and Dean's Offices;
- *Sponsored Project Administration:* Expenses of ORPA, SPA, RSRB, and related activities.

The University develops an F&A forward pricing proposal from the actual costs of a base year. UR has been negotiating multiple-year predetermined rates since FY '94. The rate is based upon an analysis of indirect costs associated with all sponsored program activity for the prior year and is developed by the Office of Indirect Cost Accounting. This proposal is submitted to our cognizant federal audit agency. Effective July 1, 1997, the University's cognizant audit agency is the Department of Health and Human Services. More information on F&A costs can be obtained from the *Faculty Senate Meeting Minutes* (May 1996).

## Negotiated F&A Rate

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The University of Rochester only negotiates a research rate with the Federal Government. (Some schools negotiate separate rates for research, instruction or other types of sponsored projects such as public service.) The current on-campus and off-campus rates are listed on the [Proposal Budgeting Information Table](#).

## Explanation and Example of MTDC Base

The F&A cost rate is applied to a Modified Total Direct Cost Base. The base is comprised of most of the direct costs of a specific project; however, there are several costs that are specifically excluded from the F&A cost charge. These exclusions have also been negotiated with the federal government. The exclusions are:

- capital equipment costing \$1,000 or more (including fabricated equipment and fully costs shop;
- tuition remission, scholarships, and fellowships;
- costs of each subcontract (for substantive work) in excess of the first \$25,000 for the entire project period;
- costs of any construction, alternation and/or renovation;
- rental costs of off-site facilities;
- patient care costs.

The calculation of F&A costs can be confusing, therefore, the following example is provided for clarification:

### Example 2-4 Figuring the MTDC Base

The total direct cost proposed to the National Science Foundation by Dr. Smith equals \$335,000. This sum includes \$12,000 worth of equipment, \$20,000 in graduate student tuition and a \$115,000 subcontract to MIT.

Total Direct Costs	\$335,000
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Minus exclusions:

Capital equipment (\$1,000 or more)	\$ 12,000
Subcontract balances over \$25,000	\$ 90,000
Fully costed shop charges	0
Off campus space rental/lease	0
Patient care costs	0
Student tuition	\$ 20,000
<b>Subtotal (Exclusions)</b>	<b>\$122,000</b>
<b>= MTDC</b>	<b>\$213,000</b>

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(Multiply by the current F&A rate)	x 59%
F&A (Indirect) Costs	\$125,670
<b>TOTAL PROJECT COSTS</b>	<b>\$460,670</b>

### Off-Campus Rate

A project is considered to be performed off-campus if the activity is conducted at an off-campus location for thirty (30) consecutive days or more. It is possible to split large projects into on-campus and off-campus rates; however, this is to be done only with the written approval of the applicable Dean's office and after careful determination of what costs are applied to the respective rates. Any exceptions to the federal definition of an off-campus rate constitute a waiver of F&A and are subject to the waiver policy noted on next page.

### Clinical Trial Rate

The F&A assessed to clinical trials supported by pharmaceutical drug companies is 30% based on total direct cost (rather than modified total direct cost). The only exclusion to the F&A charge is the IRB fee. Further discussion on clinical trial budgeting is found in Section 4.6.

### Other Applications of the F&A Rate

There are several sponsors who, through published policy, limit payment of F&A. These sponsors primarily include foundations, voluntary health organizations and state agencies. The University will abide by the written policies of these organizations. If a sponsor does not have a written policy on the payment of F&A, the full rate must be requested in the proposal unless a waiver of F&A is obtained.

It may be appropriate to propose a reduced F&A rate for non-research proposals (e.g., service, testing agreement). Approval for reduced F&A rates for non-research activities should be obtained from the appropriate Dean's office.

### Waivers of Indirect Costs

Waiver authority of F&A is vested in the Deans' offices. "Automatic" waivers are granted to those federal, state and non-profit programs that have written guidelines on limitation of indirect cost rates, such as the federal restriction of 8% on training grants or American Cancer Society's limitation of 20% on all grants. Information on the written policies of a sponsor's reimbursement of F&A costs can be obtained from ORPA. F&A waivers should be discussed with the Dean as soon as possible when planning to submit a proposal. Requests for F&A waivers are initiated by the Principal Investigator and must be approved by the Department Chair and Dean's office. Sufficient information should be provided to the Chair and the Dean in order to make an informed decision on the waiver. PI's should, at a minimum, provide a rationale as to why the waiver is required, the likelihood that an award may be jeopardized without the waiver, and the total budgetary impact on the University, School or College and Department. ORPA does not have the authority to waive or

reduce F&A. Requests for waivers in research proposals to commercial organizations are discouraged.

## 4.5 Cost Sharing

### Cost-Sharing Definition

OMB Circular A-110 defines cost sharing as “that portion of project or program costs not borne by the federal government.” Cost sharing is the amount of project costs that the University of Rochester will contribute towards a sponsored project regardless of sponsorship.

### Matching Grants

Matching grants are grant programs that require that funds be matched proportionately by other sponsors or the institution. Some of our federal and state sponsors require matching support from non-governmental sources, such as from industry.

### Proposing Cost Sharing

The University’s [Policy and Procedures on Cost Sharing](#) defines allowable and unallowable cost sharing. In general, contributed effort will be the primary source of University cost sharing. The policy further describes the approval process required for cost sharing; a [Proposed Cost Sharing Commitment Form](#) must be completed at the time of University Sign-off for all mandatory cost sharing and significant voluntary cost sharing. The Dean’s office should be contacted well in advance of the deadline when cost sharing is involved. It is the University’s policy that PI’s should limit voluntary cost-sharing commitments to those instances where a cost sharing commitment is a stated criteria for review.

#### Note

Significant cost sharing does have an effect on the University’s F&A rate.

## 4.6 Budgeting for Industry-Supported Clinical Trials

In general, the PI is usually presented with a per patient cost by the pharmaceutical company. It is the responsibility of the PI to ascertain whether the per patient amount is adequate to cover all trial expenses. The **Clinical Research Standard Operating Procedures Regarding Financial Oversight and Billing Compliance** provide the University’s expectation for responsible budgeting and negotiation. It is accessible through ORPA’s Clinical Trial Resources Share Point site at <http://uofr.rochester.edu/SiteDirectory/ORPA/CTP/default.aspx> .



## PRE-AWARD SERVICES

### 5.1 Overview

Financial assistance may come to the University of Rochester via: (1) sponsored programs; (2) gifts; and (3) individual student support or fellowships. ORPA often works in concert with the various University Development Offices in the announcement of funding programs and the submission of proposals, especially those programs that limit the number of applicants. In the area of corporate and foundation support, the Development Office(s) can provide additional service in locating potential sponsors of projects and in providing assistance with proposal writing and presentation. ORPA administers fellowships from federal sponsors such as NIH National Research Service Awards, NSF Graduate Fellowships and the Department of Education Jacob Javits Fellowships. Proposals and awards solely for individual student scholarships, student loan support, University-internal graduate awards and fellowships are normally not coordinated or processed through ORPA. Coordination of these awards is described below:

### 5.2 Student Support and Fellowships

Students seeking funding information should first check with their school, college or the following offices:

#### Office of Financial Aid

The Office of Financial Aid offers financial aid advising and processes undergraduate loans and awards, scholarships and grants.

#### Office of Graduate Studies

The Office of Graduate Studies administers University-wide graduate fellowship awards, such as the Sproull, Hooker, Messersmith and Ball fellowships. This office also coordinates the Provost's Fellowships, which are for prospective minority doctoral students. Since graduate studies are decentralized to the college level, all financial support (e.g., scholarships and awards) is ultimately signed off through the Associate Dean for Graduate Studies office for each College/School.

#### Associate Deans for Graduate Studies

Fellowships are awarded directly from the River Campus colleges and the School of Medicine and Dentistry; a list of these can be found in the *Graduate Studies Official Bulletin*. Other fellowships for graduate work from the Eastman School of Music are described in their own bulletin.

## 5.3 ORPA Pre-Award Resources

### GENIUS/SMARTS

GENIUS/SMARTS is a comprehensive database developed by InfoEd International, Inc. GENIUS, Global Expertise Network for Industry, Universities and Scholars, is a global web-based network and database of scientific and scholarly expertise. GENIUS contains primary source profiles of scholars and researchers at leading universities and research institutions throughout the world, including the University of Rochester. SMARTS, Spin Matching and Research Transmittal System, provides faculty with a targeted electronic link to comprehensive current U.S. federal and non-federal and international research funding information as well as automatic notification of funding opportunities.

### SPIN

Sponsored Projects Information Network (SPIN), another InfoEd International product, is a computer database with detailed and up-to-the-minute information about thousands of government and private funding opportunities. SPIN searches are a service provided by the ORPA Pre-Award Specialist, and the SPIN database is available to the university community for its convenience. Information regarding registration and use of both the GENIUS/SMARTS and SPIN databases is available through the ORPA office.

### ORPA Web Page

The ORPA website helps to facilitate the University faculty in obtaining important grant and research administration information quickly. The site is found at:

<http://www.rochester.edu/orpa>

Government, non-federal and private agencies can be found quickly through the funding opportunities section. There is a separate section for sponsors, which includes the National Institutes of Health and the National Science Foundation and contains links to funding policies, deadlines and application forms. The ORPA website continually captures new information to better inform the University community of available funding and cutting-edge research.

### Electronic Media

ORPA provides links to many electronic media services including the Federal Business Opportunities, Computer Retrieval of Information on Scientific Projects (NIH CRISP), Federal Register of Domestic Assistance, Federal Register, Code of Federal Regulations, NIH Guide, NSF Guide to Programs and E-Bulletin .

## ORPA Library

ORPA maintains a source file of current guidelines and funding information for many sponsors. Several reference books and periodicals that list funding sources are available through ORPA including the *Guide to Federal Funding for Education*, *New York State Grants Guide*, *Guide to Grantmakers in the Rochester Area*, *Guide to Grantseeking on the Web*, *Proposal Planning and Writing*, *Grant Application Writer's Handbook*, and *The Chronicle of Higher Education*.

## Funding Information Dissemination (aka UR-Funded)

The long-standing Faculty Interest Profile database (FIP) has been replaced with GENIUS/SMARTS. Faculty registered in GENIUS/SMARTS automatically receive funding information via email through the system. Broad Agency Announcements and major programs from government, non-federal and private agencies are reviewed by ORPA and forwarded through e-mail, by fax, or by hard copy to the Department Chair and applicable faculty. ORPA maintains a database that contains each faculty member's preferences for dissemination of funding information. Faculty may change their preferences or choose not to receive these notifications by contacting ORPA.

