Office of Research Administration Manual

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PREFACE

Faculty and staff who direct sponsored projects under Thomas Jefferson University and Hospitals (Jefferson) auspices have an important public, as well as personal responsibility to conduct and manage those projects carefully. This manual is intended to assist with the fulfillment of that responsibility. In addition, its purpose is to acquaint new investigators and other key personnel with the policies and procedures of Jefferson, to inform them of the various services available to them, and to serve as a reference and guide for information and assistance.

The key principles underlining good stewardship of all sponsored programs are as follows:

- All expenditures must be allowable and allocated to the award based on the sponsors' guidelines. These expenditures must be initially charged to the award to which they apply, in order to eliminate the use of cost transfers after the fact;
- Award funds must be expensed in accordance with the proposed research plan and in accordance with the approved established budget;
- Time and effort on sponsored programs must be monitored, accounted for and certified. Significant reductions in effort must receive the prior written approval of the University and sponsor;
- All transactions involving the potential charging of personnel to an award, require the prior approval of the Principal Investigator;
- Jefferson must honor sponsors' contractual requirements for reports and other deliverables; and
- All sponsored projects must be proposed and administered in accordance with Jefferson policies and procedures.

1.01 Jefferson's Mission Statement and Goals

Thomas Jefferson University is dedicated to the health sciences. We are committed to:

Educating professionals in a variety of disciplines who will form and lead the integrated healthcare delivery and research teams of tomorrow
Discovering new knowledge that will define the future of clinical care through investigation from the laboratory to the bedside, and into the community
Setting the standard for quality, compassionate and efficient patient care for our community and for the nation

As we Define the Future of Clinical Care

We accomplish our mission in partnership with Thomas Jefferson University Hospital, our education and clinical care affiliate.

In support of Jefferson's mission, the Office of Research Administration is dedicated to:

- Assisting the community in the preparation and submission of proposals for the furtherance of scientific and scholarly knowledge;
- Managing sponsored projects in accordance with sponsor and University policies;
- Providing training and educational resources to support research and scholarly activities.

1.02 University Policies

Link to Jefferson's Policies and Procedures Manual.

1.03 College Organizational Charts and Faculty Handbooks

Link to the JMC Faculty Handbook and Organization Chart.

1.04 Jefferson's Commitment to Training

Before participating in sponsored research at Jefferson, all personnel must participate in a class which overviews their responsibilities in managing research, relevant Federal regulations, and University procedures. There are separate monthly programs for faculty, technical staff and online programs for administrators. Dates, registration instructions, and information about other ORA training opportunities are available at Register for Training on ORA's website. ORA maintains a database which documents the training of all personnel who participate in sponsored projects.

ORA's training program is in addition to the mandatory training program on the Institutional Integrity Agreement, which is sponsored by the Office of Compliance.

In accordance with Policy 110.10, "Education of New Research Personnel," until new employees have completed the mandated training, supervisors are responsible for closely monitoring them for adherence to University policies and sponsor regulations.

Other Jefferson offices provide training programs to support investigators and other staff in their research responsibilities. See the training page on ORA's website, for a description of these programs and links to the sponsoring offices.

1.05 Code of Conduct

Link to [Jefferson's Code of Conduct.]

1.06 Guidelines for Defining: A Gift vs. Grant/Contract

While the Office of Research Administration's (ORA) name indicates that it has administrative responsibilities related to the conduct of research at Thomas Jefferson University, it is actually involved with all sponsored projects. Sponsored projects fall within several general functional categories. Examples of those categories are: research, training, clinical trials, public service, fellowships, and equipment awards.

In general, sponsors of those activities include agencies of the Federal government, state and local governments, foundations, international organizations, research institutes, societies, and corporations. These organizations fund sponsored projects through a variety of mechanisms such as contracts, grants, letter agreements, purchase orders, cooperative agreements, and a variety of awards that fall under the general rubric of subawards.

To elaborate on the difference of a gift vs. grant/contract the following better defines the characteristics of gifts and grants/contracts:

Gifts:

- Donor does not impose contractual requirements; and
- Funds are awarded irrevocably.

Grants/contracts:

- Sponsor:

1 requires a detailed budget be followed, with any deviations requiring sponsor approval;
2 requires a financial and/or programmatic reporting;
3 defines a period of performance during which the funds can be used;
4 requires that unused funds must be returned to the sponsor;
5 imposes restrictions with respect to patents, copyrights and/or rights in data;
6 award requires Jefferson's involvement in the testing or evaluation of proprietary products;
7 requires an audit of the award; and
8 requires that the work performed is directed by a specific scope of work rather than a general area of research.

It is the responsibility of ORA to administer all sponsored awards, while the Controller's Office is responsible for appropriately classifying gift receipts in the general ledger. In addition, it is the responsibility of the operating department to expend the donor's funds in accordance with their intent and within the confines of University policies.

1.07 Proposal to Award Cycle

In general, the following actions outline a typical proposal to award cycle:

- Determine an appropriate program announcement for the submission of an application/proposal;

- Application/proposal is prepared by the Principal Investigator (PI) in consultation with ORA;

- Submit proposal package to ORA at least five (5) business days prior to deadline. It must include: an ***entire*** copy of the completed proposal with an original cover page, one additional copy of the cover page, and ORA internal forms with required signatures;

- ORA reviews the entire proposal for compliance purposes. ORA will notify the department of any errors and once corrected by the department, the ORA Director will sign the original cover page and the additional copy of the cover page. The original cover page is returned to the department for further submission requirements;

- Award is negotiated by ORA if necessary;

- Award is sent to ORA and forwarded to PI and department administrator for review;

- Once ORA accepts the award on behalf of the University, a budget is established and a new account number authorized. ORA forwards all information to the Sponsored Programs Accounting Office (SPAO) to be entered into the University's accounting system;

- PI begins project and expends funds according to the scope of work proposed to the sponsor and the established budget;

- ORA approves potential charges to awards;

- SPAO requests reimbursement of expenditures of the award;

- ORA monitors award for compliance and submission of reports;

- SPAO provides the necessary financial reports per the terms and conditions of the award;

- PI is responsible for the final progress report and prepares other sponsor required documents, i.e., report of inventions.

Responsibilities of ORA During the Proposal to Award Cycle

ORA is responsible for the review and certification of the proposal/application for Jefferson. The ORA staff reviews the application for compliance with the sponsor's requirements and Jefferson's policies and procedures relating to fiscal requirements as well as human subjects and vertebrate animals certifications/assurances. ORA serves as the repository for all records (excluding financial records routinely maintained by the Controller’s Office and SPAO) pertaining to extramurally sponsored projects, including Jefferson’s approved proposals and negotiated awards and all official correspondence relating to the award.

Administrative Requirements of ORA

Signature by the designated Official in ORA indicates that the proposal/application meets the compliance requirements of the sponsor as well as those of the University. All grant and contract proposals must be accompanied by the appropriate University forms with original signatures of the PI, any key personnel, department administrator, and the corresponding Department Chairperson. No proposal will be released without these signed forms.

Pre-award Process

Proposals are checked and certified for mathematical accuracy, employment status and institutional base salary of all personnel, as well as assuring that the compensation reflects the actual effort percentage allocated in the proposal. Fringe benefit and F&A cost (formally indirect costs) rates and calculations are verified to correspond with Jefferson’s federally negotiated agreement.

All direct costs are reviewed to assure compliance as defined in OMB Circular A-21 as being allowable. Proposed consulting and subcontracting costs must be accompanied by a Letter of Intent, budget, and scope of work. Potential subawards to another organization must have the signature of the authorized official of that organization on the Letter of Intent as well as a copy of an approved F&A Cost Negotiation Agreement.

All cost sharing requests must be pre-approved and documented on the electronic Proposal Transmittal Form (e-PTF).

Post-award Process

Once an award is received, negotiated, and fully executed, ORA will send a copy of the award to the PI and department administrator. ORA will request an account number from SPAO. Once received, ORA will provide SPAO with a budget and a copy of the award document.

Once a grant account is established, submit all appropriate PAF’s to ORA for approval for each employee working on that project. This is necessary to ensure that the correct percentage of effort and dollars are being expensed to the account as proposed. If the PAF information does not match the budget, justification is requested from the originating department.

ORA is responsible for generating subaward agreements to other organizations. Once an award is received that includes a subaward, it is the responsibility of ORA to notify the PI that the subaward will be generated.

All Request to Purchase (RTP) forms for equipment purchases, regardless of amount, must receive prior approval of ORA for allowability purposes. All other RTPs in excess of $5,000 require the prior approval of ORA.

