Office of Grant and Contract Management

Principal Investigators and Co-Investigators: Eligibility, Roles, and Responsibilities

2014

UNT Health Science Center

Principal Investigators and Co-Investigators:

Eligibility, Roles, and Responsibilities

Definition(s)

Principal Investigator (PI) – A Principal Investigator is the primary individual responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, training or public service project, contract, or other sponsored project in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research. PIs will share in the return of F&A.

Co-Investigator (Co-I) –Co-Is are key personnel who have responsibilities similar to that of a PI on research projects. While the PI has ultimate responsibility for the conduct of a research project, the Co-I is also obligated to ensure the project is conducted in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research.

Faculty Participants – University of North Texas Health Science Center faculty may be involved in projects as key personnel without the same responsibilities of a PI or Co-I. These faculty are not responsible for the conduct of the project. Faculty participants may participate in the research, may collect salary, and may have a role in publications. The term "Faculty Participant" is used below to refer to this category.

Eligibility

Being granted PI and Co-I status is a privilege granted to eligible University personnel who meet the criteria identified below. All persons granted PI and Co-I authority must accept all of the responsibilities associated with the application for and administration of awarded sponsored projects.

Each PI certifies with every proposal submission that all information provided is true and complete and that the proposal conforms to the University policies and procedures applicable to sponsored activities. In order to be certified as a PI, a researcher must confirm that he/she will comply with all regulatory compliance directives; that all information submitted within the proposal is true, complete, and accurate to the best of his/her knowledge; that any false, fictitious, or fraudulent statements or claims may subject the investigator(s) to criminal, civil, or administrative penalties; and that the investigators(s) agree to accept responsibility for the conduct of the project and to provide all required reports as applicable if a project is awarded as a result of the proposal.

If a proposal is submitted with multiple PIs, all PIs must submit their own External Proposal Transmittal Form.

Upon receipt of an award, each PI and Co-I must assume responsibility for project management of the award and carry out the project with the highest professional standards and within the time period awarded. The PI assumes responsibility to read, understand, and comply with all of the terms and conditions contained in the award. Finally, the PI must confirm that he/she understands his/her responsibility to abide by University and sponsor policies, procedures and directives for the proper administration of sponsored projects.

Who can be a PI?

Persons eligible to be PI shall be full-time and/or part-time regular and/or non-regular faculty. The Health Science Center encourages faculty members, individually or in collaborations, to seek outside support for research that will contribute to new knowledge. Although the Health Science Center has established various procedures related to the conduct of research projects, the responsibility for managing these projects lies with authorized PI or project directors.

Individuals without faculty status may serve as PI under the following conditions: (1) as Co-Investigators with an individual of appropriate rank, or (2) with approval from the Vice President for Research.

Examples of individuals who generally need the approval of the Vice President for Research to be a PI are:

- Graduate students (unless the sponsor's program guidelines require the student to be listed as PI on the proposal application in which case the student's faculty mentor/advisor shall be the PI of record on the External Proposal Transmittal Form and responsible for the conduct and oversight of the project)
- Visiting professors (any rank)
- Visitors in a post-doctoral position
- Adjunct Professors
- Anyone not in a permanent employee status

Who can be a Co-I?

Persons eligible for designation as PI are also eligible to be designated as Co-Is. No graduate students may be designated as Co-Is. Persons who are located at other universities and who do not hold appointments in eligible categories at the University of North Texas Health Science Center may not be designated as Co-Is. Relations with collaborators at other universities, research institutes or corporations should be handled through subcontracts to the institutions involved.

PI Responsibilities:

PROPOSAL PREPARATION AND SUBMISSION

General The PI confirms that the entire proposal meets requirements outlined in the Program Announcement, Request for Application (RFA), Request for Proposal (RFP), or other application instructions. Examples of such requirements include, but are not limited to, award minimums/maximums, page limitations, font/margins, electronic file type/size, deadlines, and mailing addresses. The PI may delegate this responsibility to Department Administrative Staff. If the PI's unit lacks Department Administrative Staff for proposal preparation, award management, or other sponsored programs administration requirements, he/she assumes these responsibilities or seeks support from the respective Department Chair or Dean.

Technical Proposal

The Principal Investigator:

- Prepares the technical proposal and may collaborate with others in its preparation.
- Identifies the need for subrecipient agreements.
- Determines whether on- or off-campus space in addition to that already assigned to the PI is needed. (The PI identifies the need, and requests it from his/her supervisor, or other appropriate University manager.)
- Takes responsibility for keeping his/her CV or biosketch updated.
- Ensures that procedures used are consistent with sound research design and do not unnecessarily expose subjects to risk/harm.
- Assures that the design is appropriate to the proposed question.
- Determines that the project will contribute original scholarship.