## 5.4 Limited Proposal Submissions

Some programs contain restrictions that limit the number of applications per institution. The University of Rochester has institutional procedures in place for selecting nominees/candidates for these programs and coordinates the responsibility for restricted programs either through ORPA or the Development Offices. In general, the responsibility for selection of candidates for limited submission programs from more than School/College resides with the Provost.

The Limited Proposal Submission Matrix lists the most common limited submission programs, their limits, and the coordinating office. It is available by contacting ORPA.



# PROPOSAL REVIEW, APPROVAL AND PROCESSING

## 6.1 Overview

Each proposal must be reviewed and approved prior to submission to the funding agency. The review and approval may vary depending upon the nature of the proposal (e.g., new vs. continuation) and the extent upon which the proposed research needs additional review by University regulatory committees (e.g., human subjects, animals, and biohazards).

The [\*University of Rochester Proposal Sign-Off Form\*](#) must accompany the proposal. The approving signatures on the Sign-Off Form provide assurance that:

- the proposed project will further the teaching, research and clinical objectives of the University;
- appropriate personnel and facilities are available to carry out the project;
- all reasonable and allowable costs are included in the budget; and
- all policy and compliance issues have been addressed.

## 6.2 Review and Approval Responsibilities

As noted on the back of the Sign-Off Form, each person that provides a required signature has certain responsibilities in the review and approval process. Specific signatory responsibilities are described below.

### Principal Investigator

The title “Principal Investigator” is normally available only to full-time faculty positions, or full-time positions enjoying similar rights and privileges. The principal investigator is the person who:

- prepares a detailed description of the project (Statement of Work) and costs;
- assumes full responsibility for the scientific and intellectual direction of the project;
- supervises training of students and post docs;
- submits technical, progress, invention and financial reports on a timely basis;
- complies with federal and state laws and regulations including completion of an annual conflict of interest disclosure;
- assumes fiscal management of the project;
- complies with terms and conditions of award; and
- adheres to University policies, including completion of an Employee Intellectual Property Agreement (one time only).

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The PI's signature on the Principal Investigator's Certification section of the University Sign-Off form signifies that the PI accepts responsibility for all of the above, and includes confirmation that the conflict of interest disclosure has been completed and updated if necessary.

### Department Chair

The signature of the Department Chair signifies that the proposal has been considered and approved for the following conditions:

- the relevancy and appropriateness of the project and its long-range impact to the Department;
- the Department accepts the obligation of space and/or personnel allocations, renovations or cost-sharing requirements;
- the project as proposed can be carried out within the Department's financial and administrative constraints; and
- the Chair has received a Conflict of Interest Disclosure from the PI and any policy issues, such as potential conflicts of interest, have been considered and resolved.

### Dean

The signature of the Dean signifies that the proposal has been considered and approved for:

- exceptions to PI status or waivers of less than full recovery of indirect costs;
- new/renovated space required by the project;
- cost-sharing or matching commitments by the School or College; and
- management potential or perceived conflicts of interest.

### Office of Research and Project Administration

The signature of the ORPA Research Administrator signifies that:

- the University of Rochester has reviewed and endorsed the proposal.
- in the University's best estimation, the Statement of Work can be performed at the proposed funding level;
- any unique policies of the School/College have been considered;
- the proposal meets the requirements of the potential sponsor; and
- University of Rochester will comply with all federal and state laws and regulations, as well as University policies.

Other signatures may be required depending upon the nature of the proposal. These additional signatures are described in the explanation of the considerations of the Sign-Off Form.

IMPORTANT

If a proposed project is cross disciplinary and involves personnel salary recovery or facility use from departments other than the department of the PI, the chair and dean of those involved personnel must review and approve the project..

## 6.3 Required Information on the Sign-Off Form

The top part of the Sign-Off Form requests identification of basic information about the proposal. While largely self-explanatory, some clarification on this part of the form is provided below:

### Principal Investigator

As noted in the *Faculty Handbook* and the University's [Principal Investigator Eligibility Policy](#), only full-time faculty members may be named Principal Investigators. Any deviation from this requires the approval of the Chair and Dean.

### Deadline

The date the proposal must be received by the sponsor should be noted. The deadline may be a postmark date, or the date of receipt by the sponsor. Please check the sponsor's instructions carefully.

### Proposed Start Date and End Date

For new proposals, the proposed project period should be stated. For continuation proposals, state the budget period.

### Total Project Budget

For new proposals, state the total cost of the proposed project. For continuation proposals, state the total cost of the budget year being requested.

### Proposal Type

1. New. Proposals that are being submitted for the first time.
2. Continuation. Request for continued (e.g., 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup> year) support on a project that has already been approved, and for which funds have been previously committed by the sponsor. Also known as a non-competing continuation.
3. Supplement. Request of additional support for a currently funded project (e.g., NSF, REU, DOD AASERT, and NIH Minority Supplements).
4. Re-Submission. Proposals that have been rejected and are being resubmitted to the same agency.

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5. Renewal. Request for additional support beyond original project period. These proposals are subject to the same sponsor review criteria as new proposals.

## F&A Rate

The facilities and administrative (indirect) cost rate used in the proposal budget should be stated.

## Purpose

1. Research. Scientific inquiry with scope of work normally defined by the University PI.
2. Training. Agreement that provides specific support for training of students or postdocs.
3. Fellowship. Individual award providing support for training of students or postdocs.
4. Service. Work performed at University or other facilities in support of an external request; scope of work generally is defined by the sponsoring agency. Clinical services are a subset of service agreements where specific tests/assays are completed or patient services rendered.
5. Other. Other activities that are supported by external sponsors and fall under the definition of sponsored programs, such as curriculum development, travel and conference grants.

## Project Location

1. On-Campus. The project is conducted in University-owned facilities or buildings
2. Off-Campus. The project is conducted at an off-campus location and the activity is conducted off-campus for thirty (30) consecutive days or more.

## Administrative and Policy Considerations

The bottom half of the Sign-Off Form lists various considerations and certifications required to be made by the Principal Investigator. Brief discussion and clarification on these considerations is provided below.

1. New Space or Renovation. The University undertakes careful review of any proposed change to campus facilities. Review takes into consideration program need, availability of resources, safety code, feasibility of renovation and aesthetic considerations. Any proposal involving the request for new facilities or renovations to existing space or building systems should be discussed with the Dean. As stated on the Sign-Off Form, the Director of Medical Center Space Planning must approve new space or renovation requests for the Medical Center.
2. Cost Sharing. Cost sharing is defined as the portion of project expenses that is not funded by the sponsor. A Proposed Cost-Sharing Commitment Form must be completed for all mandatory cost sharing and significant voluntary committed cost sharing. ORPA will not authorize proposals including cost sharing unless this form has been completed and approved.

3. Human Subjects. DHHS defines the use of human subjects in research as “*a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge...*” using “*living individual(s) 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.*” (Code of Federal Regulations Title 45, Part 46.102(d) (f)). The FDA defines research as “*any experiment that involves a test article and one or more human subjects, and that may be submitted to the FDA or held for inspection by the FDA as part of an application for a research or marketing permit.* For research involving drugs, an experiment is “*any use of a drug except for the use of a marketed drug in the course of medical practice.*” The FDA defines “human subject” as “*an individual who is or becomes a participant in research, either as a recipient of a test article or as a control. A subject may be either a healthy individual or a patient.*” For research involving medical devices, a human subject is also “*an individual on whose specimen an investigational device is used.*” Some funding sponsors (e.g., NIH) now require human subjects approval only at the time the proposal is identified to be in a fundable range after peer review (“just-in-time”). Even if the sponsor adheres to such just-in-time approval requirements, the University requires that all gene transfer research and all protocols for new investigators be reviewed by the Research Subjects Review Board (RSRB) prior to proposal submission. Read sponsor instructions carefully, and contact the RSRB or ORPA office if you have any questions.
4. Animals. The University Committee on Animal Resources (UCAR) must review all proposals using animals. The UCAR approval form must be appended to the Sign-Off Form. If approval is still pending, documentation from UCAR must be attached. Some sponsors will not accept pending review status; read sponsor instructions carefully.
5. Radioactive Isotopes. Any use of radioactive materials must be noted. This information is conveyed by ORPA to the Radiation Safety Office upon request.
6. Less Than Maximum F&A Costs. Check “yes” if the proposal requests an F&A rate that is either:
  - less than the full negotiated F&A rate;
  - less than the full clinical trial rate, or;
  - limited in F&A recovery in absence of a written, published policy by the sponsor.
7. Potential Prospect for Commercialization. The purpose of this question is to inform the University that the proposed project may involve non-standard proprietary information. Concerns with respect to inadvertent disclosure of patentable information should be directed to the Office(s) of Technology Transfer.
8. Subcontracts. Indicate whether a portion of the work will be subcontracted and how many subcontracts are proposed.
9. Consulting/Management/Equity Interest. Affirmative response to this question may reveal a potential conflict of interest situation and requires further evaluation in accordance with the University’s Conflict of Interest Policy. See consideration 10 below.

10. Conflict of Interest. In accordance with the University's [\*Faculty Policy on Conflict of Interest\*](#) all Key Personnel (defined as faculty members or other individuals who are named on an external funding proposal as key individuals) are required to make an annual disclosure to their supervisors of all outside remunerative and other activities related to their teaching, research and administrative responsibilities. It is the Chair's responsibility to review the named key personnel and assure that an annual disclosure form has been submitted by each.
11. Supplemental Conflict of Interest Form for NIH/NSF. For NSF and NIH proposals, a Supplemental Conflict of Interest Disclosure form is required when significant financial interest related to the research proposal exists. It is a federal requirement that such disclosures are to be submitted in advance of proposal submission to the agency.
12. Debarment or Suspension. This regulation requires that applicants for federal funds certify that neither they nor their researchers:
  - Are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any federal department or agency.
  - Have, within a 3-year period preceding an application, been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain or performing a public transaction or contract under a public transaction; violation of federal or state antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property.
  - Are presently indicted or otherwise criminally or civilly charged by a government entity (federal, state, or local) with commission of any of the offenses enumerated in the previous paragraph.
  - Have, within a 3-year period preceding this application, had one or more public transactions (federal, state, or local) terminated for cause or default.
13. Procurement Integrity Act. This Act prohibits soliciting post-government employment, offering or accepting gratuities, and soliciting or disclosing proprietary or source selection information. For contracts over \$100,000, ORPA may require that the PI sign an additional certification form.
14. Lobbying. The PI is certifying that no appropriated funds were expended to influence an office or employee of any federal agency, a member of Congress, or an officer or employee of Congress in connection with the proposal.
15. Authorization of Purchases. It is the policy of the University that PI's designate in writing those individuals authorized to incur project expenses.

