UCI ADMINISTRATIVE POLICIES & PROCEDURES

RESEARCH AND SPONSORED ACTIVITIES
Office of Research Administration
Section 480-2.1: Responsibilities for Conduct & Administration of Research for Principal Investigators and Lead Researchers

Responsible Office: Office of Research Administration
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References

- UC Research Policies and Guidelines
- UC Contract and Grant Manual
- UC Academic Personnel Manual
- UCI Research Policies and Guidelines

Summary

This policy defines the terms of Principal Investigator and Lead Researcher eligibility and describes their respective responsibilities related to sponsored projects and regulated activities.

Definitions

Principal Investigator (PI) is an employee of UCI (usually with an academic appointment) who is or becomes eligible under University policy to submit a proposal for extramural support of a research, training, or public service project. The PI has primary responsibility for the scientific, technical, and administrative conduct of a project. A PI must personally participate in the project to a significant degree; "fronting" as PI is contrary to University policy.

Lead Researcher (LR) is a title signifying eligibility to perform research involving human and animal subjects and use of recombinant DNA (rDNA). Individuals serving as LR on IRB, IACUC and IBC protocols must have a formal affiliation (i.e., a faculty or staff appointment or enrolled student) with UCI. The type of appointment an individual has determines whether they may serve as a Lead Researcher on their own or whether a Faculty Sponsor is required.

Faculty Sponsor[i] **(FS)** is a title signifying eligibility under University policy to submit proposals for extramural support of a research, training, or public service project; and to perform research involving human and animal subjects and use of recombinant DNA (rDNA).

Regulated Activities are those governed by federal and/or state regulations that require review and approval by an independent university committee prior to initiation. These include research involving human and animal subjects and rDNA. Conflict of interest review of financial disclosures is also a regulated activity.

Policy

The titles of “Principal Investigator” and “Lead Researcher” are distinct and have separate, but related, criteria to determine eligibility to perform research involving human and animal subjects.

If an individual meets the criteria for Principal Investigator by virtue of their University appointment status, s/he may also serve as Lead Researcher on a research protocol involving human or animal subjects.

Lead Researchers who do not meet the criteria to serve as Principal Investigators, as defined by the UCI policy, must have a Faculty Sponsor[i] to gain access to UCI regulatory committees, e.g., Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and the Institutional Biosafety Committee (IBC).

Principal Investigators and Lead Researchers are ultimately responsible for all aspects of conducting a research study, including the supervision of all co-investigators, co-researchers, and research personnel to whom study responsibilities might be delegated.

All Principal Investigators and Lead Researchers, key personnel and study team members must be familiar with the funded proposal or approved protocol, as well as any experimental procedures, investigational test articles involved in the research protocol.

Principal Investigators and Lead Researchers also must assure that all key personnel and study team members comply with applicable regulations, FDA good clinical practices, ICH guidelines, state laws and University policies, procedures and guidelines.

Authority and Responsibility

Principal Investigator responsibilities related to Sponsored Projects:[ii]

- develop and prepare applications for external funding according to agency guidelines and University policies;
- submit proposals to the Office of Research Administration (ORA), Sponsored Projects Administration for review in a timely manner;
- complete the UCI Administrative Approval (AA) form, which provides internal approvals from the PI, Chair and Dean or Director indicating their assumption of responsibilities;
- assume responsibility for the scientific integrity and management of projects in accordance with the terms and conditions of sponsored project awards and with the financial management of the funds; and
- be cognizant of and adhere to all externally-imposed sponsor terms, as well as internal University policies, including:
    - complying with all relevant government and University policies, regulations and laws including those related to human subjects, animal welfare, biohazards and Biosafety, occupational health and safety, civil rights and affirmative action, conflicts of interest, purchasing and equipment management.

- Commence sponsored research activities only after Sponsored Projects Administration staff execute an agreement with the sponsor, and only after receipt of regulatory committee approval(s); and

- assure and identify a source of adequate financial coverage of study costs, in order to avoid inappropriately impacting human subjects participating in research or the institution.

