



Policy No: 110.22
Effective Date: 12/26/2014

UNIVERSITY POLICIES & PROCEDURES

Category:	Research
Title:	PRINCIPAL INVESTIGATOR (PI) ROLE AND RESPONSIBILITIES FOR SPONSORED PROJECTS
Applicability:	Thomas Jefferson University
Contributors/Contributing Departments:	

POLICY

Serving as the Principal Investigator or Co-Investigator (the PI) on a Research Project (defined below) is an enormous responsibility. There are a number of federal, state, and institutional rules, regulations and laws with which the PI must acquaint him/herself in order to fully comply and fulfill stewardship obligations. This policy provides a description of the research-related role of the PI and the PIs responsibilities for conducting, administering and/or participating in research at Jefferson, whether externally or internally funded. The PIs role and responsibilities are one integral component of Jefferson's Research Compliance Program. This policy applies to all sponsored projects, including, but not limited to, sponsored projects for any purpose, clinical trials, investigator initiated research, government sponsored projects, department sponsored research, program services, and research collaborations (collectively, Research Projects).

PROCEDURE

1. The PI will be knowledgeable of his/her role in the Research Project. See, Attachment 1.
2. Each PI will abide by and carry out the responsibilities applicable to the PIs role in the Research Project. For a list of Policies and Procedures applicable to PIs and other members of the research team, see, Attachment 2.

Revision Date(s):

Review Date(s):

Responsibility for maintenance of policy: Research Compliance Officer

(Signature on File)

Approved by:
Mark Tykocinski, MD
Provost and Executive Vice President for Academic Affairs,
Thomas Jefferson University

Attachment 1: Description of Principal Investigator Role and Responsibilities

- Regulatory Requirements/Policies & Procedures Adherence
- Record and Research Property Retention
- Audit
- Continuing Education
- Faculty and Key Personnel Management
- Opportunity Identification
- Scientific Oversight
- Publication Management
- Space Allocation
- Subrecipient Monitoring
- Proposal Preparation: Technical
- Negotiations with Sponsor
- Proposal Preparation: Administrative
- Proposal Preparation: Budget
- Acceptance of an Award
- Inventions and Patents
- Conduct of Research
- Conflict of Interest Disclosure and Management
- Billing for Clinical Services
- Final Technical Report
- Effort Certification and Salary Allocation
- Budget Management
- Account Establishment
- Cash and Revenue Management
- Personnel Management
- Expense Allocation and Purchasing
- Equipment Purchasing, Tracking and Safeguarding
- Financial Reporting
- Project Closeout

REGULATORY REQUIREMENTS/POLICIES & PROCEDURES ADHERENCE

Jefferson faculty and staff are responsible for ensuring compliance with all federal, state and local laws and regulations, sponsor requirements and all Jefferson policies and procedures.

Compliance with federal, state and local laws and regulations, and all Jefferson policies and procedures includes but is not limited to:

- National Institutes of Health Grants Policy Statement
- Office of Management and Budget Circular A-21, through 12/26/14
- Office of Management and Budget Circular A-110, through 12/26/14
- Office of Management and Budget Circular A-133, through 12/26/14
- OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards
- 45 Code of Federal Regulations, Title 46, Protections of Human Subjects and associated policies, including Institutional Review Board requirements
- 9 Code of Federal Regulations, Title 1 - Animal and Animal Products, the Animal Welfare Act and other associated regulations and policies, including Institutional Animal Care and Use Committee requirements
- Conflict of interest Requirements
- Environmental Health and Safety requirements, including Institutional Biosafety Committee requirements
- All Jefferson policies and procedures

The Principal Investigator (PI) is responsible for making certain that all staff and support personnel are properly trained in the practices and techniques required to ensure safety, for supervising the safety performance of those involved, for providing safe and healthful working conditions for employees, and for fostering environments conducive to high-quality research.

A PI is an individual designated by Jefferson to have the appropriate level of authority and responsibility to direct the research project. The PI is responsible and accountable to Jefferson, or, as appropriate, to a collaborating organization, for the proper conduct of the research project, including the submission of all required reports.