16. Collaborative Inter-School/College Programs: By mutual consent of the respective Deans, Chairs and Principal Investigators, sharing of indirect cost recovery may be designated on awards supporting collaborative inter-School/College projects. This allocation is determined at the time of proposal sign-off utilizing the [Sharing of Indirect Cost Recovery Form](#). For further information, please refer to the *Policy on Sharing of Indirect Cost Recovery for Collaborative Inter-School/ College Extramurally Funded Programs*.
17. Program Income. It is the responsibility of the PI to identify sources of actual or potential program income at the proposal stage. For a detailed explanation of what constitutes program income and related responsibilities of accounting for such, refer to the University's [Program Income Policy](#).

## 6.4 Routing of the Sign-Off Form and Proposal

Depending on the type of proposal, routing (sign-off) will involve the review and approval by various University offices. Full review by the PI, Chair, Dean and ORPA is generally required, unless the proposal is for an industry-supported clinical trial, or for the school of Medicine & Dentistry, excluded in accordance with its sign-off policy, or otherwise noted below. Additional information on the university's proposal process is found in the ORPA Guide entitled [Guidance for the Submission of Sponsored Project Proposals](#). Please note this list is not encompassing. Contact ORPA if there are questions with respect to proposal routing.

- **Preliminary Proposals:** As noted in Chapter 4, preliminary proposals are not normally required to go through the sign-off (routing) process; however, cost-sharing and other resource commitments should be discussed with the Dean's office in advance of submission. A copy of the preliminary proposal should be sent to ORPA.
- **Continuation Proposals:** Sign-off requirements for continuation (non-competing) proposals vary with each School/College and the appropriate Dean's office should be consulted. Note that the School of Medicine and Dentistry and the College do not normally review continuation proposals.

Other University reviews and/or signatures may be required if the proposal involves the following resources or research materials:

### Space or Facilities of Strong Memorial Hospital

If facilities such as patient rooms (other than the CRC), SMD laboratories, clinics or other SMD resources will be utilized in the proposed research, obtain the signature of the SMH Senior Director of Finance (x3-2072, MED 1-5532A).

### University Vivarium

The Vivarium reviews that the proposal contains appropriate per diem rates and that the Vivarium is able to house the number and types of animals proposed in the research. Obtain the signature of an authorized Vivarium representative (x5-2651, MED G-6726).

## Clinical Research Center

The Clinical Research Center (CRC) reviews the protocol associated with the proposed research, ensures that the research is in keeping with the CRC's mission and that the commitment for the CRC patient beds, space or staff is feasible. Obtain the signature of the CRC Director (x5-2907, MED G-5035).

## Biostatistics and Computational Biology

If the proposal involves the services of the Department of Biostatistics and Computational Biology, please obtain the signature of the Chair (x5-6696, SRB 4107). The Chair will review that adequate costs and professional effort have been included to support biostatistical services.

## Biohazards or Carcinogens or Recombinant DNA

Review by the Executive Secretary of the Institutional Biosafety Committee (IBC) is necessary to ensure that the University has adequate facilities to conduct the proposed research. Initial review has also been delegated by the IBC to the Radiation Safety Office and to ORPA. This signature is required to comply with federal and state regulations covering biohazards. If biohazards are involved, it is required that the level be checked. If you are unsure of what level the biohazards is classified, please contact the Institutional Biosafety Office (x5-3241)

## Personnel or Resources of Other Departments or Divisions

For those proposals indicating salary effort of faculty or staff of other University departments, divisions or units or resources (such as a lab or other facility), it is necessary to obtain the signature of the participating Chair(s) and Dean(s).

## Documentation Required during the Routing Process

Unless otherwise approved by the authorizing individuals, a copy of the full proposal must accompany the Proposal Sign-Off Form, including all budget forms and budget justification. All other forms required by the Sign-Off Form must be appended to the Sign-Off Form. The original proposal signature page must be routed to ORPA for institutional signature. The original University Sign-Off Form will be retained by ORPA. A copy of the full proposal (if not provided during the sign-off process) must be sent to ORPA within two weeks of the deadline date or the date of sign-off.

### Note

Individual departments may have other review and signature requirements in addition to those stated above.

## 6.5 Routing of Proposals for Industry-Supported Clinical Trials

Sign-off for these clinical trials is accomplished using the **University of Rochester Proposal Sign-Off Form For Industry-Sponsored Clinical Trials**. This form is accessible through ORPA's Clinical Trial Resources Share Point site at <https://uofr.rochester.edu/SiteDirectory/ORPA/CTP/default.aspx>. Clinical trial documentation (normally an internal-to-the-University budget and description of the protocol as submitted to the IRB) should go through University sign-off at the time the protocol and per patient budget have been determined. Dean's Office review will be required only if the study proposes:

- cost sharing;
- waiver or reduction of the 30% industry clinical trial F&A cost rate;
- additional space or renovation of current facilities.

In order to evaluate and document the proposed clinical trial's relationship to the state missions of the University of Rochester, the University requires that a Research Profile (located on the back of the sign-off form) be completed and routed through sign-off. It is the responsibility of the Chair or Unit Chief to review the Profile. The original copy of the Profile will be retained in ORPA.

### Note

The clinical trial agreement with the sponsor will not be signed by ORPA and, therefore, the study may not begin, until University sign-off has been completed.

## 6.6 Protection of Proposal Information

To protect against improper use by others and premature disclosure to the public of ideas, information, and data contained in a proposal, Principal Investigators may wish to include the following or a similar general statement on the face page of the proposal:

*"The contents of this proposal may not be disclosed to the public beyond the normal distribution necessary for proper review and evaluation for possible funding, nor used by the Government for any other purpose, without the express written approval of the Principal Investigator (or the Project Director) and an authorized official of the University."*

Alternatively, specific portions of the proposal may be prefaced on each page containing individual salary information or proprietary scientific information or data with a legend similar to the following:

*"Following is information that the University of Rochester considers proprietary and which it requests not be released to persons outside the Government (or sponsors) for evaluation purposes."*

## 6.7 Proposal and Award Tracking

Information from the proposal is immediately entered into ORPA's sponsored programs management system UR-Coeus. This information is critical for accurate reporting to the Dean's Offices and other University offices, as well as for ORPA's ability to answer sponsor inquiries. Further, if an award is made, incomplete information will delay the processing of an account number

## 6.8 Mailing the Proposal

Generally, the Principal Investigator's Department is responsible for making the necessary copies of the proposal and for mailing.

## 6.9 Site Visits

A site visit may be part of a sponsor's review of the proposed research. Site visits are generally made for very large and expensive projects, such as for program projects and center grant proposals. Normally, the site review team will be made up of scientific and administrative officers from or representing the sponsoring agency, sometimes a fiscal consultant, and a varying number of scientists specializing in the field with which the grant proposal is concerned. The site visit team generally reviews the following criteria:

- scientific merit of each component of the program and of the overall program;
- requested budget;
- use of human subjects/animals (notify UCAR and IRB of the visit as appropriate);
- contributions of subcontractors and collaborators;
- administrative structure;
- resources and environment; and
- overall strength of applicant institution and University's commitment to the project.

The agenda for a site visit is the responsibility of the Principal Investigator and should be submitted to the site visit Executive Secretary no later than one month prior to the visit. This will give the Executive Secretary a chance to review the agenda, as well as to review it with the site visit Chair.

They may suggest revisions based on their experience. These revisions should be accepted if at all possible. The following strategies have been provided to further assist PI's and Departments.

## Strategies

Place yourself in the site visitor's roles and remember that their task is to acquire additional information. Make it easy for them to write their reports by:

- providing a handout at the beginning of the site visit that includes copies of all slides and materials to be used at the site visit, organized and tabulated according to the agenda. The site visitors will use these directly to write program descriptions and their critiques.
- having all presenters available at all times throughout the site visit (in the room or on call).
- understanding that careful and critical rehearsals of presenters is essential.
- using an ample-sized conference room, preferably one with an oval or u-shaped table, and make sure presentation equipment is working.
- Being prepared to follow up on questions in writing. Do not assume because you made a specific comment during the site visit that it will become a part of the formal written record.

## Points to be Avoided

- Do not change budget requests the night before the visit. A revised budget constitutes a new application.
- Do not call or write individual site visitors or the site visit chair before or after the site visit unless requested specifically to do so.
- Please contact ORPA if an administrative official is necessary at a forthcoming site visit or if you have questions with respect to preparations for a site visit.

## 6.10 Pre-Award Audits

Any contract where budget exceeds \$500,000 per year is subject to a pre-award audit. This audit will occur prior to an award being issued. If an audit (Field Pricing Report) is required, the federal sponsor generally requests DHHS (local division) to review the proposal budget to ensure that it is adequately documented and that all rates are current.

Pre-award audits are generally coordinated through ORPA, but always require cost and pricing documentation provided by the PI and department.



## AWARD ACCEPTANCE

### 7.1 Types of Awards and Negotiations

#### What is An Award?

An award is broadly defined as financial support for a specific research project, training program, equipment purchase or service. The most common types of awards are grants and contracts.

#### Grants

Grants are normally financial assistance for basic research or training, with the scope of work originating with the Principal Investigator. Grants have general, standard terms and conditions that do not normally require negotiation by ORPA.

#### Contracts

Contracts are financial support of a specific task, with the scope of work usually originating with the sponsor. Contracts have terms and conditions, specific to the sponsored award, which generally must be negotiated prior to acceptance to be in accordance with University policy. These negotiations will be done by ORPA with the Principal Investigator being kept informed of the status.

Regardless of the type of award received, the University has certain responsibilities to the sponsor to complete technical reports and, in most cases, financial reports. A discussion of post-award responsibilities is found in Chapter 8.

### 7.2 Signature Authority

Signature authority for sponsored program contracts is with ORPA or the Senior Vice President for Administration and Financial Affairs and Chief Financial Officer. When the contract has been completely executed, a copy is sent to the Principal Investigator for his files.

#### Note

Investigators are cautioned not to sign University agreements for sponsored programs support, patents or copyright licenses, biomaterials sharing, equipment loans, and clinical trials. These agreements bind the University to certain obligations and, as such, can only be signed by those who have delegated corporate authority from the Board of Trustees, through the President and the University officers. Individuals signing agreements to which

authority has not been officially delegated are entering into personal agreements and will not necessarily be able to count on use of University facilities or be covered by University services, including professional or general insurance.

## 7.3 Account Establishment

Once a proposal has been funded and an official notification of the award (e.g., Notice of Grant Award, letter of award, fully executed contract) has been received from the sponsor, ORPA will request an account number for the project from ORACS. Currently, this can take from five (5) to ten (10) working days.