All cost transfers regardless of dollar value, reimbursement for all domestic travel $5,000 or more, and all foreign travel must have the approval of ORA**. CAUTION:** Many federal sponsors require **prior approval** of the sponsor for foreign travel, regardless if it was included in the proposed budget. In addition, the use of foreign flag air carriers is prohibited except in rare situations. **READ ALL TERMS AND CONDITIONS CAREFULLY!**

For other types of payment requests see Section 4.05 of this Manual.

1.08 Assignment of Inventions

The Patent and Trademark Law Amendment Act of 1980, more commonly referred to as the Bayh-Dole Act, sets forth the regulations for transfer of inventions generated by universities and funded by the federal government to the commercial market place.

Thomas Jefferson University and Hospitals (Jefferson), as a recipient of federal funding, is required to comply with the Bayh-Dole Act, as implemented by 37 CFR 401.14. The Act requires organizations to establish a written agreement with all employees and students (excluding clerical staff) to disclose promptly each subject invention made under a federal award and to execute all papers necessary to file a patent application.

In addition, when Jefferson accepts federal awards, we are also accepting the responsibility to obtain written agreements from our employees and students participating in the federally sponsored activity. Therefore, all employees and students must electronically sign an Assignment of Inventions Agreement in PeopleSoft. The Agreement sets forth an employee/student's agreement to promptly disclose in writing all inventions and to assign the rights to Jefferson.

Additional information regarding the Bayh-Dole Act can be obtained at the Council of Government Relations.

1.09 RESERVED

1.10 RESERVED

2.01 Introduction

Funds provided to Thomas Jefferson University for sponsored projects must be administered in accordance with both the sponsors' terms and the University's own policies and procedures. The purpose of the *ORA Manual* is to support investigators and administrators in fulfilling their responsibilities. It provides investigators with a reference for Jefferson's procedures for proposing and managing sponsored projects. The procedures apply to all sponsored projects, whether research, clinical trials, or training grants. It also provides guidance for understanding requirements that sponsors impose on universities as terms of awards.

Procedures for managing sponsored projects are subject to change. As the University or sponsors revise their requirements, ORA will update this Manual accordingly.

The ORA Manual is not a single resource for managing sponsored projects. Other Jefferson offices maintain research related requirements. Investigators and administrators should use this manual in conjunction with requirements set forth by the Controller's Office, the Office of Scientific Affairs, the Office of Animal Resources, the Office of Environmental Health and Safety, and Radiation Safety, the Office of Compliance, and the University's general policies.

Each sponsored project must also be managed in accordance with the terms that Jefferson accepted from the sponsor. Federal awards are subject to the requirements of OMB Circular A-21, A-110, and A-133, as well as the relevant agency guidelines/policies.

Where Jefferson has a policy in an area not specifically addressed by the sponsor, or where Jefferson's policy is more restrictive than the sponsor's, Jefferson's policy must be followed.

2.02 Who Can Submit Proposals/Applications?

In order to submit a proposal/application to a potential sponsor, the PI must have a paid appointment as a Jefferson faculty member. The appointment can be tenure or non-tenure tract. The following academic ranks are recognized as part of the faculty member's title:

- Instructor
- Assistant Professor
- Associate Professor
- Professor

Individuals with faculty appointments that are pending should contact ORA prior to sending a proposal to ORA for institutional review, since these situations will be considered on a case-by-case basis.

Mentors for pre and post-doc fellowship applications must also have a faculty appointment at the time of proposal/application submission.

In addition, ORA will not approve a proposal/application that contains any salary increases, promotions, or faculty appointments that are contingent upon the receipt of an award.

2.03 RESERVED

2.04 Allowability of Costs

All expenditures on sponsored projects must comply with Jefferson policies, the cost principles of OMB Circular A-21, sponsor guidelines/policies, and the terms and conditions of the award. An expenditure is "*not allowable*" if it is explicitly prohibited by any of these documents.

Costs must be "*allocable,"* meaning that they must benefit the project charged. If a charge benefits several projects, it must be assigned to those projects, based on the relative benefits to each project. To allocate costs, use reasonable methods to estimate actual consumption.

Costs must be *reasonable*, reflecting the actions that a "prudent person" would take. They must be consistent with ethical business practices, and applicable laws.

Costs must be *consistent* with Jefferson's DS-2 Cost Accounting Disclosure, as set forth in the Policy
103.25. Costs incurred for the same purpose in like circumstances must be treated consistently, as either direct or F&A costs, across all functions or activities of the institution, unless special circumstances exist.

Exceptions to the consistency standard, for complex programs and significant data collection.

OMB Circular A-21, Exhibit C permits exceptions to the requirement for consistency in "unlike circumstances," where expenses usually covered through the F&A cost pool may be directly charged. For example, in the case of complex programs, or significant data collection, where the administrative or clerical effort directly benefits the project or program, it may be appropriate to charge the salaries directly. Consult with ORA to determine whether Exhibit C exceptions apply. Maintain documentation supporting the decision. **Note: These situations must be discussed and approved at the proposal/application stage.**

Definitions of Types of Costs:

Direct costs are costs that can be specifically identified and assigned with relative ease and with a high degree of accuracy to sponsored projects, or institutional accounts that charge sponsored projects, such as internal service organizations.

The basis used for allocating direct costs to projects must bear a direct relationship to those projects. This allocation of costs should be made at the time of purchase. If an appropriate basis such as actual usage cannot be identified to allocate the costs with relative ease and with a high degree of accuracy, the costs must be treated as F&A costs.

Facilities and Administrative Costs (F&A Costs) are also known as indirect costs or overhead. They are general institutional expenditures that are incurred for multiple or shared projects. They cannot be specifically identified with relative ease and with a high degree of accuracy to a sponsored project. They include:

Facilities:
- Depreciation of buildings
- Equipment depreciation
- Operation and Maintenance
- Student Services
- Library Administration
- Sponsored projects administration
- Departmental sponsored projects administration.

F&A costs are applied to sponsored projects as a percentage of the sponsored project's direct costs.

Clerical and administrative salaries, general-purpose equipment, subscriptions, memberships, postage, local phone service, office and general supplies are normally treated as an F&A cost.

F&A Cost Rate is a composite rate applied to sponsored projects as a percentage of the project's direct costs, for the purpose of charging the project its share of the University's F&A costs. The federally negotiated F&A Cost Rates for research and other sponsored activities are developed by the University in accordance with OMB Circular A-21 and negotiated with the Department of Health and Human Services (DHHS), the University's federal cognizant agency.

2.05 Effort Reporting

Federal regulations require the certification of effort charged to all sponsored awards. Effort reporting provides the means to verify that salaries and wages charged to sponsored awards accurately reflect the effort devoted. ORA is responsible for the distribution, collection, review, and retention of all effort certification reports.
ORA’s review of effort reports includes the following:

- Timely return;
- Completed accurately;
- Determine that the total effort equals 100%; and
- Prior approval for significant reductions in effort was obtained.

Certification of effort is required at least semi-annually for professorial and professional staff and monthly for non-exempt employees. Each Jefferson employee charged to a sponsored award must have his or her total effort certified. Total effort is defined as **100% of an employee's** University activity. Since sponsored activity may only account for a percentage of an employee's total effort, each individual must also account for effort devoted toward administration, instruction, and/or other University related activities. Jefferson policy requires that the employee, PI, or a responsible individual with direct knowledge of the actual effort on each project certify the effort for all employees. **Note that** more than one individual may be required to certify an employees total effort.

Federal agencies reserve the right to audit effort certifications on awards they sponsor. If reports are found to be incomplete or inaccurate, severe penalties may be imposed on both the individual certifying the information, as well as the University.

In Policy 107.15 the University defines sanctions, which may be imposed for failure to comply with the institutions effort reporting requirements.

Effort Related Resources:

OMB Circular A-21 (Effort Reporting Requirements): OMB Circular A-133: (Audit Standards):

Jefferson Policies and Procedures – Effort Certification for Professorial and Professional Staff

Jefferson Policies and Procedures – Effort Certification for Non-Exempt Staff

Jefferson Policies and Procedures – Retroactive Changes to Effort Certification for Faculty and Non-Faculty

Jefferson Policies and Procedures – Investigations and Disciplinary actions related to violations of the Corporate Compliance Program

2.06 Cost Transfers

Federal regulations restrict the transfer of expenditures into and between sponsored awards. Those regulations state that all cost transfers must be completed promptly after discovering the original erroneous charge and must provide adequate justification for the transfer or reallocation. Therefore, to ensure that all cost transfers affecting sponsored awards are in compliance with Federal requirements, the following process must be followed:

- **Salary Transfers:** all requests to transfer salary expenses should be processed using a Personnel Action Form (PAF). In those situations when a PAF cannot be used the Cost Transfer Form (CTF) may be substituted. The department must justify the need to use the CTF in lieu of the PAF.