PIs are members of the team responsible for ensuring compliance with the financial and administrative aspects of the research project. They work closely with designated officials within Jefferson to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge support of research findings in publications, announcements, news programs, and other media; and ensure compliance with other sponsor and organizational requirements.

RECORD AND RESEARCH PROPERTY RETENTION

All Jefferson faculty and staff are required to retain Jefferson records and research property in accordance with sponsor requirements as well as Jefferson policies and procedures. See, policies on Retention of University Records (Policy No. 102.39) and Retention of Tangible Research Property (Policy No. 110.05).

AUDIT

Jefferson is subject to internal and external audits, site visits, and inspections, including those by Jefferson's Internal Audit Department and various regulatory, sponsoring, and commercial entities, among which are an annual financial audit and audit of our federal expenditures. It is the responsibility of all Jefferson faculty and staff to cooperate with all auditors, and to be prepared to provide documentation to justify transactions on a research project and discuss allocation of costs and other related issues. In addition, faculty and staff should be prepared to discuss their personal knowledge of applicable laws and regulations regarding research projects and Jefferson policies and procedures with auditors. Faculty and staff should notify Jefferson officials of any requested external audits in accordance with Jefferson policies and procedures. For example, see policy on Inspections by Regulatory and Licensing Agencies (Policy No. 121.31).

CONTINUING EDUCATION

PIs are required to attend educational sessions and/or certify in relevant subjects and to ensure that key personnel working on their research projects have attended all necessary educational sessions and/or certified in necessary subjects. For specific training and education opportunities and requirements, contact the applicable administrative office.

Further, each member of the Jefferson community is responsible for maintaining a current working knowledge of all areas of research as they relate to the individual's particular role and responsibilities. All supervisors are responsible for developing an annual training plan with their employees. Employees should address suggestions and concerns regarding continuing education in research to the appropriate professional development contact.

FACULTY AND KEY PERSONNEL MANAGEMENT

The PI is responsible for (1) ensuring key personnel understand the Notice of Award or other agreement, which contains the terms and conditions of the agreement and sponsor requirements; (2) ensuring key personnel carry out the research project as written; and (3) reporting the absence or withdrawal of key personnel from a research project during any consecutive period of three months or more, or reduction of time devoted to the project by 25% or more, to the Office of Research Administration (ORA).

OPPORTUNITY IDENTIFICATION

The PI is responsible for seeking research project funding opportunities in accordance with his/her Jefferson appointment.

SCIENTIFIC OVERSIGHT

The PI is responsible for scientific integrity of the research project, oversight of research project personnel, and all aspects of the research project from application, to award, to close out.

PUBLICATION MANAGEMENT

The PI is responsible for reporting publications to sponsoring agencies as required and complying with Jefferson's publication, authorship and industry relations policies, including but not limited to those prohibiting ghostwriting. See, policies on Authorship (Policy No. 110.04); Copyright Infringement (Policy No. 104.03) and Industry Relationships (Policy No. 107.25).

SPACE ALLOCATION

The PI is responsible for ensuring Jefferson space is used for Jefferson purposes and complying with all applicable facilities policies and procedures.

SUBRECIPIENT MONITORING

The PI shall oversee and be responsible for the administrative, fiscal and scientific aspects of a subrecipient agreement, if such an agreement has been executed. Prior to requesting and entering into a subrecipient agreement, the PI should first demonstrate that Jefferson resources are not available in direct support of this research endeavor. See, policy on Jefferson's Subrecipient Monitoring (Policy No. xxx.xx).

PROPOSAL PREPARATION: TECHNICAL

The PI has the primary scientific and ethical responsibility for any proposal including ensuring that proposal is written in accordance with acceptable scientific methods. The PI prepares the technical proposal and may collaborate with others in its preparation. The PI identifies the needs for resources, additional space, and/or renovations or

modification to existing space to conduct the research, which shall be in accordance with Jefferson's strategic mission.

NEGOTIATIONS WITH SPONSOR

The PI is responsible to work with ORA and provide all needed information needed for ORA to negotiate the approved project scope and project budget. The PI will notify ORA and the appropriate regulatory office(s) where project scope changes will affect approved protocols or require communication with the sponsoring agency. See, policy on Authority Levels for Commitment of University Resources (Policy No. 103.28).