### Internal Award Notice

When the account number is received, ORPA will then produce the internal Notice of Award, which will indicate the University ledger 5 account number for the budget period, the F&A (indirect) cost rate, report due dates, outgoing years' committed support, and indicate any unusual requirements for the award. The Notice of Award, along with a copy of the sponsor's award notice or executed contract, is sent to the Principal Investigator, the Department Administrator and ORACS. Distribution of the Notice of Award differs among Schools/Colleges.

## 7.4 Pre-Award Account Establishment

### Contingent Ledger 5 Accounts

Under certain conditions, an Investigator or Department may request an account prior to the actual receipt of the award. This can be done according to sponsor guidelines and regulations through completion of a [\*Request to Issue a Contingent Ledger 5 Form\*](#).

#### Note

In most cases, pre-award account establishment cannot occur more than ninety (90) days prior to the actual award start date (without sponsor approval). The Department Chair or Division Chief must indicate approval of the request by signing the form and providing an alternate unrestricted account number, indicating willingness to assume fiscal responsibility for any charges if the award fails to materialize.

The [\*Request to Issue a Contingent Ledger 5 Form\*](#) must be completed by the Principal Investigator. Project title, project period, expected award amount, and the F&A (indirect) cost rate must be stated. In addition, on the back of the form, the Principal Investigator must state why pre-award costs are necessary.



## POST-AWARD ADMINISTRATION

### 8.1 Financial Management

#### Principal Investigator Responsibility

The Principal Investigator is ultimately responsible for accomplishing the technical goals of the project and also for fiscal management in accordance with sponsor and University regulations. These fiscal management responsibilities include:

- authorizing only those expenditures that are reasonable and necessary to accomplish the project goals and are consistent with the sponsor's terms and conditions;
- spending no more than the amount authorized by the sponsor for the project period;
- charging project costs directly to the appropriate project account (thus avoiding unnecessary cost transfers);
- reviewing expenditures in a timely fashion to assure their appropriateness and correctness;
- documenting cost-share commitments; and
- documenting and monitoring program income.

Therefore, personnel action forms, requisitions, purchase orders, travel and conference reports, and Requests for Payment should carry the signature of the responsible Investigator or other person specifically authorized in writing (as noted on the grant proposal Sign-Off Form) to make charges against the account.

ORPA and Sponsored Programs Accounting (SPA) will assist investigators and administrators in order to comply with financial and postaward regulation compliance. Principal Investigators and administrators should refer to the *Finance Manual* and the Finance web site for proper financial management practices.

#### Plan Confirmation System (Time and Effort Reporting)

The University is required by the federal government to review and certify to the time and effort spent by employees on sponsored programs via the Plan-Confirmation System. This system reflects activity applicable to each sponsored agreement and to each category needed to identify F&A (indirect) cost and the functions to which they are allocable. Certification is done twice per year to cover calendar year and academic year salary distribution plus summer salary obligations. The certification is in the form of a statement signed by the employee, PI, or responsible officials, stating that the salary and wage distribution is a reasonable reflection of effort devoted during the period.

## Rebudgeting

Sponsors have different policies for the rebudgeting of funds. Some sponsors allow latitude in making budget revisions and most requests for budget revisions from one budget category to another can be handled on the institutional level. ORPA staff can help to determine whether the award agreement and sponsor permit reallocation among budget categories. A written request to the sponsor, countersigned by ORPA, may be required. Any rebudgeting request must detail how this request will benefit the statement of work on specific aims.

### Note

In accordance with University policy, rebudgeting into clerical and administrative personnel on federally funded awards may only be done if these positions have not been specifically deleted by the agency or prior approval from the agency is not required. Any appointment or payroll reallocation form for clerical or administrative personnel indicating a ledger 5 account should be accompanied by a justification of costs and routed through ORPA for approval.

## Accounting Corrections

Errors in charges or accounting can be corrected by written justification and certification to ORACS. Adjustments must be requested as soon as possible. Requests for transfers sixty (60) days after the ledger dates require the signature of the PI and Department Chair. Requests for transfers in excess of ninety (90) days require the signature of the PI, Department Chair and Dean. This requirement holds true even for transfers necessitated by data entry error since ORACS has no control over the accuracy of data input. Therefore, careful review of monthly ledgers is critical to avoid delayed corrections.

## Deficits

If the project's expenditures exceed the sponsor's award and/or payment upon completion of project, the Principal Investigator will be asked to identify another funding source (normally an unrestricted or department account) to cover the cost overrun or uncollected accounts receivable. Please reference the University's *Policy Relating to Restricted Accounts in Deficit Position* which can be obtained from ORACS, or the [\*Policy on the Transfer of Surplus/Deficit Balances on Ledger 5 Accounts\*](#).

## Personnel Policies

Employees that work on sponsored programs will be subject to University personnel policies and procedures. Various reference manuals, including the *Faculty Handbook*, *Personnel Policies and Procedures Manual* (for non-academic employees) and *Regulations of the Faculty* should be consulted and followed.

Payroll costs for employees working on a sponsored project should be reflected at the level of effort proposed and actually performed. Any salary adjustment, including promotional increases, must be consistent with institutional procedures.

## Summer Compensation

As noted in Chapter 4, monthly salary for summer employment of academic staff members that are on nine-month appointments is computed by taking the annual salary for the forthcoming academic year and dividing by nine. Faculty members with academic year appointments can normally request no more than 2.5 months per year summer employment from sponsored programs. Three months of summer employment requires additional approval from the Department Chair and Dean.

### Note

Some sponsors may have additional restrictions on summer employment. For instance, the NSF will not pay for more than two (2) months of summer compensation per year.

## Extra Compensation

Intra-University consulting by faculty is assumed to be undertaken as a University obligation that requires no additional compensation. However, in unusual cases where consultation is across departmental lines or involves a separate or remote operation and the work performed is in addition to the faculty member's regular duties, extra compensation may be allowable provided that such consulting agreement is specifically provided for in the agreement or approved in writing by the sponsoring agency. Payment for extra compensation from ledger 5 accounts must be approved by ORPA, in addition to other required signatures, on the Form 211 (Extra Compensation).

## 8.2 Other Post-Award Changes and Approvals

Any revisions to the performance of a project that require sponsor approval must be coordinated through and endorsed by ORPA. In general, the following revisions require sponsor approval:

1. change in the State of Work or research objectives;
2. increase in the amount of funds budgeted;
3. change in status of the PI or key personnel working on the project;
4. change in budget that does not fall within authority prescribed by a sponsor;
5. change in period of performance.

Requests to modify an award are coordinated through ORPA for sponsor approval. Normally, sponsor approvals are handled by sending a letter that details the need and justification for the change. This letter is written by the PI and countersigned by ORPA.

As mentioned in the rebudgeting section above, sponsors have differing administrative policies and ORPA should be consulted when considering a revision to a sponsored program.

## No-Cost Extensions

The expiration date of a grant or contract usually may be extended if additional time is needed to assure successful completion of the project. These are referred to as no-cost extensions. The project's budget period may be extended where justified, normally, for up to twelve (12) months beyond the ending date of the budget period as shown on the award notice, but this depends on the sponsor's policies. Extensions are generally made without additional funds.

Some federal sponsors have delegated authority to universities to approve one-time, no-cost extensions on grants. For these sponsors, the PI must notify ORPA of the necessity of the no-cost extension including the required time needed and a justification for the extension. It is ORPA's responsibility to notify the sponsoring agency and to make internal adjustments to the award.

Written requests for no-cost extensions (for those agencies and awards where we have no delegated authority) must be made at least sixty (60) days before the end of the currently active budget period. Written requests should be generated by the PI and include:

- the reason why the extension is needed;
- the month, date and year that the PI expects to complete the work, and
- the amount of residual funds and how they will be used during the no-cost extension.

## Change in Principal Investigator

Generally, if a PI is absent from a project for a period of three (3) months or more, a substitute PI must be proposed and approved by the sponsor. It is possible for a PI to take a sabbatical and continue to actively work on the sponsored project; this situation is not considered an absence. The PI must notify ORPA and the sponsor's program officer, at least thirty (30) days before departure or as soon as the expected absence is known.

Requests for change in PI should include a justification for the change, the curriculum vitae of the new proposed PI, and any budget changes resulting from the change (such as differences in salary). The new proposed PI, Department Chair and Dean must endorse the request.

## Transfer of Principal Investigator

If the PI moves to another institution, the grant may be transferred with the PI, pending approval from the Department Chair, the new institution, and the sponsor. Generally, the grant does transfer with the PI; however, criteria for this decision include considerations such as time left on the project, remaining funds and whether the new institution has adequate facilities, equipment and/or staff. Normally equipment purchased for a sponsored program will transfer along with the program, however, University equipment disposition procedures must still be followed; see below.

## Purchasing Procedures

Purchase of goods and services for sponsored projects must comply with both University policies and sponsor restrictions. The *Purchasing Guide* should be followed in making purchases for

sponsored programs just as for any other procurement. In addition, particular conditions of the award should be consulted. Some awards prohibit certain purchases, others may require advance approval of the sponsor – advice on these restrictions is available from ORPA. Another thing to keep in mind is the allowability and allocability of any purchases made from sponsored funds, and the time period of the award for which purchases are made and charged to the project. Note that a Purchase Order for any item that is to be paid for from sponsored program funds must be completed during the approved period of the grant or contract. The Purchase Order must be dated and issued prior to the end of the grant period. Purchases should be allocated to the appropriate sponsored research projects. If more than one grant funds a research laboratory and the item will be used by one or more projects, the expense should be appropriately charged to each grant.

## Purchases Near to Termination Date

Items not received during the project period are not considered by an agency to be of benefit to the project and may be disallowed. Therefore, orders for supplies and equipment should be placed well in advance of the account expiration date to ensure delivery and use before the project terminates.