- **Non-Salary Transfers:** all non-salary cost transfers must be processed using the Cost Transfer Form (CTF). The CTF must be completed correctly and contain all the necessary supporting documentation and approvals before submission to ORA. ORA will provide financial and programmatic review and approval. Once approved, ORA will forward the CTF to the SPAO for processing into the institution's financial records.

> All cost transfers must be supported by documentation that contains a full explanation of how the error occurred and a ***certification of the appropriateness of the transfer***. **Note:** The PHS Grants Policy Manual states that an explanation, which merely claims that the transfer was made to "correct an error" or "to transfer to correct project," is not sufficient. It also states that frequent errors in recording costs may indicate the need for accounting system improvements as well as the possible need to enhance internal controls.

To ensure that all transfers on federal awards are completed on a timely basis, the department must initiate all cost transfers within 90 days from the point in time that the financial statement is made available. Note: There are non-federal sponsors that may require a shorter period of time.

2.07 Account Deficit

Expenditures cannot exceed the total approved budget established for the project. In those situations where expenditures exceed the budget, the PI in conjunction with the department administrator is responsible for removing the deficit. The following process is in place for the removal of deficit amounts on sponsored awards:

- The Controller's Office will notify the custodian/administrator that the account is in deficit and to request a secondary funding source;

- The custodian/administrator then has one hundred and eighty (180) days from notification to remove the deficit;

- One hundred and fifty (150) days after the initial notification, the custodian/administrator will be notified that the deficit will automatically be charged to the secondary funding source or departmental/divisional operating account; and

- One hundred and eighty (180) days after the initial notification the transfer will take place.

Please refer to the Jefferson Costing (103.25) and Deficit Spending Policies (103.22) for additional information.

2.08 RESERVED

2.09 Establishing and Administering University Service Centers

Service Centers should operate as nonprofit businesses. Rates should be based on actual costs and established billing rates and must be consistent with Jefferson's cost accounting standards. Costs of recharge center operations must be accumulated separately and excluded from the University's F&A cost rate. Costs and revenues should be identified by service.

At least every 6 (six) months, revenues should be compared to the full cost of providing each service to ensure that federal awards are not, in effect, subsidizing other services. If a Service Center over-recovers or under-recovers its costs in a given year, it should revise its rates for the subsequent period to accurately recover costs for the total period.

See Policy 103.24 for further information on University Service Center.

2.10 Title and Ownership of Equipment

The PI is responsible for custody, control, and proper maintenance of equipment used in a sponsored project.

Most sponsors allow the University to retain title to equipment upon acquisition though in general, the sponsor is allowed 120 days after expiration of the award to claim such equipment. It is imperative to be familiar with the sponsor's requirements regarding ownership and title to all equipment.

PIs leaving Jefferson and wishing to transfer equipment to another institution, should consult with ORA to determine title of equipment purchased with sponsor funds.

Keeping Track of Equipment

Each piece of capital equipment is labeled with a bar-coded tag by SPAO to help track its location. SPAO conducts a biannual inventory of all JMC and sponsored programs (100 and 080 accounts) capital equipment. In order to maintain the accuracy of the fixed asset financial system, the Controller's Office must be notified of movement of equipment both within and out of the University as well as equipment transferred to Jefferson. This is accomplished by the submission of an Asset Disposition Form, contact the Controller's Office for additional information.

Stolen Equipment

Consult the Risk Management Office immediately upon identifying the loss of equipment. Costs for replacing equipment should not be passed on to sponsors. If the PI chooses not to replace the equipment, the sponsor may require reimbursement.

2.11 Record Retention and Access

OMB Circular A-110 requires universities to retain financial records, supporting documents, statistical records and all other records pertaining to a federal award for 3 (three) years from the date of submission of the FSR. However, Jefferson requires you **maintain all project records through May 18, 2004, in addition to the above requirement**.

The University, Investigators and administrators are responsible for knowing and complying with the record retention requirements of their particular sponsors. [NIH's requirements are posted in the NIHGPS (page 142), and NSF's requirements are available in the NSF Manual (section 350).] A few sponsors (the Commonwealth of Pennsylvania, for example) require longer retention of financial records.

Research Records

Research records include (but are not limited to) material contained in research notes, laboratory notebooks and in other media such as computer disks and machine printouts. Research materials or products generated by the research may be archived. Investigators have an obligation to ensure that for all aspects of their research program, sufficient records are kept to document the experimental methods and accuracy of data collection, as well as the methods and accuracy of data interpretation. The records archived should be the originals whenever possible. If any questions regarding the research are raised during the 3 (three) year retention period, the records shall be kept until such questions are fully resolved. In the event an investigator leaves the University for any reason, s/he must notify his/her supervisor of the designated custodian and location of research records covered by this policy.

Some research records must be retained for longer periods. Consult the Office of Human Research for requirements regarding retention of human subject records. Records that support patent applications should be kept for as long as needed to protect the patents. Consult the Office for Technology Transfer for details.

Access to Data

The University has the right to access supporting records for all research at the University. Such access to the records shall be for reasonable cause, at reasonable times and after reasonable notice. The University's right of access to the data shall continue regardless of the location of the responsible investigator. Information or data that would violate the confidentiality of sources or subjects involved in the research should not be disclosed. Extramural sponsors providing support for research at Jefferson may also have the right to review the data and records resulting from that extramural support. Key personnel who are an integral part of a research project have the right to review all records and data that are part of that project.

2.12 Responding to Alleged Misconduct in Research

The University's Policy regarding the handling of alleged misconduct in research is set forth in Policy 110.02.

2.13 Conflict of Interest

The following urls contain information and forms relating to Jefferson's Conflict of Interest Policy:

Policy Number 107.03: CONFLICTS OF INTEREST POLICY FOR EMPLOYEES

Policy Number 107.03 Attachment A: Operating Definitions

Policy Number 107.03 Attachment B: Statement of Principles Regarding Avoidance of Conflicts of Interest For Employees of Thomas Jefferson University

Policy Number 107.03 Attachment C: Annual Certification of Compliance

Policy Number 107.03 Attachment D: Research Certification

Policy Number 107.17: CONFLICT OF INTEREST POLICY: DISTRIBUTION TO NEW EMPLOYEES

Policy Number 107.18: CONFLICTS OF INTEREST POLICY - ENFORCEMENT AND SANCTIONS FOR NON-COMPLIANCE

2.14 RESERVED

2.15 RESERVED

3.01 Introduction

The PI is responsible for preparing the proposal in accordance with Jefferson policies and in accordance with sponsor guidelines.

When questions arise either in preparation of a proposal for extramural support, or in seeking supporting agencies for your proposal, early contact should be initiated with colleagues, department administrator, chairperson, ORA, OSA, and the AISR staff in the Scott Library.

If a proposal is being sent to a private foundation and if it is not part of a regular "request for application/proposal," the Development Office should be contacted to make them aware of your intent and to receive further guidance and assistance. This is an important aspect for the Development Office as they are responsible for avoiding conflicting requests of foundation resources. The Development Office can also provide additional guidance and assistance when seeking private support.

Preliminary Discussions with Division Head, Departmental Chairperson, or Deans

All proposals should be reviewed by the division head, departmental chairperson, and dean (as appropriate), and department administrator prior to submission to ORA as they must approve the proposal and the use of departmental personnel, space, and facilities. Advance notification enables administrators to assess potential impacts, raise questions before the proposal's final processing, and make any required arrangements/adjustments. Some examples of issues which would necessitate discussions would include but are not limited to:

- very large or center-type proposals;
- extensive faculty effort;
- cost-sharing or matching requirements;
- subcontracting to other entities;
- a significant use of Jefferson equipment and facilities;
- interdepartmental collaboration;
- the relationship with on-going Jefferson projects or objectives and missions;
- additional staff and/or space; and
- F&A cost reductions/waivers.

3.02 Types of Proposals/Applications

In general, proposal submissions for federal awards will fall into one of the following types (please note that many foundations will use similar terminology):

Pre-application or Preliminary Proposal: A pre-application establishes communication between the sponsor and the applicant to determine whether a full proposal should be submitted and to obtain advice that will improve the proposal's chance of success.

New: A new proposal application is one that has not been previously funded by the sponsor.

Competing: Considered to be a new proposal by the sponsor to continue the research the sponsor has previously funded.

Continuation: Continuation applications are for continued support on current projects that the sponsor anticipates funding.