PROPOSAL PREPARATION: ADMINISTRATIVE

The PI has the primary administrative responsibility for all aspects of a proposal.

The PI confirms that the entire proposal meets the administrative requirements outlined in the funding opportunity instructions. Examples of such requirements include deadlines, dollar limits, page limitations, font type and size.

The PI is responsible for submitting proposals to ORA for review and signature in accordance with standard procedures.

PROPOSAL PREPARATION: BUDGET

The PI assumes primary financial responsibility for all aspects of proposal submission according to sponsor guidelines. The PI prepares or directly supervises the preparation of the categorical budget and justification, specifies the appropriate facilities and administrative (F&A) cost rate from Jefferson's negotiated rates, identifies matching funds or in-kind contributions, and documents cost-sharing and anticipated program income. The PI also identifies all available financial resources available in direct support of this or other research endeavors. The PI identifies potential budget overlap for related projects. See, policy on Cost Sharing and Matching Funds for Sponsored Projects (Policy No. 103.26).

ACCEPTANCE OF AN AWARD

The PI is responsible for reviewing, approving and ensuring he/she and staff understand and comply with the Notice of Award, which contains the terms and conditions of the award and sponsor requirements.

The PI is responsible for submitting to ORA an approved budget, revised as needed, based on the level of funding in the Notice of Award as soon as possible so that the account may be established.

INVENTIONS AND PATENTS

As a condition of employment, the PI, faculty and staff are responsible to sign and submit an Assignment of Invention agreement to assign to Jefferson all patentable, or deemed patentable, inventions. The agreement is maintained by ORA. The PI is responsible for notifying ORA, and the Office of Technology Transfer, and sponsors as required, in the event that the PI's research project results in a new invention or patent agreement. The PI is responsible for completing, signing, and forwarding to ORA all applicable sponsor reports and internal forms, as requested by ORA. See, policies on Patent Policy (Policy No. 102.15), Policy of Equity Acceptance, Handling & Sale of Technology Licensing Arrangements (Policy No. 102.37), and Material Transfer Agreement Policy (Policy No. 110.11).

CONDUCT OF RESEARCH

The PI is responsible for both the administrative and scientific requirements of conducting research. The PI is responsible for ensuring that all research is conducted according to sponsor regulations and TJU policies and procedures. As a guideline, the ethical conduct of research includes but is not limited to the following:

- Authorship
- Data stewardship and management
- Protection of human subjects, including IRB non-compliance
- Animal protections
- Mentoring and training of those working on research project
- Conflict of interest
- Research misconduct
- Clinical Trial Billing
- Laboratory safety and protections

See, policies on Code of Conduct (Policy No. 107.02) and Responding to Alleged Misconduct in Research (Policy No. 110.02). Additional Jefferson policies exist for each bulleted topic.

CONFLICT OF INTEREST DISCLOSURE AND MANAGEMENT

The PI is responsible for fidelity in the performance of functional duties and should conduct such duties for the purpose, benefit and interest of Jefferson. The PI is responsible for compliance with Jefferson's policy on Conflicts of Interest.

When submitting a proposal, the PI must certify that all significant financial interests related to the project have been disclosed.

Clinical Investigators must indicate any significant financial interests regarding protocols to the Institutional Review Board (IRB) and must follow all IRB policies and procedures in the process.

See, policies on Conflict of Interest for Employees Policy (Policy No. 107.03), and Conflicts of Interest Policy - Enforcement and Sanctions for Non-Compliance (Policy No. 107.18).

BILLING FOR CLINICAL SERVICES

The PI is responsible for ensuring that clinical services associated with research studies are billed appropriately and in compliance with relevant laws, regulations and contractual obligations and in compliance with Jefferson's policy. See, policy on Integrated Clinical Research Billing (Policy No. 110.18).

FINAL TECHNICAL REPORT

The PI is responsible for the preparation of a final technical (scientific) project report in accordance with sponsor guidelines within the time frame specified by the sponsor. The Investigator must provide a copy of the report transmittal letter and any related forms to ORA.

EFFORT CERTIFICATION AND SALARY ALLOCATION

The PI has the primary administrative responsibility in all aspects regarding Effort Certification from submission, to award, to close out of the project.