## Equipment Purchases

The definition of equipment can be found in Chapter 4. Ideally, all equipment purchases are itemized and approved in the original proposal. Prior approval may be needed from the sponsor to buy equipment not previously authorized. As a rule, general-purpose equipment such as computers or furniture will not be approved unless it's justified as used primarily or exclusively for the actual conduct or research or technical activities. Therefore, any requisition requesting general-purpose equipment not itemized in the approved budget must include a justification from the PI. This justification must be retained with the Department. Additional guidance with respect to equipment purchases is found in [\*Guidelines on Determining the Allocability and Allowability of Equipment Purchased from Sponsored Program Funds.\*](#)

## Equipment Fabrication

Fabrication is defined as special purpose equipment that is to be assembled or fabricated that will result in an article of non-expendable tangible property. Fabrication is allowed when it is more economically feasible or if fabrication is the only means of acquiring specialized equipment. The special purpose equipment must result in an article of non-expendable tangible property having a useful life of more than one year and a total acquisition cost of \$1,000 or more. Usually, the fabrication is approved by the sponsor in the proposal budget. It is the PI's responsibility to notify ORPA when a special purpose equipment item is to be fabricated. A memo documenting the description of the item, a scientific justification, a breakdown of the items and costs that will be used in the fabrication and the total cost of the components must be sent to ORPA. Upon receipt of that memo, ORPA will send a separate memo of approval to the PI with copies to Sponsored Programs Accounting and Property Accounting. Property Accounting will then notify the PI of the property tag number assigned to the fabricated piece of equipment. This tag number must be referenced on all requisitions for components of the fabrication. It is also the PI's responsibility to notify ORPA and Property Accounting when the fabrication has been completed. Please refer to the University's [\*Policy on Fabrication of Special Purpose Capital Equipment.\*](#)

## 8.3 Purchasing Outside Services

### Consultants

Investigators wishing to engage an independent consultant should contact Purchasing Services to obtain a Services Request Form and for assistance in preparing the requisition and attachments. Investigators should also refer to Personnel Policy No. 122, *Employee/Employer Relationships vs. Independent Contractors* and be familiar with the independent contractor/consultant request and contracting process. Questions with respect to the process should be referred to Purchasing Services. When hiring an external consultant, the Principal Investigator should keep in mind the following tests that determine the appropriateness of such a consultant.

- That the consultant is doing work independently without supervision;
- That the consultant has not been a recent employee of the university; and
- That the consultant is using his/her own facilities or equipment to conduct the work.

Again, prior sponsor approval may be required for the use of consultants not authorized on the approved budget. For further guidance, please contact your ORPA representative.

### Subcontracts or Subrecipient Agreements

A subcontractor or subrecipient is normally defined as a third party contracted to conduct a significant portion of the scope of work or research plan included in the research proposal. As such, use of a subcontractor is normally included in the funded proposal and is integral to the completion of the work (see Chapter 4). Therefore, a subcontract almost always requires prior sponsor approval.

#### Note

A subcontract issued from ORPA is normally for substantive work (e.g., the subrecipient is responsible for programmatic decision making and its performance is measured against meeting the objectives of the project); a purchase order for services issued by Purchasing Services is normally for vendor services (e.g., the vendor is providing goods and services within their normal business operations). ORPA and Purchasing Services can provide assistance on making the determination between a subrecipient and a vendor.

Prior to a subcontract being issued by ORPA, the PI must complete a [Request to Issue a Subcontract](#) form at the commencement of the subcontracting arrangement. A subcontract document (utilizing a University Purchase Order) is generated by ORPA, including a scope of work and budget, and appropriate flow-down terms and conditions of the prime grant or contract. When the subcontractor has agreed to the terms and conditions, the Purchase Order is activated and the

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subcontractor can invoice the University for incurred expenses. It remains the Principal Investigator's responsibility to monitor the activities of the subcontractor, to verify invoices submitted for payment, and to inform the prime sponsor and ORPA if significant changes are contemplated affecting the agreed-upon arrangement. For more information, a copy of the University's *Subcontract Policy and Procedures* is available from ORPA, or refer to the "[ORPA Guide for Subcontracting](#)".

## Human Subjects Payments

Because of the special IRS considerations inherent in payment of human subjects, please contact ORACS prior to initiating payments. The University has developed [Policy and Procedures on Payments to Research Subjects](#). These procedures, available from ORACS, should be consulted.

## Travel

The University's travel policies are detailed on the [Finance website](#); these travel policies and procedures apply to travel on sponsored accounts, unless the sponsor's policies are more restrictive. To be allowable, travel must directly benefit the sponsored project. The terms and conditions of the award will specify whether sponsor approval in advance (and in addition to approval on the approved budget) is required.

## Foreign Travel

Foreign travel may require specific prior approval for each trip and American flag carrier restrictions normally apply. Please consult ORPA if foreign travel restrictions are unclear.

## Property Management

Sponsors normally require that property purchased under sponsored agreements be used exclusively or primarily for the use of the sponsored project. Sponsors also differ in their vesting of title or reporting requirements. Some sponsored property will remain the property of the sponsor and should be managed with strict control. The Plant and Debt Accounting Office (within Finance) is responsible for the University's equipment management system, including inventory, record keeping, sharing, audit and disposition. Questions with respect to property management should be directed to Plant and Debt Accounting X5-6451.

## Vesting of Title

In general, for most government contracts, the University is directly accountable for each item of equipment at termination of the contract. Under most government grants, equipment is vested with the University, with the exception that certain agencies reserve the right to transfer the equipment following completion of the grant. This right is reserved to facilitate cases where the PI transfers to another institution and the grantee has no further need for the equipment.

## Surplus Property

The purpose of the University's Surplus Property program is to manage re-circulation on disposition of surplus property centrally to ensure appropriate controls and make items available University-wide. Administration of the program is the responsibility of Purchasing Services. Departments with surplus property should notify Purchasing Services/Surplus Property by processing a Property Disposition Form. Purchasing Services works closely with Property Accounting to assure that asset records are updated, a fair transaction price is established for any item(s) sold, and equipment purchased with government funds is not sold or transferred without proper authorization. ORPA will be involved when authorization is required. For further information, please refer to the [Surplus Property Policy](#).

### Note

Unauthorized removal, disposal, or expropriation of University or government owned, loaned or donated property constitutes a serious breach of University policy.

## Transfer and Disposition of Equipment

There are various federal regulations regarding the transfer and disposition of property. These regulations vary under differing circumstances of ownership (title), original cost, source of funds and current market value. In a situation where the PI is transferring to another institution, the equipment purchased under a sponsored project normally will transfer with the project. Even under this circumstance, a Disposition Request must be completed and Chair approval must be sought. Property Accounting will advise Principal Investigators or department administrators, upon request, with what technical requirements must be met regarding the transfer or disposition of equipment involving use of federal funds. For further information, please refer to the University's [Equipment Disposition Guidelines](#) available on the ORPA website.

## Intellectual Property

If at any time during the course of a sponsored project it is determined that there may be a potentially patentable invention or discovery, it is important to contact the UR Ventures Office. Generally, an invention disclosure is submitted to and reviewed by UR Ventures, and the decision is made with respect to pursuing patenting and licensing. Many sponsored program agreements require the submission of an invention disclosure report within a relatively short time frame. UR Ventures and ORPA will coordinate the submission of any disclosure or periodic invention reporting to the sponsor. For further information on the respective roles of ORPA, Ur Ventures and PIs with respect to intellectual property, please refer to the [ORPA Guide for Administration of Intellectual Property at the University of Rochester](#).

Definitions of and policies pertaining to copyrights, inventions, patents and the disclosure process are addressed in the University's Patent Policy found in the *Faculty Handbook* and [Policy on Intellectual Property and Technology Transfer](#). Questions that arise with respect to intellectual property developed

during the course of the sponsored program should be directed to the UR Ventures Office (x6-6600).

## Publications

Investigators are expected to publish results of their research activities. This right should be retained in all sponsored agreements. Credit should normally be given to the source of support of the project through an appropriate footnote; however, specific instructions in each grant or contract will govern. Under federal contracts and grants, all reports or papers submitted for publication should also bear this statement: *“Reproduction in whole or in part is permitted for any purpose of the United States Government”*. Some sponsors require prior or simultaneous submission of papers or abstracts to the sponsor; again, the award document and internal Notice of Award set forth specific requirements.

## Research Data

PI's should be familiar with University and faculty obligations and responsibilities regarding access to and retention of research data. Please refer to the University's Interim Policy on [Access to and Retention of Research Data](#) found on the ORPA web site.

## Freedom of Information

State and federal statutes guarantee the right of access to information about public agencies. When federal funding is involved, the Freedom of Information Act (FOIA) is the governing statute. Recent legislation dictates that research data related to published research finding produced under a federal award that were used by the government in developing a regulation be subject to FOIA. For further information on this legislation and procedures to be followed if faculty are requested to supply research data are found on the ORPA web site (e.g., “Research Data and FOIA”). With limited exceptions, University records such as policy documents and funded research proposals must be disclosed to the public upon request. In summary, only personnel and medical information and proprietary data (trade secrets, commercial information, unpublished information) can be withheld from disclosure under FOIA. Note that only information on funded proposals is released.

Normally, FOIA requests are directed to ORPA. ORPA will contact the Principal Investigator to inform him/her of the request and to ascertain whether there is any proprietary information that should be withheld. ORPA will, as standard practice, request deletion of any budgetary information from the proposal or grant prior to release.

## 8.4 Reporting Responsibility

Financial reports, management reports, reports of findings or progress, case report forms (for clinical trials), and invention disclosure are of primary interest to any sponsor. Most formal agreements will specify the type, form and frequency of reports. The Principal Investigator is solely responsible for meeting technical and all other programmatic reporting. ORACS is responsible for submitting financial reports using the University's standard accounting systems, reports and forms.

## Delinquent Reporting

Failure to submit the reports in a complete and timely manner can delay payment for final project

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expenses and favorable consideration of pending proposals. Some sponsors will not only withhold future awards to individual delinquent faculty, but also to any faculty member anticipating sponsor funding within the University.

IMPORTANT

The University considers timely reporting essential to the proper stewardship of sponsored funds. Therefore, ORPA will not sign off on any new proposal for faculty whom are delinquent in technical reporting by more than six (6) months.

## Close-out

ORPA is responsible for assisting PI's with closing a sponsored project by ensuring the timely submission of required final reports. Sponsors will differ in the types of reports that may be required at closeout. Most federal sponsors will require financial, invention and technical reports. Generally, these reports are due thirty (30) to ninety (90) days from the expiration date shown on the grant document.

## Final Technical Reports

Some sponsors require use of their own forms for final technical reports, or encourage electronic submission of final reports. These forms (such as NSF's FastLane "Final Project Report" form) are available in the sponsor's application packets, with the award document or on-line. Follow the sponsor's instructions for the preparation of final technical reports, which normally include a list of publications resulting from the sponsored project.

IMPORTANT

A copy of the face page of the final report or its transmittal letter should be forwarded to ORPA.

## Final Invention Reports

Copies of the appropriate final invention report or a certification form will be sent to the PI by ORPA. The PI must complete and return the form to ORPA; ORPA will mail the final invention reports to the sponsor.

## Final Financial Reports

A draft Summary Report of Expenditures (financial report) is prepared by the ORACS and will be sent to departments approximately thirty (30) days after the close of the project period. Expenditures against closing accounts should be processed as early as possible and arrangements made to move personnel and other on-going charges to another account. Draft summary reports should be returned to ORACS within three (3) weeks in order for them to complete the final report and meet the sponsor deadline, normally ninety (90) days after termination of the award. For more information, please contact ORACS.