Proposal Budget

The Principal Investigator:

- Prepares or directly supervises the preparation of the budget and its justification.
- Selects the appropriate facilities and administrative or indirect cost rate from the negotiated rates, under guidance from the Office of Grant and Contract Management (OGCM).
- If appropriate, makes a Facilities & Administrative cost (i.e. Indirect Cost) waiver request to OGCM who will coordinate with the Vice President for Research and Innovation for final approval;

- If required by the sponsor, requests matching funds from Department Chair and/or Dean or identifies in-kind contributions from appropriate sources.
- If required by the sponsor, proposes cost sharing through contributed effort or other approved mechanisms and seeks approval from appropriate University officials.
- Identifies all available financial resources in direct support of this or other research endeavors (other support) either at proposal submission or "Just In Time" in accordance with sponsor requirements.

Regulatory Requirements

The Principal Investigator:

- Prepares the appropriate forms for the University Human Subjects IRB, or the Animal Care IACUC, the Radiation Safety Office and/or Biosafety Office, if the proposal involves:
    - human subjects;
    - live animals as subjects;
    - recombinant DNA, infectious agents, narcotics or biological toxins;
    - human blood or body fluids;
    - radioactive materials and/or ionizing or non-ionizing radiation-producing equipment;
    - hazardous materials; or
    - Protected Health Information (PHI).
- Discloses all potentially significant conflict of interest situations, successfully completes the Conflict of Interest Training, and prepares a Research Conflict of Interest Disclosure Statement annually and submits it to the Office of Research Compliance.
- Affirms that he/she is not excluded or debarred from receiving Federal funds, and is not delinquent in student loans.
- Ensures that other personnel involved in the project sign the University External Proposal Transmittal Form (EPTF) as required.

External Proposal Transmittal Form (EPTF)

The Principal Investigator:

- Prepares or directly supervises the preparation of the External Proposal Transmittal Form. (The PI must be the person who checks the boxes in section 7 of the EPTF; this responsibility may **not** be delegated.)
- Discloses the involvement of other departments or schools/colleges and ensures External Proposal Transmittal Form (EPTF) is initiated by all Co-Is.
- Signs the External Proposal Transmittal Form. This responsibility cannot be delegated and the signature certifies that each item on the form is filled-out completely and accurately.

PRE-AWARD REQUIREMENTS

Pre-Establishment/ Pre-Award of Expenditure ProjID

The PI may request pre-established ProjID, if necessary and allowable by the sponsor's guidelines. Many federal sponsors allow for 90 day pre-award costs; however, in the event an official award is not received, all expenditures will be the responsibility of the PI, Co-I and respective Department/Unit Head and/or Dean, or Director of the relevant school, college or institute. Therefore, the Department/Unit Head will authorize and approve all pre-established ProjIDs. (Department Administrative Staff should be cognizant of the need for (and use of) pre-established ProjID, which minimizes cost transfers and/or payroll reallocations.)

Small Business Subcontracting Plan

When applicable and required by the Sponsor's requirements, the PI works with OGCM, the Business Services Center Purchasing Office and Department Administrative Staff to establish a Small Business contracting plan and to define roles and responsibilities throughout the project period of performance.

Negotiations with Sponsor

Formal negotiations with the sponsor are conducted only by OGCM staff. All submissions of revised budgets and revised work scopes, as well as other information requested by the sponsor, must be coordinated with and submitted by OGCM to the sponsor.

The Principal Investigator role in negotiations:

- Negotiates informally and forwards the approved revised project work scope to OGCM for submission to the sponsor.
- In collaboration with Department Administrative Staff and OGCM, the PI modifies the project budget in line with the sponsor's instructions for modification. (Department Administrative Staff should be involved in any budget modification, as this can impact other budgeting and effort issues on other projects or DeptIDs.)
- The PI communicates with the Co-Is and other Faculty Participants concerning any changes in scope of work or budget that would substantially impact their participation in the project. When Co-Is or other Faculty Participants have their participation impacted substantially, the PI should provide to them verbatim copies of the relevant sections from peer reviews when those are available.
- Notifies the appropriate regulatory office if changes to project scope will affect approved protocols.
- Obtains approvals if cost sharing becomes necessary.