Supplemental: Submitted to the sponsor when requesting additional funds for an existing project.

Revised New or Revised Renewal: If a proposal has been rejected, the PI often has an opportunity to use the reviewer's comments to revise the proposal for resubmission. Changes should be marked or italicized. The sponsor's program officer should be contacted for application guidelines.

Many federal agencies have application kits in electronic format that can be downloaded from the web. Checking the sponsor’s requirements regarding the completion of a proposal is essential prior to the development of the proposal.

PIs submitting proposals to state and local agencies, private organizations, associations, and industry sponsors are encouraged to contact these sponsors for program guidelines.

Help in Proposal Writing

Departmental colleagues, particularly the department chair, may be the most helpful resource for sample proposals and help on proposal writing.

Proposal Review Process by the Sponsor

In general, a team of experts or prominent researchers in the particular field of study will review the proposal for its technical content and cost. Although selection of these reviewers lies fully within the sponsor's authority, some sponsors may allow the PI to suggest individuals well qualified to review their proposal. The PI may also be permitted to list those who should not be part of the review process.

Rejections

Sponsors typically receive more applications than can be funded. To be competitive, each proposal must be prepared in accordance with sponsor guidelines.

Many sponsors provide explanatory information with their letters of notification. This information often includes the process by which the proposal was reviewed, the number of proposals and awards, and information about budget availability. Copies of proposal reviews may also be supplied. Contact the program officer or sponsor for further information.

Appeals

Some sponsors may have an appeal process if an applicant feels that the proposal's handling or peer review has been inappropriate. Check the sponsor's guidelines for further information. The appeal process may take several months to complete, therefore it may be more effective to use the reviewers' comments to revise and resubmit the proposal.

3.03 Funding Opportunities Resources

The Scott Library has resources to assist you in identifying potential sources of sponsored projects support. These resources include print and electronic media. The Scott Library will also provide free individual consultation and subsidized search services. Please contact Academic & Instructional Support & Resources (AISR) for an appointment for a consultation at 215-503-2477.

3.04 Sub-proposals to Other Institutions

Jefferson's standard proposal procedures apply to sub-proposals to other institutions. A complete copy of the sub-proposal, including a budget, scope of work, Proposal Transmittal Form (PTF), and any other applicable forms must undergo Jefferson's standard review process.

Departments should prepare a "Letter of Intent" for ORA to endorse. The letter should reference the project title and the PI, and indicate the expected dates, amounts of the award, and confirm that Jefferson is prepared to negotiate a subaward from the prime institution in accordance with Jefferson's policies and the terms and conditions of the prime sponsor.

Note that the hospital is a separate legal entity from the university, and as such, must maintain its own accountability for its employees. The hospital has a right to know (via all appropriate PTF signatures) which of its employees are working where. The hospital also has an obligation to report monthly (via the effort reporting system) on 100% of each employee's effort - even exempt employees. In order for the hospital to accomplish these things, the university must provide the hospital with a subcontract for any university grant funding used to compensate hospital employees.

The best time to establish a subcontract is at the beginning of the project, before any charges have been incurred. Hospital services that do NOT require a subcontract include those services that have a standard, published price, and do not involve responsibility for a specific aim of the project. For example, pharmacy or lab charges. These may be charged to 080 accounts using an IDC. For questions about how to establish a subcontract with Jefferson Hospital , contact your preaward representative in ORA.

3.05 Role of the IACUC in the Review of Proposals

It is the responsibility of Jefferson's IACUC to review, process, and approve animal use protocols in conjunction with the corresponding funding application/proposal submitted to the sponsor. In order to accomplish this activity, the IACUC has determined what documents must be submitted to the IACUC and when. The following will assist faculty with their submission.

NIH Just In Time Submission

Effective October 1, 2002, the NIH implemented a just in time review for animal use protocols. Faculty who have been notified by the NIH that their proposal is in the fundable range are required to submit the following documents to the IACUC for review:

- Office of Animal Resources Protocol Form (RO-5).
- A copy of the signed NIH Cover Page;
- Specific Aims page;
- Section F (Animal Subjects section) of the research plan;
- Proposal Transmittal Form (PTF, formerly RO1) indicating that IACUC approval is pending; and
- The section of the summary statement indicating that the study section of the NIH has either approved the animal use described in the application, or has noted any concerns that need to be addressed.

If the protocol and appropriate sections of the proposal are not in agreement, the PI will be notified and required to provide additional information to the IACUC.

Proposals to Non-NIH Sponsors Indicating Pending

PIs submitting proposals to non-NIH sponsors and indicating at the time of submission that animals will be used but the protocol is pending, must submit the equivalent documents listed above.

Proposals Indicating IACUC Approval (All Sponsors)

If a proposal indicates that the animal protocol(s) has been approved prior to the proposal submission, ORA will review the proposal and the protocols indicated on the PTF on file in the Office of Animal Resources prior to ORA's approval of the proposal. The PI will be notified if any discrepancies should arise.

IACUC Approval Letters to Sponsors

In situations where the IACUC has determined that the animal protocol(s) and animal use sections of the proposal submission agree, OAR on behalf of the IACUC will generate an approval letter for the sponsor. The letter will state that the proposal and protocol match and will be sent to the PI for forwarding to the sponsor and ORA. (This letter does not replace the IACUC animal protocol approval letter. The purpose is to confirm to the sponsor that the proposed use of animals in the proposal has been approved.)

3.06 RESERVED

3.07 Developing and Justifying Proposal Budgets

The PI and the department administrator are responsible for developing and justifying a proposal budget that is a reasonable estimate of the costs of performing the proposed project. The basis of the budget is derived from the proposal's research/methodology plans.

General Budget Principles:

- All proposed costs must comply with Jefferson's policies, sponsor guidelines, and the OMB principles of allocability, allowability, reasonableness, and consistency.
- Costs that are normally reimbursed through the F&A cost pool may not be requested as direct costs on federal proposals, unless they meet the definition of "Complex programs" or "Significant data collection" set forth in OMB Circular A-21.
- The budget section of the proposal typically has two components: the budget itself, and the detailed justification of the cost items.
- A budget is both an estimate and a firm offer on the part of the University. After an award has been made, re-negotiation may be difficult.
- Some sponsors establish dollar limits for first-year direct costs, with maximum increases for following years. Budgets should comply with the limits because applications that exceed them may be rejected.
- To facilitate the award activation process, budgets should be prepared with the University's financial accounting system codes (natural account codes). Natural account code information is available from department administrators.
- Budgets must be based on accurate institutional base salaries, fringe benefits and F&A cost rates. Budgets should incorporate an appropriate escalation factor (usually 3%) for costs in future years **(no escalation factor is allowed for NIH Modular submissions)**.
- All proposals/applications submitted to a federal sponsor ***must*** incorporate the negotiated F&A cost rate unless the federal sponsor expressly limits the rate.

Personnel

- **Realistic effort projections are essential to a proposal's credibility**. Under-estimating effort may force unplanned cost-sharing; over-estimating and overcharging effort constitutes fraud. On average, total compensation constitutes about 2/3 of direct costs. Federal reviewers evaluate effort requests carefully.
- **List all project personnel**. All Jefferson employees who will work on the project must be listed as personnel, even if they will not be paid from the award (**Note: Key Personnel-zero % effort or "as-needed" effort will not be accepted by ORA**). If they will not be paid from the award, then their effort is *cost-shared*. *Jefferson discourages this practice and requires that you obtain appropriate approval.*
- List the PI first, followed by other key personnel. Show individuals who have not yet been hired by the University as "To Be Named (TBN)." Indicate their anticipated roles and salaries on the project.
- **Type of Appointment**. All Jefferson employees are on 12 (twelve) month appointments.
- **% Effort**. No employee may receive additional pay because of participation in a sponsored project. (Each employee's effort, from all sources, must equal 100%.)
- **Institutional Base Salary**. Institutional base salary rates must be accurate. Do not include researchers' JUP clinical compensation in Institutional Base Salary.
- **Salary requested** = % effort **x** Institutional Base Salary
- **Fringe Benefits** = Salary requested **x** Jefferson's negotiated rate. This current rate is available on ORA's website, and applies to all salaries, except graduate students and post-doctoral fellows on training grants.

- **Total Personnel** = Salary requested + Fringe Benefits.
- **Salary caps**. Some federal sponsors (NIH) limit each individual's salary to the Executive Level I. Contact ORA for the current cap.