## Final Property Reports

Final property reports will be prepared, certified and mailed by Plant and Debt Accounting. If title vests with the sponsor at time of completion and the PI wishes to have the title transferred to the University, he/she should contact Plant and Debt Accounting. Plant and Debt Accounting will prepare the letter to the sponsor requesting transfer of title to the University.

## Close-out Audit

Some sponsors may ask DHHS or their auditors to perform a closeout audit before any final payment of a contract or grant is made or before it is administratively closed by the sponsor. If the PI is contacted by a sponsor who would like to perform a closeout audit, please contact ORACS at x5-1648.

## 8.5 Record Retention

Federal regulations require grantees and contractors to prepare, maintain and keep adequate records of sponsored project activities. Non-federal sponsors, especially pharmaceutical sponsors, are also very specific with respect to the retention of study records. These requirements are generally incorporated into the University's [\*Policy on Record Retention\*](#).

Original ledger sheets, purchase orders, invoices, personnel files, payroll records and other official documents are retained by central University administrative offices. Therefore, it is not necessary for Principal Investigators or department offices to retain such documentation. Departments must, however, retain original copies of budget documentation, expenditure statements signed by the Principal Investigator, and all source documents and invoices that are used to charge direct costs on a grant or contract for a period of three years following final close-out of the award and payment. Final close-out, for the purposes of record retention is defined as final payment by the sponsor.

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This guideline does not apply to state contracts which often have a longer retention period of six (6) years or when there is an audit or litigation in process.



## OTHER AWARDS AND AGREEMENTS

Various types of non-federal awards/agreements are made to the University; special considerations are inherent in the acceptance of these awards. All awards must adhere to the basic policy considerations of the University, such as the ability to freely publish results.

### 9.1 Industry Agreements

It is the policy of the University to encourage interactions and research with the private sector. Such interactions are essential to the vitality of the University and this activity is recognized as an integral part of the University's mission and goals.

Research supported by industry should not commence prior to the execution of an agreement outlining each party's responsibilities. This agreement should contain basic understandings such as the agreed-upon statement of work, agreement on the University's ability to publish subject to sponsor review and the ownership of intellectual property. While it is the responsibility of ORPA to negotiate the terms and conditions, PI's should be familiar with the policies of the University in order to convey these accurately to a potential sponsor. This will permit all parties to have a clear understanding of the proposed research project and will allow negotiations to proceed smoothly.

The following considerations are important in dealing with industrial sponsors:

#### Statement of Work

The statement of work should be in sufficient detail that allows both parties a clear understanding of the research project and the expected deliverables (e.g., the technical reports or a prototype). Allowances should be made for changes in research direction by the PI. Should the statement of work change significantly, a provision should be made for a cost adjustment.

#### Time Period and Cost

A fixed period for the agreement should be stated with mechanisms for extension or renewal of the project. Full costs of the research should be paid by the sponsoring industry, including full recovery of the F&A rate.

#### Conflict of Interest

Consideration should be given as to existing or potential conflicts of interest between the investigator, the University, and the sponsoring organization.

## Warranties and Guarantees

The University conducts research programs using best and reasonable efforts, consistent with good scientific practices. As a result, it does not guarantee or warrant research products.

## Termination

Conditions of mutual termination, such as the departure of a PI or unforeseen circumstances, should be stated.

## Endorsement of Research Results

Because the University imposes no limitation on the freedom of the faculty in the choice of fields of inquiry or the media of public dissemination of the results obtained, any results obtained or disseminated are the sole responsibility of the PI and do not carry institutional endorsement of the University. Consequently, the University does not permit the use of its name in advertising or promotional material related to the results of sponsored projects.

## Sample Research Agreement

When the above considerations are used as guidelines, the final agreement should be one that is mutually beneficial to the University and the sponsor. The University's standard [research agreement](#), which may be sent to sponsors, is found on the ORPA web site.

## 9.2 Industry-Supported Clinical Trials

As stated elsewhere in the Manual, clinical trial agreements are broadly defined as the testing of a drug biologic or device on human subject. Because clinical trials are a form of industrial agreements, the considerations listed above in Section 9 apply to clinical trial agreements. The **Clinical Research Standard Operating Procedures Regarding Financial Oversight and Billing Compliance** provide the University's expectation for responsible budgeting and monitoring. This document should be reviewed prior to the initiation of a clinical study. It is accessible through ORPA's Clinical Trial Resources Share Point site at <https://uofr.rochester.edu/SiteDirectory/ORPA/CTP/default.aspx>. In addition, the following other matters deserve specific attention.

### Indemnification

Clinical trials are prone to legal action by third parties claiming to be harmed directly or indirectly by the research protocol. Both the investigator and the University could be parties to a lawsuit emanating from clinical research. Therefore, it is important that clinical research not be undertaken until a clinical trial agreement, which includes an appropriate liability/indemnification clause, is entered into by the University and the sponsor.

## Payment for Injuries

In addition to an indemnification clause, the sponsor is normally expected to pay for any injuries to subjects that are the direct result of the study.

## Confidentiality of Patient Records

Sponsors of clinical trials often require that records be provided that indicate the effects of drug intervention on patients involved in a study. It is the policy of the University and its affiliated hospitals to maintain the confidentiality of patient records. The terms of a clinical trial make a distinction between research records, study records and patient records, the latter being strictly confidential.

## Sample Clinical Trial Agreement

The University's standard [\*clinical trial agreement\*](#) is provided on ORPA's web site. Faculty are encouraged to contact ORPA as soon as feasible, so contract negotiation can take place in a timely manner. Please refer to the ORPA Guide entitled [\*Guidance for University Approval of Sponsored Clinical Trials\*](#).

## 9.3 Testing Agreements

Testing agreements are broadly defined as the conduct of a specific procedure on specific material supplied by the sponsor. An example of a testing agreement is an assay agreement, or the analysis of materials on University-owned equipment. Acceptance of any testing agreements by the University is contingent upon the agreement by the PI, Chair and Dean that the project is in accordance with the missions of the University and that it contributes to the objectives of the Department and School/College. Other considerations of testing agreements follow:

### Publication

While the data resulting from a testing agreement is often linked with the sponsor's materials, (which may or may not be proprietary to the sponsor), the agreement should provide for publication by the University of overall results or methods.

### F&A Costs

While the University does not have a published F&A rate for testing agreements, the sponsor should pay the full costs of the project. The Chair and Dean must agree upon the F&A rate assessed to a testing agreement.

### Financial Considerations

Payment for testing or analysis performed on a piece of equipment purchased with federal funding may be accountable as program income to the federal award. In addition, faculty members are cautioned that any testing arrangement must be competitive with the costs assessed by commercial organizations, and any inappropriate use of testing agreements may be subject to unrelated business income tax.

## Sample Testing Agreement

A sample [\*material testing agreement\*](#) is found on the ORPA web site. Again, faculty are encouraged to contact ORPA as soon as feasible if a testing arrangement is contemplated.

## 9.4 Equipment Loan Agreements

Equipment loans are agreements whereby a sponsor may loan certain equipment to the University, such as hardware, software and/or documentation for research use. One such example is an agreement whereby the University and the company participate in a joint research program using the company's equipment, and share the results, including data. This type of agreement usually does not involve money, but enables the University and industry researchers the opportunity to use each other's facilities. This type of agreement may involve both ORPA and Purchasing Services, to ensure that the terms are consistent with those typically negotiated with an equipment vendor and places the University in a position of minimal risk and liability. Other considerations of these equipment loan agreements are the eventual disposition of the loaned equipment, cost of equipment maintenance, possible confidentiality of equipment specifications or performance, and ownership of intellectual property generated as a result of the use of the equipment.

## 9.5 Material Transfer Agreements

Material Transfer Agreements (MTA's) are contracts by which tangible research property or unique research resources, such as biological organisms or computer software, are provided by external sources to University investigators for research purposes, or vice versa. Some standard considerations of MTA's are:

1. the provided substances generally are biological materials that are not used on human subjects and do not involve liability to the donor for the recipient's use of the material;
2. the recipient generally agrees to give intellectual property rights, such as licenses, to the donor, or limited rights if derivative materials are later developed;
3. unused materials are returned to the donor;
4. a report of research results is normally the deliverable in exchange for the use of the material; and
5. the donor may charge the recipient for costs of producing and shipping the material.

ORPA negotiates MTA's.

## 9.6 Industrial Affiliates Programs

Industrial Affiliates Programs, supported by corporate gifts, are designed to facilitate the transfer of knowledge between academia and industry. Industrial Affiliates Programs are not considered sponsored programs and are normally run by a faculty director. Membership contributions vary from program to program, but most Industrial Affiliates Programs offer member companies: interaction with faculty and students, access to basic and applied research that supplements the companies own activities, recruiting ties to University students, and/or copies of faculty publications.

### IMPORTANT

Any Industrial Affiliates Programs that offer licenses of intellectual property to member institutions must contact ORPA for drafting of a license agreement.

## 9.7 Intergovernmental Personnel Act Agreements

Intergovernmental Personnel Act (IPA) Agreements are contracts whereby a University employee may serve or cross train in federal agencies for limited periods of time. Some or all of their salary and staff benefits are paid by the federal agency under Title IV of the Intergovernmental Personnel Act, while they are still considered University employees. Normally, provision has been made for their return to the University. Faculty or staff contemplating an assignment under an IPA must consult with the appropriate Chair and Dean. The Chair and Dean will review the appropriateness of the arrangement, and the impact upon the University. IPA's are not normally considered sponsored programs and acceptance of IPA agreements differs among schools/colleges. Contact ORPA for further information.

# RESEARCH REGULATION UNDER UNIVERSITY COMMITTEES

The following are brief descriptions of the functions and operations of the University's research regulation and compliance committees. Additional information can be obtained by calling the support offices for each committee directly.

## 10.1 Human Subjects

### Definitions

The daily administration of the University's Human Research Protection Program (HRPP) is overseen by the Office for Human Subject Protection (OHSP). Please consult the Office for Human Subject Protection website ([www.rochester.edu/ohsp](http://www.rochester.edu/ohsp)) and the policy page ([www.rochester.edu/ohsp/policies/guidanceDocuments.html](http://www.rochester.edu/ohsp/policies/guidanceDocuments.html)) for specific information about conducting human subject research at the University of Rochester.

*Human subject research is any activity that either:*

- Meets the DHHS (Department of Health and Human Services) definition of research and involves human subjects as defined in the DHHS regulations; or
- Meets the FDA (Food and Drug Administration) definition of research and involves human subjects as defined in FDA regulations.

*Research as defined by DHHS regulations:* A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. A "systematic investigation" generally means there is a study plan or protocol that is followed. Contributing to "generalizable knowledge" means there is or will be a report, publication, poster, communication, etc. providing the results and conclusions of the research to other people/clinicians/researchers outside the department/institution.