Acceptance of Award

When the PI receives from OGCM the Notice of Award (NOA) email that stipulates the approved budget and the terms and conditions of the award, he/she should immediately initiate

communication with Department Administrative Staff for the review of the NOA for their part in helping the PI administer the project.

POST-AWARD CONDUCT AND MANAGEMENT OF THE PROJECT

General

PIs should reference the Division of Research and Innovation web site: (http://web.unthsc.edu/research) or contact appropriate university offices to obtain information about rules and requirements governing sponsored funding. PIs are responsible for knowing what actions require sponsor approval and for obtaining that approval with involvement/assistance from OGCM.

Investigators should become familiar with the rules and guidelines for responsible conduct of research including supervision of students and trainees, data gathering and retention, authorship, and publication. Adherence to the rules and guidelines will protect an investigator and his/her laboratory in the event there are questions of research integrity. Guidelines can be found at https://www.unthsc.edu/research/office-of-research-compliance/the-responsible-conduct-of-research-rcr/ under Responsible Conduct of Research.

Conduct of the Research

The Principal Investigator:

- Is responsible for all actions required to manage and complete the scientific and programmatic aspects of the sponsored project.
- Initiates programmatic changes to the project and seeks approval from the sponsor via request to OGCM when required.
- Initiates the hiring or assignment process and approves the selection or appointment of individuals to the project, and is responsible for communicating staff changes to Department Administrative Staff.
- Defines and communicates roles and responsibilities for each project employee.
- Regularly meets with project team to keep them informed of the status of project activities.
- Ensures the integrity and safeguarding of notebooks and scientific data.
- Ensures the completion, accuracy and timeliness of programmatic (technical) reports.
- Initiates requests for and monitors subrecipient agreements prepared by OGCM.
- Ensures the quality, timeliness, and programmatic (technical) performance of subrecipients.
- Initiates a materials transfer agreement with the OGCM when using or providing materials to or from another source.

<u>Budget Management</u>

While the PI retains primary responsibility for financial accountability, the PI or the Department/Unit Head can delegate an authorized representative to act on his or her behalf for ProjIDs. ProjIDs should be managed by persons trained in these responsibilities. OGCM is responsible for ProjID management at the University level and responsible for all payments, invoices, financial reporting, etc. to the sponsoring agency.

The Principal Investigator:

- Ensures only individuals working on the project are paid on the project.
- Ensures the percent of time paid to individuals working on the project reasonably reflects the percent of time worked on project.
- Maintains adequate documentation to support time worked and paid on the project.
- Communicates significant percentage changes in time worked on the project by project employees to the Department Administrative Staff so ePARs can be processed to accurately reflect the changes.
- If project employees work on multiple external projects, ensures allocation of time worked and salary paid is appropriate across all projects.
- Certifies after the fact effort reports for all project team employees.
- Initiates purchases.
- At the time expenditures are initiated, determines that expenditures are allowable, allocable, and reasonable; approves them; and provides scientific justification for the transaction, if necessary.
- Initiates the process of documenting cost sharing and/or matching and for ensuring that cost sharing obligations are met from allowable and verifiable sources, including those by third party collaborators, if included in approved budget.
- Initiates requests for rebudgeting to OGCM who determines if internal or external approval is required based upon sponsor requirements.
- Initiates cost transfer requests. When salary transfer requests are made, ensures these are based on actual effort expended and not merely as budgeted (per OMB Circular A-21 and Uniform Guidance).
- Identifies and proposes a resolution of any ProjID deficit.
- Reviews subrecipient invoices for appropriateness and, to monitor progress of the work, approves payment of subrecipient invoices.
- Uses available systems for financial monitoring, identifies and resolves errors in the ProjID in a timely manner. If appropriate and required at budget period end, the PI requests that remaining balances are carried forward.

<u>Program Income</u>

The Principal Investigator:

- When applicable, is required to understand the definition of program income.
- Identifies all program income and notifies OGCM when program income is anticipated and received.

- Initiates the processes and proposes the allocation of program income.
- Monitors receipt of program income.
- Reviews program income reported to the sponsor by OGCM.

Effort Reporting

The federal and state government require an effort report when an individual is compensated by or has agreed to contribute time (cost share) to a sponsored project. All faculty who serve as investigators on sponsored projects are personally responsible to certify the amount of time they and their employees spent on project activities.