The PI is responsible for ensuring accurate and timely completion of his/her Effort Certification Report and reports for all Jefferson employees working on his/her research projects according to the established timeframes.

The PI is responsible for seeking the approval of a sponsor prior to making any significant change in the level of effort for key personnel or prior to the use of a substitute PI. Furthermore, the PI is responsible for seeking sponsor approval prior to any absence from campus of three or more months. See, policy on Status Change for Principal Investigators and Key Personnel on Sponsored Projects (Policy No. 110.09).

The PI is responsible for managing commitment of effort and project overlap, and to inform ORA and/or sponsors accordingly.

The PI is responsible for ensuring compliance with all federal regulations regarding effort certification as well as Jefferson policies and procedures. See, policies on Effort Certification (Policy Nos. 110.06 and 110.07).

BUDGET MANAGEMENT

The PI has the primary administrative responsibility for all aspects of a research project. This includes ensuring that expenses related to the project do not exceed funds received from the sponsor. The PI will review monthly financial reports and work with administrative staff to ensure that all expenditures are allowable, allocable, and consistent with and within the approved research project budget, reasonable, processed on a timely basis and meet the terms and conditions of the sponsoring agency. See, policies on Costing Guidelines for Sponsored Projects (Policy No. 103.25) and Unallowable Costs for Sponsored Projects (Policy No. 103.21).

ACCOUNT ESTABLISHMENT

The PI will receive a general ledger account for the research project and is responsible for ensuring staff use the proper account for expenditures and cash received.

CASH AND REVENUE MANAGEMENT

The PI has the primary administrative responsibility for all aspects of a research project including the timely receipt of cash from a sponsor and assisting in collection activities when applicable.

PERSONNEL MANAGEMENT

The PI is responsible for allocating salary for all research project personnel based on a best estimate of the actual effort that will be expended on the project at the time of proposal preparation. The allocation must be allowable and allocable according to sponsor guidelines.

If the PI expects significant changes in effort throughout the project, the PI will revise the salary allocation in advance of those changes.

The PI is responsible for reviewing monthly reports to ensure that personnel charges including travel and expense reimbursements are allowable, allocable, consistent, reasonable and within the project budget. See, policies on Report of Travel Expenses (Policy No. 102.02) and Employee Reimbursement Request (Policy No. 103.35).

EXPENSE ALLOCATION AND PURCHASING

The PI is responsible for allocating expenses at the time of purchase. The PI will develop a reasonable and consistent methodology for expense allocation among research

projects, and will ensure that laboratory personnel understand and employ the appropriate allocation methodology.

The PI is responsible for all purchases made against a research project account, and will review monthly financial reports to ensure that charges made to the account are allowable, allocable, consistent, reasonable and within the project budget. See, policies on Purchase Request (Policy No. 118.02), Procurement Credit Card - Use of (Policy No. 103.00), Purchases from Foreign Sources (Policy No. 118.10), Request for Payment (Policy No. 103.15), and Interdepartmental Transactions (Policy No, 103.18).

EQUIPMENT PURCHASING, TRACKING, AND SAFEGUARDING

The PI is responsible for initiating equipment purchases according to the project budget, or submitting capital rebudgeting requests, as necessary.

In the event of a PI's departure from Jefferson, the PI must obtain the approval of the Department Chair in order to transfer any equipment necessary for the continuation of a project. In the case of assets purchased with a research project, refer to sponsoring agency's asset disposition instructions. See, policy on Capital Budget Process (Policy No. 103.08).

FINANCIAL REPORTING

The PI is responsible for reviewing the monthly financial reports that are distributed by the Sponsored Programs Accounting Office to ensure that the charges made to accounts are accurate, allowable, consistent, reasonable and allocable to the particular research project.

The PI will review and approve the Federal Financial Report or any other sponsor-required report as requested by the Sponsored Program Accounting Office.

PROJECT CLOSEOUT

The PI has the primary administrative responsibility for all aspects of a research project. The PI will ensure that all research project deliverables are provided to the sponsor in accordance with the agreement, and that research project accounts are cleared within a reasonable time frame after the completion of the research project.