*Research as defined by FDA regulations:* Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the FDA under these sections of the Food, Drug and Cosmetics Act, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. For research involving drugs, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.

*Human subject as defined by DHHS regulations:* A living individual about whom an investigator (whether professional or student) conducting research obtains:

- Data through intervention or interaction with the individual, or
- Identifiable private information

*Human subject as defined by FDA regulations:* An individual who is or becomes a participant (“subject”) in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. For research involving medical devices, a human subject is also an individual on whose specimen an investigational device is used.

*Minimal Risk:* The probability and magnitude of harm or discomfort anticipated is not greater, in and of themselves, than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For research involving prisoners, the definition is modified by a restriction to the daily lives of ‘healthy persons’.

*Protocol:* The plan of a scientific experiment or treatment.

*Employee or Agent* - An individual who:

- (1) acts on behalf of the institution;
- (2) exercises institutional authority or responsibility; or
- (3) performs institutionally designated activities, including but not limited to staff, students, contractors, and volunteers, regardless of whether the individual is receiving compensation.

## Overview

The Office for Human Subject Protection (OHSP) is comprised of four divisions:

- The **Research Subjects Review Board (RSRB)** is responsible for reviewing research conducted or supported by employees or agents of the University to ensure that the rights and welfare of the human subjects are adequately protected. Investigators wishing to request use of an external IRB (Institutional Review Board) must contact the RSRB for consultation prior to IRB submission.
- **Research Education & Training Division** is responsible for assisting researchers in protecting the rights, welfare and safety of human subjects by providing programs and educational resources in research ethics and human subject safety, with an emphasis on the proper conduct of research.
- **Quality Improvement Division** is responsible for the ongoing evaluation of the effectiveness of the HRPP by promoting Institutional and investigator compliance with human subject protection regulations and requirements.
- **Clinical & Management Systems Division** is responsible for oversight and maintenance of the RSRB Online Submission System.

Per the University’s Federalwide Assurance with the DHHS, the University will apply the basic federal protections set forth in 45 CFR 46, Subpart A, to all human subject research conducted or supported by employees or agents of the University of Rochester, regardless of sponsorship. A copy of the University’s Federalwide Assurance, OHSP policies and guidelines for conducting human subject research and submitting proposals are available on the OHSP website: [www.rochester.edu/ohsp](http://www.rochester.edu/ohsp).

### **Human Subjects Training**

OHSP requires all study team members to successfully complete human subjects training through an on-line program called the Collaborative Institutional Training Initiative (CITI Program) *prior* to conducting any human subject research. Research personnel, regardless of role, must complete training commensurate with the risk level associated with the type of research conducted (e.g., minimal risk, greater than minimal risk biomedical or greater than minimal risk behavioral). Each training course conducted through CITI consists of several short online learning modules with a brief quiz after each module. Additional information regarding this training can be found on OHSP's Research Education & Training website:

<http://www.rochester.edu/ohsp/education/certification/initialcertification>

## 10.2 Animal Subjects

Animal as defined in the context of research use is defined as “any live or dead vertebrate animal used in research, research training, experimentation, or biological testing or for related purposes”.

The University has established a University Committee on Animal Resources (UCAR) which, among other things, oversees the animal care and use programs and facilities of the University. In addition, the faculty and staff of the Division of Laboratory Animal Medicine (DLAM) assume responsibility for working with other faculty to ensure the best possible preventive, diagnostic, and clinical care for animal subjects.

To ensure that the above goals are met, the University requires that all research or teaching programs that utilize laboratory animals be prospectively reviewed by the University Committee on Animal Resources.

Any faculty member who intends to use either live or deceased vertebrate animals for research and testing purposes must submit an animal use protocol to the University Committee on Animal Research (UCAR).

The University requires that a protocol for the care and use of laboratory animals be filed for every activity involving animals. No animals may be purchased or used without an approved animal protocol. Only the Vivarium can purchase animals.

## 10.3 Recombinant DNA Research and Biohazards

In conformity with NIH Guidelines and NYS regulations, the University has established the Institutional Biosafety Committee (IBC). The IBC has the responsibility of reviewing all research protocols involving DNA recombination, even those for which no outside support is contemplated, to insure that the levels of physical and biological containment are adequate. The investigator is responsible for describing those elements of the research involving DNA recombination, estimating the containment required, and establishing adequate training for all personnel working on the project. The IBC reviews the physical facilities and evaluates the appropriateness of the proposed physical and biological containment levels for the experiments using more than P1-EK-1 conditions (as defined in the NIH Guidelines). The Chair will evaluate the P1-EK-1 experiments and refer the protocol to the entire Committee when he or she deems it appropriate.

To assist investigators, the Committee has drawn up a checklist to be submitted along with the protocol that covers the required procedures. Under New York State regulations, a submission is required even for experiments identified as “Exempt” by the NIH guidelines. The University’s Chief Environmental Health and Safety Officer, the Chair of the University Biosafety Committee, and ORPA are available to answer any questions researchers may have about University policy and procedures concerning recombinant DNA research. Checklists and examples of research protocols may also be obtained from their offices.

For most granting agencies, approval of the protocol is not required prior to submission of the grant application, but preliminary review is done either by ORPA, Radiation Safety or the Biosafety Office at time of University Sign-Off.

## 10.4 Radiation Safety

Radioactive isotopes and radiation-producing equipment are important tools for research, teaching, and patient care. Use of these tools could be risky unless adequate controls and surveillance are maintained. The University subscribes strongly to the principle that all radiation exposures shall be as low as reasonably attainable regardless of allowable exposures set by regulatory agencies.

This principle is implemented by the University’s Radiation Safety Committee, which was established by a resolution of the Board of Trustees and reports to the President. It is charged with the full responsibility for determining that the health and safety of the university’s employees, students, and visitors are safeguarded through the proper handling and use of radioactive materials and radiation-producing machines. Members of various departments and divisions using radioactive materials and radiation-producing equipment serve as members. Within the Medical Center, a separate committee exists, reporting directly to the Dean of the School of Medicine and Dentistry and Vice Provost for Health Affairs, with special responsibility for the application of radiation and radioactive material in the treatment of diseases.

For those using radioactive materials or radiation-producing machines, a *Radiation Safety Manual* has been prepared and approved by the Committee on Radiation Safety. Before any radioactive materials will be issued to an investigator, the Radiation Safety Office requires demonstration of competence in their use through training and successful completion of an examination. All technical associates working with the investigator must have attended an elementary radiation safety course and have passed an examination. The *Radiation Safety Manual* outlines the general policies and procedures to be followed, and is the basis for the University’s licenses to use such materials and equipment. Failure to adhere to the published regulations can result in a revocation of the University’s licenses. The Chair of the Committee on Radiation Safety can, at any time, recommend to the President immediate cessation of those activities that the Committee deems unsafe.

To assist the University (and the Committee) in meeting its legal obligations and to help investigators and practitioners in the development of radiation safety, a Radiation Safety Office has been established as a unit in the University Risk Management and Environmental Safety (URMES). This office should be consulted on all operating matters pertaining to the safety of employees or third parties where radiation-producing materials or machines are involved. The office has been assigned the following responsibilities:

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1. To obtain the necessary permits, license, and permissions from the various city, state, and federal authorities to process, use, and dispose of radioactive isotopes and radiation-producing machines; and to see that such things are done as are necessary to maintain the permits and licenses;
2. To procure, monitor, and assist in the waste disposal of all radioactive isotopes;
3. To monitor and survey all radiation-producing machines;
4. To maintain the necessary records pertaining to purchased radioactive isotopes and all radiation-producing machines;
5. To assist in the maintenance of the safety of all persons who may be on University property and are exposed to possible injury from radiation, and, specifically, to procure, monitor, and survey dosimeters for all University personnel whose employment necessitates, according to the best current practice, that they be so protected; and
6. To maintain detailed and accurate exposure records for such personnel.

The costs of the services provided are charged directly to the using investigator or activity. A schedule of prices will be made available upon request to the Radiation Safety Office.

## 10.5 Committee Information

Each of the University research regulation committees have established application deadlines, meeting schedules, procedures and forms. Please contact them for additional information:

Committee	Ext.	Website
Animal Research (UCAR)	5-1693	<a href="http://www.urmc.rochester.edu/ucar/">www.urmc.rochester.edu/ucar/</a>
Biosafety (IBC)	5-3014	<a href="http://www.safety.rochester.edu/homepages/ibchome.html">http://www.safety.rochester.edu/homepages/ibchome.html</a>
Human Research (OHSP)	5-2398	<a href="http://www.rochester.edu/ohsp/rsrb/">http://www.rochester.edu/ohsp/rsrb/</a>
Radiation Safety (RSC)	5-3781	<a href="http://extranet.urmc.rochester.edu/radiationsafety/">http://extranet.urmc.rochester.edu/radiationsafety/</a>
Radioactive Drug Research (RDRC)	5-1473	<a href="http://extranet.urmc.rochester.edu/radiationsafety/research">http://extranet.urmc.rochester.edu/radiationsafety/research</a>

## PRACTICAL TIPS

Practical Tips is intended to provide the reader with practical information about ORPA, such as location, contacts, available forms and documents, courier service to the Medical Center community, and networking opportunities for sponsored program administrators.

### 11.1 Where is ORPA Located?

ORPA is located on the 5<sup>th</sup> floor of the Hylan Building. The reception area is in Room 517.