Consultants

- List each consultant's name and show total costs.
- In the justification section, explain the consultant's role and the basis for costs: number of days and expected rate of pay, or price/deliverable. Show detail for other consultant expenses (travel, etc.). A letter of intent from the consultant on their business letterhead, documenting the basis for the rates is required. Consultants' fees may not exceed their standard rates.
- Jefferson personnel cannot be consultants, therefore may not be compensated on Jefferson awards.

Travel

- Identify travel for University personnel only. Distinguish between foreign and domestic travel.
- Explain each trip's purpose, destination, duration, and number of travelers in the justification section.

Equipment

- Equipment is defined as items costing $5,000 or more and having a useful life of one year or more.
- Itemize equipment requests and justify why the equipment is necessary to support the science.
- Ensure that the equipment is not reasonably available elsewhere in the institution.
- • Do not request general-purpose equipment unless it can be established that the equipment will be used exclusively for scientific project purposes. General purpose equipment includes office equipment, office furnishings, computers, etc. General purpose equipment typically is used for multiple activities so it is generally inappropriate to charge as a direct cost.
- Analyze cost and price, to ensure that the request is reasonable.
- Exclude equipment from the base, when calculating Modified Total Direct Costs (MTDC).

Supplies

- Supplies, by definition, cost less than $5,000 and have a life expectancy of less than one year.
- Many sponsors require itemization of supply categories (e.g. glassware, chemicals, etc.).
- Indicate the number and species of required animals and cost.

Patient Care

- Show aggregate costs. Show detailed basis for costs and patient accrual in the budget justification. Indicate other anticipated sources of support, such as third party payers or pharmaceutical companies.
- Patient care costs are excluded from the (MTDC) base.

Alterations and Renovations

- Itemize by category.
- Justify necessity of costs. Provide square footage and costs, as applicable.
- Alteration and renovation expenses are excluded from the MTDC base.

Other Expenses

- **Animal maintenance**. Indicate unit care costs and number of care days.
- **Publication costs**. The costs of disseminating the results of sponsored research in scholarly journals may be charged directly. Justify the basis for the cost estimate.
- **Rentals and leases**. It may be more appropriate to rent equipment than to purchase it. The total rental costs should not exceed the cost of purchase.
- **Service contracts**. Costs for non-programmatic services, such as equipment maintenance and routine testing. Service contracts *are* included in MTDC.
- **Tuition**. Graduate students' work on the project may be compensated, in part, by paying their tuition. Tuition is not included in the MTDC base.
- Other categories may also include patient travel, long distance telephone costs, and donor fees. Justify all costs.

Subaward (Consortium)

- Subaward organizations must submit detailed and summary budgets. They should show their F&A cost rates and base.
- Jefferson is responsible for ensuring that subaward budgets are realistic and are based on accurate rates. Jefferson's PI should review the subaward budget to ascertain that the costs appropriately reflect the work to be performed. ORA requires a copy of the subaward institution's most recent F&A cost rate agreement, to verify that rates are accurate.
- Jefferson's direct cost budget includes the aggregate direct and F&A costs for all subawards.
- The first $25,000 of *each* of the subawards will be included in Jefferson's MTDC base. Subsequent subaward costs, for the balance of the competitive period, are excluded. If the total cost for a given subaward is less than $25K, then in continuation years, Jefferson will continue to charge its F&A costs, until the threshold is met.

Facilities and Administrative Costs

- Jefferson requires all sponsors to support their fair share of the cost of the infrastructure that makes research possible at the institution. Exceptions are very rare, and granted only with the approval of the dean's office.
- Calculate "Modified Total Direct Cost" (MTDC) for each project year. This is accomplished by taking the total direct and subtracting:

  Equipment
  Tuition remission
  Patient care
  Alterations and renovations
  Rental costs of off-site facilities
  Subaward costs over $25,000 for each subaward, during the total project period. (Jefferson collects its F&A costs on the first 25,000 of each subaward. Once a given subaward reaches $25,000, Jefferson ceases to charge F&A costs for the balance of the competitive segment.)

To obtain annual F&A costs, multiply the annual MTDC by Jefferson's F&A cost rate, which is available from the ORA website.

Total Costs: Direct Costs + F&A Costs = Total Costs

3.08 Cost Sharing and Matching Funds

"Cost sharing" and "matching" both describe costs associated with a project, which are not contributed by the sponsor. The two terms are often used interchangeably. However, cost sharing in general is at the expense of the University while matching usually requires obtaining funding from other sponsors such as Foundations.

Cost Sharing that sponsors require as a condition of proposal submission is called "mandatory." Cost sharing not required by the program announcement is "voluntary" and is ***discouraged*** by the University.

The key principals to keep in mind regarding cost sharing/matching are:

- Only mandatory cost sharing should be included in the application. Voluntary cost sharing does not enhance the competitiveness of the application. Any cost sharing committed in the application becomes mandatory if an award is made;
- Organizations providing funding as a match to a project must submit a letter stating such. The timeframe must agree with that of the sponsored award; and
- All cost sharing or matching funds must be documented. The documentation must show that the expense is relevant to and concurrent with the sponsored project.

- Salary and wage documentation is provided through the effort certification system.
- Non-salary items used for cost sharing or matching must be identified through an appropriate account or reflected in other documentation as costs to the project. The Sponsored Programs Accounting Office (SPAO) should be consulted to determine the proper documentation.

The department chairperson and College Finance must approve all cost sharing, with the exception of the NIH salary cap.

Procedures for Documenting and Tracking Cost Sharing

1. ORA is responsible for verifying the University's commitment to cost share on an award as identified on the PTF.

2. Once the University accepts an award that includes cost sharing, the department will be responsible for tracking the personnel cost share commitment through the effort certification process.

3. Non-personnel cost sharing requirements will be noted on the establishment letter sent from ORA to the PI, department administrator, and SPAO. All reporting requirements for these items will be the responsibility of the SPAO and the department.

3.09 Signature Authority

The Office of Research Administration is responsible for signing all sponsored agreements on behalf of Thomas Jefferson University. The director of the Office of Research Administration and associate dean of Operations are authorized to commit the institution contractually for sponsored programs. Jefferson will not recognize or honor sponsored agreements signed on its behalf by unauthorized individuals.

Types of sponsored agreements include:

- Grants, contracts, and cooperative agreements from federal, state and city agencies;
- Awards from foundations and associations;
- Clinical trials;
- Other corporate agreements;
- Sub-awards from Jefferson to cooperating institutions; and
- Professional Services Agreements (PSA).

Material Transfer Agreements (MTA) and Licenses to inventions are negotiated through the Office of Technology Transfer. All MTA's are signed by the vice chair of research.

3.10 Research Agreements: Negotiations

ORA is responsible for managing all contractual negotiations for sponsored projects. ORA will coordinate negotiations with investigators, the Office of Legal Counsel, the Office of Technology Transfer, and other offices as appropriate.

Investigators and administrators should contact ORA immediately if a sponsor representative calls to negotiate terms of the project. Failure to do so may result in ORA having to re-open negotiation on points the sponsor believed to be settled.

Negotiation issues include:

1. The technical plan, or scope of work;
2. Scientific control and direction of project;
3. Key personnel;
4. Period of performance;
5. Confidentiality of data and access to patient records;
6. Publication rights;
7. Ownership and disposition of intellectual property;
8. Financial Issues: Sponsor commitment, cost sharing, F&A costs, allowable costs, program income, record retention and audit procedures;
9. Deliverables and reports;
10. Invoices and payment;
11. Equipment accountability and disposition;
12. Protection of human subjects;
13. Animal welfare;
14. Subawards;
15. Indemnification and insurance;
16. Disclaimers of warranties; and
17. Provisions for termination or modification of agreement.

3.11 RESERVED
3.12 RESERVED

4.01 When Can Work on a Sponsored Project Begin?

Work on a sponsored project can only begin after an authorized University Official accepts the award. The PI **cannot** accept awards or sign agreements on behalf of the University. Before an award is accepted, the award notification or agreement with accompanying terms and agreements must be reviewed and approved by the ORA. Once the award is accepted, ORA will notify the PI of the official start date for the project.

In some instances, work may begin before the official start date. If the sponsor allows pre-award costs, work may begin during the pre-award period permitted by the sponsor. **However, pre-award costs are incurred at the department's own risk.** If the project is not funded or the start date is delayed, the department will be responsible for absorbing any pre-award costs incurred that cannot be expensed to the award.

