Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2011-011.0
Policy Title: Research Personnel

Purpose

The purpose of this policy is to identify who may act as a Principal Investigator for research studies and to describe expectations and obligations of research personnel.

Definitions

See policy 2011-007.0 for definition of:

Principal Investigator | Co-Investigator

Policy

Principal Investigators:

With the exception of studies supported by the CT Institute for Clinical and Translational Science (CICATS) and some student research projects, in the majority of cases only paid faculty of UConn Health, or University of Connecticut in Storrs or branch campuses qualify to serve as principal investigators on IRB applications for studies conducted at UConn Health.

- Only one person may be designated as the principal investigator.
- Students, fellows or other trainees may be designated as co-investigators but not principal investigators.

There are two exceptions to the paid faculty requirement as related to student research. For student projects conducted in the course of curricular activities, an individual with a clinical faculty appointment at UConn Health (i.e. non-pay faculty appointment) may act as PI for the student. UConn Health may accept a Hartford Hospital, CT Children's Medical Center, or St. Francis Medical Center employee as the Principal Investigator based on the affiliation agreement between UConn Health and these institutions to provide educational opportunities to our students. This also applies to any other site with which UConn Health develops or has such an agreement. UConn Health reserves the right to require that a UConn Health faculty member serve as PI for student projects.

Other requests for someone other than a paid faculty member to serve as PI will be reviewed on a case-by-case basis by the Director of the HSPP. The non-paid faculty fundamental criterion will be the strength of the accountability of the proposed PI to the institution. For other individuals, consideration will also be given to qualifications including degrees, licensure and prior research experience; the nature of the proposed study, and the individual's position and level of authority of that position.

Research Personnel:

The IRB may require that the research team include an individual holding a medical or dental degree, or an individual having some other specified expertise as a means for ensuring subject protections. The research team should also consist of at least one co-investigator who could fulfill the role of the principal investigator in the event of extended absence of the current principal investigator, e.g. due to sabbatical leave, medical leave or change in employment.

HSPP and IRB Expectations of Investigators and Research Personnel:

Principal Investigator: The IRB holds the principal investigator responsible for the overall management of an approved study. Management of the study encompasses the ethical, technical, administrative and fiscal

elements of a project. The principal investigator may delegate certain tasks but retains ultimate responsibility and accountability. Elements for which the principal investigator is responsible include, but are not limited to:

- understanding and applying relevant professional standards to the conduct of the study
- initiating the research team to the study and their respective roles and responsibilities
- supervising all study personnel and ensuring that all personnel abide by the ethical principles of respect for persons, beneficence and justice as outlined in the Belmont Report,
- communicating with and supervising study personnel to ensure they are knowledgeable of, and conducting the study in accordance with, the approved protocol (including approved modifications),
- protecting the rights and welfare of subjects,
- reporting any real or potential conflicts of interest of the PI or any study personnel and compliance with conflict of interest policies and management plans,
- reporting any changes in UConn Health affiliation for key study personnel to the IRB(e.g. PI or Co-I move to another institution but remain on study team),
- communicating with subjects, e.g. obtaining consent, informing subject of new information that may affect their willingness to continue to participate in the study, responding to complaints or requests for information
- ensuring protected health information is only used/disclosed in compliance with HIPAA.
- overseeing the budget and expenditures related to the study
- ensuring that adequate resources are available, including staff, equipment, supplies, bed space, storage space etc., to conduct the study at UConn Health and any other performance site for which the principal investigator is responsible,
- keeping the IRB informed of all funding sources of the study
- ensuring accurate billing of research related activities (e.g., subjects should not be billed for expenses covered by the sponsor, there should be no charges assessed to insurance carriers for procedures or treatments covered by the sponsor),
- disclosing information pertaining to adverse events including frequency of occurrences, severity of occurrences and duration of occurrences,
- requesting approval from the IRB for, and notifying the sponsor of, modifications to an approved study prior to implementation, e.g. requesting changes in the study personnel, in the consent form, or in the approved protocol,
- requesting continuation of an approved study by specified deadlines,
- maintaining and retaining research records and informed consent documents,
- providing the IRB with audit or inspection reports or findings issued by regulatory agencies, cooperative research groups, contract research organizations, the sponsor or the funding agency
- when applicable, the investigator's plans to communicate with representatives of the community from which individuals will be recruited about community concerns, values and expectations
- when applicable, maintaining accurate records on the receipt, use and disposition of excess drugs/devices, and
- conducting the study in compliance with internal policies and applicable regulations

All Study Personnel (including PI and co-investigators): The IRB holds all study personnel responsible for meeting certain obligations. These obligations include, but are not limited to:

- having knowledge of the ethics and regulations governing the protection of human subjects,
- being familiar with and following the reporting requirements regarding noncompliance and unanticipated problems,
- documenting contact with subjects, e.g. obtaining informed consent or informing them of changes that may affect their willingness to continue participating,

- complying with applicable IRB policies and procedures,
- knowing the appropriate use of an investigational intervention (drug or device) as described in the protocol, investigator brochures, product information/drug labeling, and various other available sources such as newsletters, safety alerts, or communications from sponsors,
- providing a thorough explanation of the study in lay terms to the subject during the consent process, and
- providing a subject the opportunity to ask questions and have them answered.

Procedure

Requesting Approval for PI who is not UConn Health/UConn Paid Faculty (exclusive of CICATS studies and clinical non-pay faculty for student projects)

- The intended PI must submit written requests for an exception to the Director of the HSPP and the request must include:
    - for non-pay faculty positions
        - a description of the level and nature of involvement s/he has with UConn Health,
        - how that involvement relates to the mission of UConn Health, and
        - to what data s/he is requesting access.
        - and the points noted below for other non-faculty positions.
    - For other individuals who are paid employees who do not hold faculty appointments
        - a summary of qualifications to conduct the study (degrees, licensure, prior research experience),
        - a brief description of the nature of the proposed study,
        - position held and level of authority of that position to provide oversight for the study (e.g. to spend funds if needed, to supervise and direct study team etc.)
- The Chair of the department in which the research will be conducted must also submit a letter to the DHSPP supporting the request and accepting administrative responsibility for the proposed appointment as PI.
- The DHSPP will inform the PI, department chair and the IRB Office, via copy of the memo noting the approval, if such a request is approved.
- If not from UConn Health, the individual seeking appointment as the PI also completes the Individual Investigators Form, obtains applicable signatures, and submits the form with the IRB application material.

Research Personnel:

- The PI self identifies on the IRB application form.
- The PI identifies within the IRB application other study personnel including co-investigators, study coordinators and persons/positions authorized to obtain consent.
- The IRB staff screen this information and members review this information to ensure necessary expertise is present.
    - If not, the IRB imposes a contingency to obtain necessary expertise.

Expectations:

The HSPP and IRB ensures that research personnel are fulfilling expectations through the continuing review process, through reports from the research compliance monitoring program, and through receipt of participant feedback forms.

Related Policies

2009-001 – Reporting Unanticipated Problems to the Institutional Review Board
2009-002 – Reporting Non-Compliance to the Institutional Review Board

2009-005.0 – Monitoring of IRB Approved Studies
2011-008.1 – Informed Consent – Process
2011-009.3 – Institutional Review Board – Expedited Reviews
2011-009.5 - Institutional Review Board –Review By Convened Board

Basis

Accreditation Element III.2.B

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