<b>DIRECTIONS FROM THE MEDICAL CENTER</b>
Cross Elmwood Avenue by the entrance to the School of Medicine & Dentistry
There is a sidewalk between the Medical Center Annex and Central Utilities Plant
Follow path near the cemetery
Cross Intercampus Drive
Walk through the small parking lot between the two small buildings
You will be in the Wilmot Parking Lot
The tall building to the west is Hylan
Enter the building from the court yard (this will be the second floor)
Elevators on your right will take you to the 5 <sup>th</sup> floor

## 11.2 ORPA Staff Listing

<b>Name</b>	<b>Title</b>	<b>Phone</b>	<b>E-Mail</b>
Gunta J. Lidars	Associate VP for Research Adm.	5-5373	gunta.lidars@rochester.edu
Donna L. Beyea	Associate Director	5-8037	donna.beyea@rochester.edu
Brenda Kavanaugh	Associate Director	5-1504	bkavanaugh@orpa.rochester.edu
Cheryl K. Williams	Associate Director	5-8033	cheryl.williams@rochester.edu
Anthony Beckman	Research Administrator	5-8033	abeckman@orpa.rocheter.edu
Jennifer Carlson	Research Administrator	5-8033	jennifer.carlson@rochester.edu
Anne Corriveau	Research Administrator	3-2137	anne.corriveau@rochester.edu
Laurie Naber	Research Administrator	5-4210	lnaber@orpa.rochester.edu
Lori Hume	Manager, Information Systems	5-9096	lori.hume@rochester.edu
Sharon Aten	Information Analyst	5-8044	saten@orpa.rochester.edu
Crystal Holm	Information Analyst	6-5151	cholm@orpa.rochester.edu
Charlene Sinclair	Information Analyst	5-5776	charlene.sinclair@rochester.edu
Michael Ritz	Research Compliance Officer	6-4069	michael.ritz@rochester.edu
Patty Guinan	Conflict of Interest Administrator	6-3895	patty.guinan@rochester.edu
Jena Ashley	Material Transfer Administrator	5-5115	jena.ashley@rochester.edu
Gila Balman	Material Transfer Administrator	3-4512	gila.blaman@rochester.edu
Amy Crosby	Administrative Asst. Gunta Lidars	5-5373	acrosby@orpa.rochester.edu
Jamie Carr	Assistant to Donna Beyea & Anne Corriveau	5-8036	jcarr@orpa.rochester.edu
Michelle Grizzanti	Assistant to Cheryl Williams, Anthony Beckman & Jenn Carlson	5-8033	mgrizza2@orpa.rochester.edu
Edna Odell	Assistant to Brenda Kavanaugh & Laurie Naber	5-1505	eodell@orpa.rochester.edu

### 11.3 ORPA Web Site

As noted throughout the Manual, the ORPA web site is a valuable resource for policies, information and applications forms. ORPA no longer retains a library for application forms as our major sponsors no longer provide hard-copy forms. All application forms and related University forms can be downloaded from our web site at [www.rochester.edu/orpa](http://www.rochester.edu/orpa).

### 11.4 Courier Service to the Medical Center

ORPA has a Courier Service to the Medical Center in the morning and afternoon. In the morning the Courier picks up material at 8:50 a.m. from the Dean's Office at the Medical Center in room 1-5401. The material is dropped off at the River Campus ORPA office at approximately 9:10 a.m. The Courier picks up any material from 517 Hylan Building and delivers it back to the Medical Center Dean's Office.

In the afternoon, the Courier picks up material at 2:45 p.m. from ORPA, Hylan Building and delivers to the Dean's Office at the Medical Center at 3:00 p.m. Material in the pick up box in the Dean's Office is delivered back to ORPA.

When material is picked up at the Medical Center in the morning, it often will be returned to the Dean's Office at the Medical Center by the afternoon courier service.

When material is picked up at the Medical Center in the afternoon, it usually can be returned to the Dean's Office at the Medical Center by the next morning courier service.

### 11.5 Networking for Sponsored Programs Administrators

The following University-based organizations provide valuable networks for University administrators.

#### River Campus Administrators Group

The River Campus Administrators' Group (RCAG) is an ad hoc forum of River Campus, South Campus, Eastman School of Music and Memorial Art Gallery administrators. RCAG has no formal organization structure or by-laws; membership is open to any University employee who serves in an administrative support capacity. RCAG normally meets on a monthly basis during the academic year. Meetings consist of general announcements and a talk by an invited speaker on topics that pertain to University administrator. RCAG also serves as a forum for University personnel that wish to disseminate information to a broad audience. Meetings are planned and arranged by a Steering Committee that is represented by several colleges, departments and administrative units. For further information, please contact Louise Vanni (x5-5416).

"River Rats" is a subcommittee of RCAG that consists of administrators that manage sponsored projects. River Rats meets on a monthly basis during the academic year to discuss, roundtable format, current issues in sponsored project administration and federal

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initiatives. Meetings generally consist of a report from the Office of Research and Project Administration, Sponsored Programs Accounting, Indirect Cost Accounting, University Audit, and discussion of items of concern by attendees. For further information on River Rats, please contact Sue Brightman (x5-7725).

### Medical Center Administrative Group (MCAG)

The Medical Center Administrative Group was established in 1976. Its present format dates from 1982, and represents all components of the Medical Center; the School of Medicine and Dentistry, Strong Memorial Hospital, the School of Nursing, and Health Affairs. Anyone whose responsibility include administration in the broadest sense, and who works within-or in support of-Medical Center activities may become a member of MCAG.

Research Administration/Research Accounting (RARA) is a subcommittee which works closely with staff from the Office of Research and Project Administration (ORPA) and Sponsored Programs Accounting (SPA), University Audit and Indirect Cost Accounting providing an excellent opportunity to exchange information on issues related to grant management. Members are routinely asked for their input on proposed policy changes within the University and informed about forthcoming changes from the federal government. For further information on RARA, please contact Marti Preston (x5-7242), or <http://www.urmc.rochester.edu/urmc/MCAG/index.html>.



## SAMPLE PROPOSAL COVER PAGE

This is a sample format for a proposal cover page.

### SPONSORED PROGRAM PROPOSAL

To the

SPONSOR

Submitted by the

University of Rochester  
Rochester, NY 14627

Title:

Period of Performance

Date Submitted:

Principal Investigator(s): (name, title, unit)

Endorsements:

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Principal Investigator  
(Name, Telephone #)

---

Date

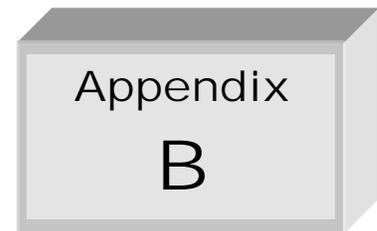
---

Authorizing Official  
(Name, Title)

---

Date

Inquiries regarding contract and grant negotiations and business correspondence should be directed to the Office of Research and Project Administration, University of Rochester, 5<sup>th</sup> Floor Hylan Building, Box 270140, Rochester, NY 14627-0140, tel. (716) 275-4031, fax (716) 275-9492



## THE ALPHABET SOUP OF RESEARCH ADMINISTRATION

### An Index of Commonly Used Acronyms

<b>AALAC:</b>	<b>American Association for Accreditation of Laboratory Animal Care</b>
<b>ACO:</b>	<b>Administrative Contracting Officer</b>
<b>AFOSR:</b>	<b>Air Force Office of Scientific Research</b>
<b>ARO:</b>	<b>Army Research Office</b>
<b>BAA:</b>	<b>Broad Agency Announcement</b>
<b>CBD:</b>	<b>Commerce Business Daily</b>
<b>CDC:</b>	<b>Center for Disease Control and Prevention</b>
<b>CFDA:</b>	<b>Catalog of Federal Domestic Assistance</b>
<b>CFR:</b>	<b>Code of Federal Regulations</b>
<b>CO:</b>	<b>Contracting Officer</b>
<b>COGR:</b>	<b>Council on Governmental Relations</b>
<b>CPSR:</b>	<b>Contractor Procurement/Property System Review</b>
<b>CRADA</b>	<b>Cooperative Research and Development Agreement</b>
<b>DARPA</b>	<b>Defense Advanced Research Projects Agency</b>
<b>DC:</b>	<b>Direct Costs</b>
<b>DCAA:</b>	<b>Defense Contract Audit Agency</b>
<b>DEAR:</b>	<b>Department of Energy Acquisition Regulations</b>
<b>DED:</b>	<b>Department of Education</b>
<b>DFAR:</b>	<b>Defense Federal Acquisition Regulations</b>
<b>DHHS:</b>	<b>Department of Health and Human Services</b>
<b>DOD:</b>	<b>Department of Defense</b>
<b>DOE:</b>	<b>Department of Energy</b>
<b>EDGAR:</b>	<b>Education Department General Administration Regulations</b>
<b>EPA:</b>	<b>Environmental Protection Agency</b>
<b>F&amp;A:</b>	<b>Facilities and Administrative Costs (formerly indirect costs)</b>
<b>FAR:</b>	<b>Federal Acquisition Regulations</b>
<b>FDP:</b>	<b>Florida Demonstration Project and its successor, the Federal Demonstration Partnership</b>
<b>FEDIX:</b>	<b>An on-line federal database serving most federal agencies for on-line searches</b>
<b>FIPSE:</b>	<b>Fund for the Improvement of Postsecondary Education</b>
<b>FOIA:</b>	<b>Freedom of Information Act</b>
<b>GPG:</b>	<b>Grant Proposal Guide (NSF)</b>
<b>GSA:</b>	<b>General Services Administration</b>
<b>IACUC:</b>	<b>Institutional Animal Care and Use Committee</b>
<b>IBC:</b>	<b>Institutional Biosafety Committee</b>
<b>IDC:</b>	<b>Indirect Costs (Now Facilities and Administrative Costs)</b>
<b>IR&amp;D:</b>	<b>Independent Research and Development</b>

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<b>IRB:</b>	<b>Institutional Review Board (for human subjects research)</b>
<b>MTDC:</b>	<b>Modified Total Direct Costs</b>
<b>NASA:</b>	<b>National Aeronautics and Space Administration</b>
<b>NCURA:</b>	<b>National Council of University Research Administrators</b>
<b>NIH:</b>	<b>National Institute of Health</b>
<b>NIST:</b>	<b>National Institute of Standards and Technology</b>
<b>NSF:</b>	<b>National Science Foundation</b>
<b>NSF/STIS:</b>	<b>An on-line search system of the National Science Foundation</b>
<b>OHSP:</b>	<b>Office for Human Subject Protection</b>
<b>OMB:</b>	<b>Office of Management and Budget</b>
<b>ONR:</b>	<b>Office of Naval Research</b>
<b>ORI:</b>	<b>Office of Research Integrity</b>
<b>ORACS:</b>	<b>Office of Research Accounting and Costing Standards</b>
<b>ORPA:</b>	<b>Office of Research and Project Administration</b>
<b>OSHA:</b>	<b>Occupational Safety and Health Administration</b>
<b>OSI:</b>	<b>Office of Scientific Integrity</b>
<b>OSTP:</b>	<b>Office of Science and Technology Policy</b>
<b>PHS:</b>	<b>Public Health Service</b>
<b>RDNA:</b>	<b>Recombinant DNA Research</b>
<b>RFA:</b>	<b>Request for Applications</b>
<b>RFP:</b>	<b>Request for Proposal</b>
<b>RFQ:</b>	<b>Request for Quotation</b>
<b>SBA:</b>	<b>Small business Administration</b>
<b>SPIN:</b>	<b>An on-line search system for research opportunities developed by the State University of New York (SUNY), now Information Education, Inc.</b>
<b>TDC:</b>	<b>Total Direct Costs</b>
<b>UBIT:</b>	<b>Unrelated Business Income Tax</b>
<b>UCAR:</b>	<b>University Committee Animal Resources</b>
<b>UR-COEUS:</b>	<b>The University's proposal and award database</b>
<b>USDA:</b>	<b>United States Department of Agriculture</b>