Before pre-award costs can be incurred, the PI must request and receive approval from ORA. To request approval for pre-award costs, the PI must submit the University Prior Approval System (UPAS) form. (see section 4.07)

4.02 RESERVED
4.03 RESERVED

4.04 Account Establishment

After an award has been accepted, ORA will request an internal account number from the Sponsored Programs Accounting Office (SPAO). Once an account number is assigned, ORA will forward an account establishment letter to the PI, Departmental Administrator and SPAO. The establishment letter will provide pertinent account information such as:

- Jefferson account number
- Sponsoring Agency
- Title of Project
- Type of Award
- Budget and Project Periods
- Detailed Budget
- Reporting Requirements
- Special Terms and Conditions

Detailed Budget

Before an account can be established, ORA must have a detailed budget that matches the amount of the award. If the proposal budget matches the award amount, ORA will use that budget when establishing the account. If the budget on file in ORA does not match the award amount, ORA will contact the department for a revised budget. An account cannot be created until ORA has an approved budget that matches the awarded amount.

Special Terms and Conditions

Attached to the establishment letter will be a copy of the award notice or executed agreement. This document will contain award specific terms and conditions. It is the responsibility of each individual involved in administering the award to not only know these specific terms and conditions but also the general award guidelines of the Sponsor.

4.05 Managing the Award

Once an account is established, proper oversight must be provided to ensure that the award is administered according to the sponsor's guidelines, Jefferson policies, and all applicable laws and regulations.

It is the responsibility of each individual involved in managing the award to know all governing terms and conditions of the award. Without firsthand knowledge of all applicable terms and conditions, it would be impossible to properly manage the award. ORA will provide the PI and/or department administrator assistance in interpreting and understanding award terms and conditions.

Expense Processing

Once an account number has been assigned, all appropriate expenses should be charged to or encumbered against the account. These include all personnel costs, supplies, consultant costs, subcontracts, equipment, and travel expenses. All expense items must be charged to the appropriate project(s) in direct proportion to the relative benefit received.

Before an expense is charged to an award, a thorough review of the expense must be completed. This review is needed to ensure that costs are reasonable, allowable and allocable under the terms of the award. All expenses charged to an award must benefit the activity proposed and supported by the award and must be incurred prior to the termination date. No new expenses or commitments can be processed against an award after the award has ended.

All expense items must be processed using the University approved forms. The forms must be completed correctly and include all required approvals. Any forms not completed correctly or missing the required signatures will be returned to the department for correction. The University approved forms for expense processing are:

- Personnel Action Request (PAR)
- Personnel Action Form (PAF)
- Request to Purchase (RTP)
- Request for Payment (RFP)
- Report of Travel Expenses
- Interdepartmental Charge Form (IDC)

Personnel Processing

All Jefferson personnel charged to a sponsored project must be processed by use of a Personnel Action Request (PAR) and/or Personnel Action Form (PAF). All personnel transactions require the approval of both the PI and Department Administrator. Once the appropriate departmental approvals are obtained, the form needs to be forwarded to ORA for approval prior to submission to Human Resources and/or College Finance.

Personnel Action Request (PAR)

The PAR is completed to:

- Create a new position; or
- Replace a vacated position.

Personnel Action Form (PAF)

The PAF is completed to:

- Charge/remove an employee to/from an award;
- Change the source distribution of an employee; and/or
- Increase salaries.

Any questions on the proper use or completion of the PAR or PAF can be addressed to the department of Human Resources.

Supply Processing

Request to Purchase (RTP)

The RTP is required for all purchases of goods and services made on behalf of Thomas Jefferson University. Only the Material Management Department is authorized to issue a purchase order. In general, Jefferson purchasing policies and procedures seek to ensure that goods and services are purchased as economically as possible, while giving suppliers fair consideration.

The PI or his/her designate is responsible for initiating all RTP's. It is the responsibility of each department to make sure that all requests to purchase goods or services on sponsored projects are budgeted, reasonable, allowable, and/or allocable under the terms of the award.

ORA review and approval is required for all RTP’s that total $5,000 and above.

Any questions on the proper use and completion of the RTP can be addressed to the department of Material Management.

Consultants/Professional Service

In order to engage a consultant at Jefferson the following documents must be completed and approved prior to commencing any work:

- Professional Service Agreement (PSA), four copies with original signatures;
- Employment Status Test;
- W-9;
- Proof of or application for Philadelphia Business Privilege License (for work done within City of Philadelphia limits)
- Request to Purchase.

Once the PSA is fully executed, a Purchase Order (PO) number will be assigned for billing purposes. Consultant invoices must include the PO number and be approved by the Jefferson PI before submission to accounts payable for processing.

Subcontracts/Subawards

After an award is made, ORA will prepare a subcontract agreement for all subcontracts identified in the original proposal. Upon receipt of the fully executed subcontract agreement, ORA will instruct the department to submit a RTP form for each subcontract. ORA must approve all RTP's. Once a PO number is established, the subcontracted institution must include the PO number on all invoices before submission to Jefferson. The PI must approve all subcontract invoices before accounts payable can process payment.

Types of Forms

Request for Payment (RFP)

An RFP is used for all non-purchase order transactions. **The RFP cannot be used as a substitute for a purchase order**. The RFP can be used for the following types of transactions: Reimbursements - Meeting Registration -Honoraria -Petty - Cash Reimbursements

Patient Refunds
ORA review and approval is required for all Honoraria and all other RFP's that total $5,000 and above.

Report of Travel Expenses

The Report of Travel Expenses is used for advances, settlements and reimbursements related to University business travel. ORA review and approval is required for all domestic travel expenses reports that total $5,000 or above and for all foreign expense travel reports regardless of dollar threshold.

Inter-Departmental Charges

The IDC form is used to charge a grant for services provided by approved service centers or JUP. It is also used to charge non-effort related fees from the Hospital for services that have a standard published price and do not involve responsibility for a specific aim of the project (pharmacy or lab charges, for example).

IDC's must be processed after the service is performed, never in advance. IDC's charging grant accounts should be processed within 30 days from when the service was provided but must be processed within one month of the grant termination or by the end of the fiscal year in which the service was performed (whichever comes first). All exceptions must be approved in advance by the Office of Research Administration.

The initiating department is responsible for ensuring that IDC's are accompanied by an invoice detailing the service provided, dates of service and rate(s) of pay. The supporting documentation should include no individually identifiable patient information in accordance with JEFFERSON policy #122.13.

ORA must approve ALL Jefferson Hospital & JUP payments from a Jefferson grant, regardless of the dollar amount. In addition, ORA must approve all IDC's exceeding $5,000. Once approved, IDC's will be forwarded to Accounts Payable for processing.

The IDC form cannot be used in lieu of a cost transfer form; cost transfer regulations do not apply. Any questions on the proper use and completion of the request for payment, report of travel expenses, or the IDC form should be addressed to the Controller's Office.

Expense Review

Each month the Controller's Office generates financial statements, which reflect the expense activity for each account. The PI and/or his/her designate must perform a thorough review of these statements to ensure that all expenses charged to the award are correct. Any expense which is charged to an award in error must be removed and charged to the appropriate funding source. Charges may not remain on an award where they are not allowable. All inappropriate charges must be removed within 90 days of receipt of the monthly report that the charge first appeared.

A cost transfer form must be completed to remove any non-personnel expense that was charged to an award in error. This form must be submitted to ORA for review and approval prior to processing by the Controller's Office.

4.06 NIH Prior Approval Requirements

Before making changes in their projects, investigators should assess whether permission from the NIH is required or the NIH waived the requirement giving the grantee, "Expanded Authorities."

The NIH and other federal sponsors have the authority to waive the requirement for its prior approval for certain activities/expenditures for certain types of awards. The grantee in accepting awards under the expanded authorities must ensure proper stewardship and that all costs must be allowable, allocable, reasonable, and consistently applied regardless of source of funding.

Listed below are the categories or type of actions requiring NIH prior approval and those that may fall under the grantee's expanded authorities if awarded as such:

Exhibit 3. Summary of Expanded Authorities

Note: All requests for NIH awarding office prior approval must be made, in writing (which includes submission by e-mail) to the designated GMO no later than 30 days before the proposed change. The request must be signed by both the PI and the authorized organizational official. Failure to obtain prior approval, when required, from the appropriate NIH awarding office may result in the disallowance of costs,

May exercise as expanded authority	Except
Carryover of unobligated balances from one budget period to the next	Centers (P50, P60, P30, other), cooperative agreements (U), Kirschstein-NRSA Institutional research training grants (T), non-fast track phase I SBIR and STTR awards (R43 and R41), clinical trials, and awards to individuals, or if the NGA indicates otherwise.
Cost related prior approvals, including research patient care costs and equipment	If the scope would change.
Extension of final budget period of a project period without additional NIH funds	If the grantee already has given itself one extension of up to 12 months.
Transfer of performance of substantive programmatic work to a third party (by consortium agreement)	If the transfer would be to a foreign component or it would result in a change in scope.

termination of the award, or other enforcement action within NIH's authority.