Lead Researcher responsibilities related to Sponsored Projects[iii] and regulated activities:

- design and conduct a research study in accordance with the underlying ethical principles for research with human and animal subjects;

- acknowledge and accept responsibility for protecting the rights and welfare of human research participants and the ethical care and use of animal research subjects, complying with all applicable provisions of the University policies dealing with protection of human and animal subjects and the use of rDNA;

- review and comprehend the University's approved Assurance documents [i.e., the UCI Federalwide Assurance of Compliance (FWA#00004071), DHHS Office of Human Research Protections; and the UCI Assurance of Compliance with Public Health Service Policy on Humane Care and Use of Laboratory Animals (#A3416.01), NIH Office of Laboratory Animal Welfare] and seek clarification of any provisions that appear unclear;

- acknowledge and accept responsibility for complying with all applicable provisions of the University policies applicable to the conduct of research;

- commence regulated activities only after the appropriate regulatory committee review and approval(s) have been granted, and any other required University review and approvals;

- comply with IRB, IACUC, and IBC policies, decisions, conditions, requirements, LR assurance statements, and ensure all research is conducted as specified in the approved protocol;

- promptly report to the IRB, IACUC, and IBC all proposed changes to previously-approved research activities and implement proposed changes only after IRB, IACUC, and IBC review and approval is granted, unless implementation is necessary to eliminate immediate hazards to the human research participants or animal subjects;

- ensure disclosure of all investigators' financial interest(s) to the University as required by University policy and to the subjects as required by the IRB;

- obtain the legally-effective informed consent of all human subjects or their legally-authorized representatives, and provide a copy of the IRB approved and signed informed consent document to each subject at the time of consent, unless specifically waived by the IRB;

- retain original consent documents and all other research documents in a manner approved by the IRB;

- retain study documentation as required by the IRB, IACUC, IBC and Sponsored Projects;

- report progress of approved research to the regulatory committees in a manner and frequency

prescribed, but not less than once a year;

- promptly report to the IRB any deviations, adverse events or other unanticipated problems in accordance with regulatory guidelines for human research participants and others;

- promptly report to the IACUC any injuries, adverse events or unanticipated problems to research animals subjects; and

- promptly report to the IRB any pending FDA or other audits, accept IRB participation in exit interview (with mutually agreed-upon IRB representative) if requested, and provide copies of written results of any audits to the IRB.

- Uphold responsibilities for subject rights, welfare and care including:

    ensuring adequate resources to conduct the study. Preparation is made and adequate facilities are provided to protect a human subject against the possibility of injury;

    ensuring adequate data and safety monitoring as applicable, and providing or arranging for medical care to any subject injured as a result of participation in investigator's research, regardless of written policies and in accord with ethical standards;

    reporting promptly to the IRB any injury to a subject for all research, including that registered under the exempt categories; and

    including a staff physician, who would provide medical care to injured subjects, on the IRB protocol for studies where there is even a remote possibility of physical injury to human subjects.

- Assure that the use of protected health information (PHI), if any, is the minimum necessary to meet the research objectives, and that PHI is not reused or disclosed to any parties other than the those described in the IRB approved protocol, except at required by law;

- respond to human research participants' complaints, concerns or requests for information; report such issues to the IRB;

- assure protection for human subjects against physical, psychological, social and/or legal harms, including the right to privacy; legally effective informed consent; and the protection of confidentiality of data, which are of particular concern when performing research involving:

    Pregnant women, fetuses, neonates and prisoners, in addition to adults and children;

    excised organs and tissues, body fluids, or graphic written or recorded information, any of which may expose the subject to medico-legal risks, public embarrassment or humiliation through breach of confidentiality and invasion of privacy;

    data collected on individuals or groups and the use of such data by the original investigator, concurrently by other investigators, or by either at a later time for research purposes;

- agree to not obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care without prior IRB approval;

- advise the IRB, Sponsored Projects, and the appropriate officials of other institutions of the intent

to admit, (i.e., transfer) into the other facility, human subjects who are involved in research protocols approved under the UCI Federalwide Assurance;

- unless otherwise authorized by the IRB, assume responsibility for insuring that assent from research subjects who are minors is obtained and documented in accord with IRB policies and requirements;

- retain protocol applications approved by the IRB and all signed consent documents in accordance with UCI IRB record retention requirements.

[i] The Faculty Sponsor must be eligible to be a Principal Investigator.

[ii] Acceptance of these responsibilities is affirmed by signature on the UCI Administrative Approval (AA) form.

[iii] Acceptance of these responsibilities is affirmed by signature on the PI Assurance form.