Attachment 2: List of Jefferson Policies & Procedures for Research Compliance

Number	Category	Title	Responsibility	Role
102.02	Administration	Report of Travel Expenses	Personnel Management	Principal Investigator
102.15	Administration	Patent Policy	Inventions and Patents	Principal Investigator
102.19	Administration	Internal Audit	Audit	Principal Investigator
102.27	Administration	Electronic Communications and Information	Conduct of Research	Principal Investigator
102.36	Administration	Tangible Research Property	Conduct of Research	Principal Investigator
102.37	Administration	Policy on Equity Acceptance, Handling & Sale of Technology Licensing Arrangements	Inventions and Patents	Principal Investigator
102.39	Administration	Policy on Retention of University Records	Record and Research Property Retention	Principal Investigator
102.40	Administration	Policy on Legal Holds	Conduct of Research	Principal Investigator
102.42	Administration	Institutional Conflicts of Interest Policy	Conflict of Interest Disclosure and Management	Principal Investigator
107.01	Compliance Administration	Compliance Hotline - Employee	Conduct of Research	Principal Investigator
107.02	Compliance Administration	Code of Conduct	Conduct of Research	Principal Investigator
107.03	Compliance Administration	Conflicts of Interest Policy for Employees	Conflict of Interest Disclosure and Management	Principal Investigator
107.06	Compliance Administration	Prohibition Against Retaliation for Good Faith Reporting of Noncompliance	Conduct of Research	Principal Investigator
107.15	Compliance Administration	Investigations and Disciplinary Actions Related to Violations of the Corporate Compliance Program	Conduct of Research	Principal Investigator
107.16	Compliance Administration	Limitations on Employment During Government Investigations	Conduct of Research	Principal Investigator
107.17	Compliance Administration	Conflict of Interest Policy: Distribution to New Employees	Conflict of Interest Disclosure and Management	Principal Investigator
107.18	Compliance Administration	Conflicts of Interest Policy - Enforcement and Sanctions for Non-Compliance	Conflict of Interest Disclosure and Management	Principal Investigator
107.21	Compliance Administration	Compliance Policies Review	Conduct of Research	Principal Investigator
107.24	Compliance Administration	Prevention of Fraud, Waste and Abuse in Connection with University Activities	Conduct of Research	Principal Investigator
107.25	Compliance Administration	Industry Relationships Policy	Publication Management	Principal Investigator
103.00	Financial	Procurement Credit Card - Use of	Expense Allocation and Purchasing	Principal Investigator
103.08	Financial	Capital Budget Process	Equipment Purchasing, Tracking, and Safeguarding	Principal Investigator
103.15	Financial	Request for Payment	Expense Allocation and Purchasing	Principal Investigator
103.18	Financial	Interdepartmental Transactions	Expense Allocation and Purchasing	Principal Investigator
103.24	Financial	University Service Centers	Expense Allocation and Purchasing	Principal Investigator