Approval Under Expanded Grantee Authorities

PIs needing to utilize the above applicable expanded authorities should document how the proposed change/action supports the project, and forward to ORA for approval. Requests for no-cost extensions should reach ORA a month before the end date, to allow ORA ten (10) days to notify the sponsor of the extension. Requests for 90 day pre-award costs should be made prior to incurring the cost. **(See following section for further information.)**

4.07 University Prior Approval System (UPAS)

The purpose of the UPAS is to provide a process to obtain certain prior ***institutional*** approvals when administering sponsored programs at Jefferson. Several granting agencies have waived some prior approval requirements and provided authority to the grantee ("expanded authorities"). Questions regarding the appropriate use of the UPAS form can be directed to ORA.

The UPAS form is Jefferson's system for documenting the scientific necessity for pre-award costs, no-cost extensions and certain types of rebudgeting, as well as confirming departmental responsibility for costs incurred under advance account status.

Advance Accounts

Advance Accounts allow investigators to incur project charges on a grant account prior to receipt of an actual award document. ***Investigators are responsible for procuring and documenting reliable sponsor confirmation of intent to make the award.*** ORA will review the documentation to determine the level of risk in issuing the account number. Should the award not materialize, the Department/Center/Institute must cover the costs incurred.

Expenses on advance accounts may not exceed 25% of the anticipated award. Capital purchases and the hiring of new personnel are not allowed. If the award is not received within 90 days of the expected start, a new UPAS to extend the advance spending authorization must be submitted or spending must come to a halt.

An advance account will not be issued if there are unresolved contractual issues between the sponsor and the University or if there are unresolved compliance issues such as the lack of IRB or other regulatory approval.

Pre-award Costs

Pre-award costs are based on sponsor authorization to incur project costs prior to the start date. Federal grants under expanded grantee authority generally allow investigators to incur costs up to 90 days prior to the start date. The costs are incurred at departmental risk should the award not materialize. Requests for pre-award costs would normally require a simultaneous request for an advance account. Requests must be made prior to incurring the costs. ***Justification for why the costs are necessary for the conduct of the research project must be thoroughly explained.***

No-cost Extensions

For federal awards under expanded authorities, Jefferson can approve one no-cost extension for up to 12 months. Since ORA must notify the federal sponsor of the extension at least 10 days before the original termination date, requests should be received in ORA a month before the end date to allow sufficient time for review. ***Justify the need for the extension, in terms of completion of the proposed scope of work.*** The availability of residual funds is not in itself a legitimate basis for an extension. Subsequent extensions will require agency prior approval. (NSF extensions must be approved internally prior to being initiated by the PI on FastLane.)

Since only one extension is allowable through UPAS for federal awards, request sufficient time to complete the project. It is not advisable to request unnecessarily long extensions however, since sponsors interpret them as "current support" when making future awards. See manual sections 4.15 and 4.16 for additional information about extensions.

For non-federal sponsors or federal awards not under expanded authorities, see the sponsor's guidelines or contact ORA for assistance.

Rebudgeting.

Jefferson prior approval to rebudget funds is required for unbudgeted capital equipment and unbudgeted foreign travel. Justify the need for the rebudgeting terms of the relevance and benefit to the aims of the project. Do not incur expenses until prior approval has been obtained or the expense will be disallowed. See manual section 4.14 for additional information about rebudgeting.

4.08 Various Sponsor Accounts

Various Sponsor Accounts (VSA's) may be established to house the allowable residual balances of completed, industrially sponsored projects. VSA accounts have an open end date and all funds are budgeted in the "Other" category. The budget will match cash in the account. No F&A costs are assigned to VSA accounts.

They may be used for any educational or research related expenses which are otherwise allowable by Jefferson policy. It is completely appropriate to utilize VSA funds to write off grant deficits, cost share and charge expenses pending award establishment.

The Chair of each department may determine whether a departmental VSA will be established, or whether each PI will maintain an individual VSA. In either case, the funds are ultimately at the discretion of the Chair.

VSA's may not fall into deficit.

It is not appropriate to deposit funds directly to a VSA without explicit ORA approval.

VSA funds belong to the University and are not eligible to be transferred to another institution in the event of faculty termination.

Because VSA's are considered to be institutional funds (as opposed to sponsored projects) certain standard grant procedures do not apply. Specifically, cost transfers between a VSA and a non-grant source are not limited to a 90 day time frame; page 2 is not required in the event the transfer exceeds 90 days. Also, University Prior Approval System (UPAS) requests are not required in order to purchase unbudgeted equipment or foreign travel expenses on VSA's.

4.09 RESERVED

4.10 Payment Receipts

All checks received by the University need to be deposited into the appropriate account immediately upon receipt. The process for ensuring timely handling of checks relies on the sponsor appropriately identifying the project on the check and mailing it to the appropriate individual.

Clinical Trial Payments

The department, at the contract negotiation stage, must identify the individual and their address who will receive contracted checks. Once the payment is received and verified, the department will forward the payment to SPAO for deposit. A memo identifying the appropriate account(s) for deposit must accompany the payment.

Other Sponsored Payments

All other payments related to sponsored activity should be received directly by SPAO for deposit into the appropriate account. Payments received by the department should be forwarded immediately to SPAO for handling.

4.11 Program Income

Program income is any income that is directly generated by a sponsored activity or earned as a result of the award. Examples of program income include:

- fees earned from services performed under the grant, such as laboratory drug testing;
- rental or usage fees, such as those earned from fees charged for use of computer equipment purchased from grant funds;
- third party reimbursement for hospital or other medical services;
- funds generated by the sale of commodities such as tissue cultures, cell lines, or research animals; and
- patent or copyright royalties.

4.12 Financial Reporting: Interim and Final

Timely and accurate reporting is imperative for meeting our contractual obligations on sponsored awards. The PI, in conjunction with the department administrator, ORA, and SPAO is responsible for preparing and submitting all interim and final reports. Failure to submit reports on time may expose the University and the PI to various sponsor imposed sanctions such as withholding payment on an award, early termination of a project or withholding future awards.

To meet our reporting obligations, ORA will work closely with the department administrator, the PI and SPAO to ensure that all reports are completed and submitted by the due date. ORA notification will be set to the following schedule:

Interim Reports

One (1) month prior to report due date, ORA will notify the PI and departmental administrator of the reporting requirement.

Final Reports
One (1) month prior to award termination, ORA will notify the PI and departmental administrator of the final reporting requirements.

ORA will continue to follow-up until all required reports are submitted.

4.13 Carry Forward of Unobligated Balances

Some federal sponsors allow for unobligated balances to be automatically carried forward from one budget period to the next within an approved project period. **Note: Not all federal grants fall under the expanded authorities. Read the award notice carefully.** The process for carrying funds forward on NIH awards when the unobligated balance (including prior year carryover) exceeds 25% of the current budget period is described below:

Awards covered under Expanded Authorities and SNAP

When preparing the progress report, the PI needs to notify the sponsor when there will be a greater than 25% balance. This notification must include an explanation of why a balance is remaining and indicate how the funds will be used during the next budget period.

If a greater than 25% balance was not anticipated at the time the progress report was submitted but a greater than 25% balance is available at the budget end date, it is the PI's responsibility to notify the sponsor. This notification should be emailed to the sponsor with a copy to ORA.

Awards covered under Expanded Authorities but excluded from SNAP

The Financial Status Report (FSR) must specify the amount to be carried forward. The notification to carry forward the unobligated balance must be provided under item 12, "Remarks."

In either case the Sponsor may request additional information from the PI concerning the carry forward of unobligated funds.

4.14 Rebudgeting

In general, federal grantees are allowed a degree of latitude to rebudget funds to meet unanticipated needs. For federal awards, all rebudgeting must comply with OMB Circular A21 and sponsor guidelines. Before any reallocation of funds is performed, it is the responsibility of the PI and/or the department administrator to consult the agency's policy manual as well as the terms and conditions of the award, in order to determine if the proposed rebudgeting action is allowable.

On federal awards, significant rebudgeting may indicate a change in scope. Significant rebudgeting occurs when expenditures in a single direct cost budget category increases or decreases by more than 25% of the total annual award amount. For situations such as this, Jefferson must consult with the grants officer to determine if the rebudgeting action constitutes a change in scope, which would require the sponsor's prior approval.