The Effort Reporting System generates and distributes a payroll report for every federal and state sponsored project. The PI signs and certifies effort for themselves and employees on the project in accordance with the University's Effort Reporting Policy and Procedures, designed in compliance with OMB Circular A-21, "Cost Principles for Educational Institutions," Section J.10, Compensation for Personal Services and "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," 2 CFR Part 200, Section 200.430, Compensation – Personal Services. See University Effort Reporting policy at https://app.unthsc.edu/policies/PoliciesPDF/Time%20and%20Effort%20Reporting.pdf

Effort Reporting on-line tutorial for PIs and Department Administrative Staff can be accessed at https://upk.admin.unt.edu/KContent/261/data/toc.html?launchFromKpath=1

Key Effort Terms:

Teaching, Educational Training and Service Salary – this salary component is determined by the actual contribution for teaching, educational training and service contributions. Teaching typically refers to classroom, on-line, and course laboratory instruction that involved direct student contact time, whereas educational training is primarily student training in clerkships, research laboratory experiences and other "non-classroom" environments.

Designated Salary – This salary component is directly dependent on funding streams for activities that faculty may participate in, e.g., research activities, administrative duties, and/or patient care activities.

Total Base Compensation – Total base compensation is equal to teaching, educational training and service salary plus designated salary.

Faculty workload models may be found at the following link: http://web.unthsc.edu/info/200129/faculty_affairs/1727/faculty_contracts

Significant changes in level of effort from those committed in the sponsor award for key personnel should be communicated to OGCM for determination if internal or external sponsor approval is required.

Project Transfer

All awards are made to the University and not to the individual investigator. In the event a PI leaves the University, he/she must notify Co-Is, Faculty Participants, the department head and dean of such departure in advance and seek appropriate next step instructions from the department head, dean, and OGCM.

Should the PI choose to leave the award with the University, the PI must notify OGCM of their departure as soon as possible and assist with the proper sponsor notification. Such notification will either be a replacement investigator, or termination of the award.

Inventions and Intellectual Property

The Principal Investigator:

- Adheres to the principles and policies outlined in the University's Intellectual Property Policy https://app.unthsc.edu/policies/PoliciesPDF/Intellectual%20Property.pdf and the Conflict of Interest Policy https://app.unthsc.edu/policies/PoliciesPDF/Research%20Conflict%20of%20Interest.pdf
- Ensures that all employees working on the project also comply with the policy.

Implementing a Small Business Subcontracting Plan (if required by the sponsor)

The Principal Investigator:

- Directs purchases that are consistent with the project budget and the approved Small Business Plan (if required by the sponsor).
- The PI or his/her delegate interacts with Procurement staff regarding progress toward achievement of Small Business Plan goals and reviews periodic reports about goals.
- Provides an explanation when Small Business Plan goals are not achieved.

Project Closure

The Principal Investigator:

- Prepares the final programmatic (technical) narrative report, which may include contributions by subrecipients or collaborators.
- Submits any close out documentation needed in order for OGCM to submit financial status reports on a timely basis.
- Provides information on other close out reports, such as for patents and equipment (to OGCM).

- Retains the scientific data in accordance with the University's Record Retention policy   https://app.unthsc.edu/policies/PoliciesPDF/Records%20Retention%20Policy.pdf ; Data Integrity and Classification policy https://app.unthsc.edu/policies/PoliciesPDF/Data%20Integrity%20and%20Classification%20Policy.pdf

Regulatory Compliance

The Principal Investigator:

- Prepares an Annual Disclosure Statement Form in order to notify his/her Department Head, Dean, and Office of Research Compliance if a potential conflict of interest exists and makes additional disclosures in a timely manner if a conflict of interest arises.
- Is responsible for adhering to all educational and training requirements as the University requires.
- Adheres to protocols and policies for research subjects, and notifies the IRB or IACUC if changes are made to protocols.
- Meets continuing IRB/IACUC protocol review requirements and assists with inspections.
- Adheres to chemical, biological, physical and radiation safety requirements, and notifies the appropriate office if accidents occur.
- Adheres to the policies and procedures for using investigational new drugs and/or devices for clinical research.
- Participates in the annual cost sharing certification (if applicable), as well as the periodic space and equipment survey.
- Takes responsibility for adherence to record retention policy for all financial and scientific documentation.
- Takes responsibility for cooperating in the audit process, whether internal or external audit staff is involved.
- Takes responsibility for accounting of PHI disclosures, as required by HIPAA.
- Takes responsibility for understanding and compliance with all institutional and sponsor policies, practices, and procedures.