Number	Category	Title	Responsibility	Role
103.28	Financial	Authority Levels for Commitment of University Resources	Negotiations with Sponsors	Principal Investigator
103.35	Financial	Employee Reimbursement Request	Personnel Management	Principal Investigator
122.00	HIPAA	HIPAA Privacy	Conduct of Research	Principal Investigator
122.17	HIPAA	Risk Analysis and Ongoing Risk Management	Conduct of Research	Principal Investigator
122.19	HIPAA	Activity Review of Information System Security	Conduct of Research	Principal Investigator
122.21	HIPAA	Assignment and Management of Information Access Privileges	Conduct of Research	Principal Investigator
122.25	HIPAA	Assignment of Facility Access Controls or Privileges	Conduct of Research	Principal Investigator
122.26	HIPAA	Policies and Guidelines on Work Station Use and Security	Conduct of Research	Principal Investigator
123.01	Information Security Program	University Information Security Policy	Conduct of Research	Principal Investigator
123.02	Information Security Program	Information Classification and Handling	Conduct of Research	Principal Investigator
115.10	Jeff IT	Device and Media Controls	Conduct of Research	Principal Investigator
115.12	Jeff IT	Mobile Computing: Smartphone and Tablet Security	Conduct of Research	Principal Investigator
115.13	Jeff IT	Email Security	Conduct of Research	Principal Investigator
121.31	Jefferson University Physicians	Inspections by Regulatory and Licensing Agencies	Audit	Principal Investigator
121.45	Jefferson University Physicians	Patient Bill of Rights and Responsibilities	Conduct of Research	Principal Investigator
104.03	Legal	Copyright Infringement; Ownership and Distribution of Copyrightable Works Created in the Course of Activities at the University	Publication Management	Principal Investigator
110.01	Research	Authorization for Consultant Services Required for Sponsored Projects	Expense Allocation and Purchasing	Principal Investigator
110.02	Research	Responding to Alleged Misconduct in Research	Conduct of Research	Principal Investigator
110.04	Research	Authorship	Publication Management	Principal Investigator
110.05	Research	Retention of Tangible Research Property	Record and Research Property Retention	Principal Investigator
110.06	Research	Effort Certification for Exempt University Staff on Sponsored Projects	Effort Certification and Salary Allocation	Principal Investigator
110.07	Research	Effort Certification for Non-Exempt University Employees and All Hospital Employees on Sponsored Projects	Effort Certification and Salary Allocation	Principal Investigator
110.09	Research	Status Change for Principal Investigators and Key Personnel on Sponsored Projects	Effort Certification and Salary Allocation	Principal Investigator
110.10	Research	Education of New Research Personnel	Continuing Education	Principal Investigator
110.11	Research	Material Transfer Agreement Policy	Inventions and Patents	Principal Investigator
110.14	Research	Policy for Postdoctoral Fellow Grant Applications	Conduct of Research	Principal Investigator
110.15	Research	Institutional Review Board Review of Noncompliance Issues	Conduct of Research	Principal Investigator

Number	Category	Title	Responsibility	Role
110.16	Research	Policy for Volunteers and External Employee Participation in Research Laboratories	Conduct of Research	Principal Investigator
110.17	Research	Collection, Storage, Use and Distribution of Tissue for Research Purposes	Conduct of Research	Principal Investigator
110.18	Research	Integrated Clinical Research Billing Policy	Billing for Clinical Services	Principal Investigator
110.19	Research	Access to Jefferson University Physicians Electronic Medical Records by Research Coordinators for Research Purposes	Conduct of Research	Principal Investigator
110.20	Research	Subrecipient Monitoring for Sponsored Projects	Subrecipient Monitoring	Principal Investigator
110.21	Research	Program Income on Sponsored Project	Proposal Preparation: Budget	Principal Investigator
110.23	Research	Costing Guidelines for Sponsored Projects	Budget Management	Principal Investigator
110.24	Research	Cost Sharing and Matching Funds for Sponsored Projects	Proposal Preparation: Budget	Principal Investigator
110.25	Research	Unallowable Costs for Sponsored Projects	Budget Management	Principal Investigator
119.28	Safety/Security Administration	Corridor Storage	Conduct of Research	Principal Investigator
119.29	Safety/Security Administration	Visitor Restrictions in Research Laboratories	Conduct of Research	Principal Investigator
119.36	Safety/Security Administration	Disposal of Biohazardous Material from Research/Teaching Laboratories	Conduct of Research	Principal Investigator
119.37	Safety/Security Administration	Emergency Response Team	Conduct of Research	Principal Investigator
119.38	Safety/Security Administration	Employee Safety Education Programs	Continuing Education	Principal Investigator
119.39	Safety/Security Administration	Safety Program	Conduct of Research	Principal Investigator
119.40	Safety/Security Administration	Internal Disaster Plan	Conduct of Research	Principal Investigator
119.45	Safety/Security Administration	Vaccinia Virus Vaccination	Conduct of Research	Principal Investigator
119.46	Safety/Security Administration	Internal Disaster Plan for Animal Research Facilities	Conduct of Research	Principal Investigator
119.48	Safety/Security Administration	Bloodborne Pathogens - Exposure Control Plan	Conduct of Research	Principal Investigator
118.02	Supply Chain Management	Purchase Request	Expense Allocation and Purchasing	Principal Investigator
118.10	Supply Chain Management	Purchases from Foreign Sources	Expense Allocation and Purchasing	Principal Investigator