Jefferson prior approval to rebudget funds is required for:

- unbudgeted capital equipment and
- unbudgeted foreign travel

In order to request institutional prior approval to rebudget funds, forward a completed UPAS to ORA. The justification should include:

- need for the rebudgeting as it relates to the work being conducted under the award; and
- reason the funds are available.

4.15 No-Cost Extension for Federal Grants

Prior to the end of a sponsored project, an investigator and the administrator should meet to assess whether they will be able to complete the proposed project by the scheduled end date. If it is determined that an extension is necessary (see conditions below) and the award is under "Expanded Authorities for Grantee Institutions", the PI may request to extend the final budget period of a project **one time** for a period **up to one year** beyond the original expiration date. Such an extension may be made when any one of the following applies:

- Additional time is required to assure completion of the originally approved project scope or objectives;
- Continuity of PHS support is required while a renewal is under review; or
- The extension is necessary to permit an orderly phase out of a project that will not receive continued support.

The fact that funds remain at the end of the grant is not in itself a sufficient justification for a no-cost extension.

In order to extend an NIH grant, please confirm that the grant is covered under "Expanded Authorities" and forward a completed UPAS to the ORA at least **one month** prior to the scheduled termination date. The request should include a justification for the extension and should be signed by the Principal Investigator and the departmental administrator. ORA will review the request and if approved, ORA will notify the appropriate GMO at NIH, as well as the SPAO, in order to update award information. The PI and department administrator will receive copies of the correspondence to NIH and SPAO for their files.

For other federal sponsors, please read the terms and conditions carefully to determine if ORA has the authority to approve a one-time, twelve-month, no-cost extension.

Federal grants or contracts that do not permit ORA the ability to approve such an extension will require written prior approval from the sponsor. Those requests must be counter-signed by the designated signatory in ORA. The account will not be extended until written authorization is received from the sponsor.

Note: A request for a no-cost extension for grants under the expanded authorities can made by completing the University Prior Approval System (UPAS) form.

4.16 Extension of Non-federal Grants/Contracts

It is imperative to read the terms and conditions of the sponsor's award to determine the parameters under which a no-cost extension is permissible. Most Foundation grants require written, prior approval from the agency. In those cases, the PI should prepare a letter to the sponsor, fully justifying the reasons for the extension and forward it to ORA for approval and signature.

Contracts and subaward almost always require written, prior approval from the sponsor in order to extend the termination date and would result in a modification to the contract/subaward.

4.17 Change in Grantee Institution

It is imperative that a PI leaving Jefferson contact his/her department administrator as well as ORA to begin the close-out and relinquishing process as soon as possible.

All federal awards require prior approval to transfer the legal and administrative responsibility of an award to another entity. For NIH awards in particular, please refer to the NIH Grants Policy Statement for specific details concerning this policy/procedure.

For non-federal awards, the sponsor must be notified of the intent to transfer the project to a new institution and also to determine whether the project can be transferred.

Since awards are made to the University and not the PI, the award must be relinquished by Jefferson. There are conditions under which Jefferson may desire not to relinquish the award and propose a change in PI to the sponsor.

It is imperative that if a PI is intending to leave Jefferson they must contact the department administrator, chair, as well as ORA to begin the close-out and relinquishing process as soon as possible.

4.18 Project Continuation and Renewal (NIH SNAP Guidelines)

The PI is responsible for the timely submission of continuation applications and any other progress reports that the sponsor may require. Failure to submit reports and continuation applications may cause the sponsor to withhold subsequent increments of the award.

For projects that fall under the SNAP rules, NIH requires that investigators address three questions on the progress report:

1. Has there been a change in the other support of key personnel since the last reporting period?
2. Will there be, in the next budget period, a significant change in the level of effort for key personnel from what was approved for this project?
3. Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year's total budget?

4.19 Close-out of an Award From an Industrial Sponsor (Clinical Trials Fixed Price Agreement)

In order to close an industrially sponsored award the following criteria must be met:
All work on the study must be completed;
The final Institutional Review Board report has been completed;
Final payment has been received; and
All appropriate expense items, especially salaries and patient care costs, have been charged to the account.

Once these conditions have been met, forward a letter to the Office of Research Administration to close the account. If there is a balance remaining, identify the account where this balance should be transferred. Remember the department is only entitled to the direct cost balance. The Medical College will retain any remaining facilities & administrative costs. A thorough explanation must be provided if there is a **significant balance** remaining in the account. The Principal Investigator and department administrator must sign the close out request.

Finally, the request should be accompanied by documentation from the sponsor indicating that the project has been completed to their satisfaction. In some circumstances, the letter accompanying the final payment from the sponsor contains an acceptable statement.

The Office of Research Administration will verify the account balance, ensure that the supporting documentation is attached and forward the request to the Sponsored

Programs Accounting Office for processing.

4.20 Close-out Procedures

Close out of sponsored projects must be completed in accordance with the terms and conditions of the award. Complete, accurate and timely closeout of awards is an important grantee obligation. Failure to comply with close out requirements may result in severe penalties to both the PI and University.

Close out of awards includes the resolution of any outstanding commitments including professional service agreements and subcontracts. A detailed review of all open commitments should be performed before the award termination date. This review is required to ensure that all required transactions are processed in time to meet all final reporting requirements.

Different sponsors have different reporting requirements and it is the responsibility of the PI, in conjunction with ORA and SPAO, to submit all required reports by the due date. To facilitate the timely submission of required reports, ORA will notify the PI and Departmental Administrator of the reporting requirements 30 days in advance of the award termination date.

For federal sponsors, the PI is required to submit a final Financial Status Report, Final Invention Statement and Certification (whether or not an invention results from the research) and Final Progress Report within 90 days of the award termination date.

Final Financial Reports

Approximately 30 days before the final financial report is due, SPAO will provide the department administrator with an account projection. This projection is only a tool and is an estimate of the account balance. It is the responsibility of the department administrator to make the appropriate adjustments based on their own accounting records.

Any outstanding commitments or transactions in process must be resolved before the final financial report is filed. No final financial report or final invoice can be submitted to the Sponsor until all financial transactions are processed. Any transactions included in the final accounting must be reviewed and approved by ORA before SPAO can complete the final financial report. Reporting requirements are identified in section 4.12.

Account Deactivation

Once all reports have been submitted and the final accounting has been completed, the award will be closed and the account number will be deactivated. The final accounting includes the completion of any budget adjustments, processing of all necessary cost transfers, and the disposition of any remaining funds.

Audit

All sponsored projects may be subject to four types of audit:

- As part of the annual general financial audit of Jefferson financial statements;
- As part of the annual audit of Federal State and City Awards in accordance with OMB Circular A-133;
- A sponsored project specific audit of finance; and/or
- An internal audit conducted by the University's Department of Internal Audit or coordinated with the Corporate Compliance Office.

Jefferson is required to provide the A-133 audit to the Federal Government and the City of Philadelphia. SPAO and ORA coordinate these audits. The Sponsor specific audit may be requested or required by contract. However, any federal sponsor must consider the procedures employed and the results from the A-133 audit. Such audits can be financial or programmatic.

Auditors usually review these records:

- Central records from offices such as SPAO, ORA and OSA;
- Payroll, employment records, and files from Academic Affairs;
- Departmental and service center files;
- Laboratory records;
- Accounts Payable documents;
- Purchasing documents; and/or
- Conflict of interest disclosures.

The sponsor or auditors should contact ORA before beginning an audit. ORA will then notify SPAO, Internal Audit and the department. If the auditor contacts the PI or department directly, refer them to ORA before scheduling any visits or releasing any documents.

At the conclusion of audits, auditors will typically conduct a meeting to review findings and tentative conclusions. For external audits, Jefferson has an opportunity at this meeting, called an exit conference, to comment on the proposed findings and to present additional information. All exit conferences are coordinated by the Department of Internal Audit. Other Jefferson representatives may be requested to attend such briefings as deemed necessary by the anticipated significance and nature of the audit recommendations. Following the exit conference, Internal Audit coordinates the University's response to audit findings and recommendations. The PI or department may be called upon to provide additional information or documentation in order to prepare the institution's response.

Financial liability for an audit disallowance, other than for those that result from deficiencies in the University's policies and procedures, rests with the department, institute, or center having primary responsibility for the project on which costs are questioned.

5.01 RESERVED

5.02 Office of Technology Transfer

The Office of Technology Transfer (OTT) was established at Jefferson to facilitate the development and marketing of inventions from both basic and clinical research.

5.03 Jefferson Policies Related to Intellectual Property

- Link to Policy 104.03 for Jefferson's Copyright Policy.
- Link to Policy 102.15 for Jefferson's Patent Policy.
- Link to Policy 102.36 for Jefferson's Policy on Tangible Research Property.