SUNY Upstate Medical University General Research Policies

Research Policy Overview

Research is vital to the success of SUNY Upstate Medical University. It is important for our teaching and patient care missions. It provides an essential environment for maintaining faculty competence and for training health care students in the art and science of their professions. The administration strongly supports the faculty's research efforts.

All faculty who are engaged in research, or contemplate doing so, must be familiar with the regulatory and contractual policies that govern research and sponsored programs at Upstate and the Research Foundation of the State of New York. The following is an overview of those policies. They are fully described in Section 5 of the Upstate Medical University Campus Administrative Manual (1989). Specific federal regulations may be accessed through links from this web site to the *Office for Human Research Protections (OHRP)*, the *Office of Research Integrity*, the *Office of Laboratory Animal Welfare* and other regulatory bodies. Questions regarding these policies should be directed to the Vice President for Research, 1258 Weiskotten Hall, SUNY Upstate Medical University.

The Research Foundation

As defined by the Board of Trustees of the State University of New York, the *Research Foundation of the State University of New York (SUNY)* is the designated fiscal agent for research and research-related programs, sponsored by extramural sources with the exception of New York State appropriations. This means that all grant applications and contracts must be administered through the Research Foundation and its local office, the *Office of Sponsored Programs*, located at 1166 Weiskotten Hall, 464-5476.

Before a grant application or contract is submitted to any agency or industry sponsor for funding, it must be reviewed and approved for submission by staff of the Office of Sponsored Programs to ensure that the project conforms to all applicable policies and that appropriate indirect costs and income fund reimbursable (IFR) provisions, such as saleof-service, are applied. Should funds be allocated to the grant or contract request from an extramural source, pre-review and approval of the proposal by the Office of Sponsored Programs will shorten the time required to establish a valid account by the Research Foundation. Under special circumstances, the campus President may give approval and provide written waiver for an extramural research account to be established by the Upstate Medical University Foundation or Faculty Student Association. Under no circumstance should extramural funds for a sponsored project be administered through a practice plan or other unrelated departmental accounts.

All grant applications and contracts are submitted by Upstate as the application organization on behalf of an Principal Investigator (PI) or Project Director (PD) only if the PI/PD has faculty status. Under some circumstances, a staff member or full-time graduate student may submit an application, but the staff member's or student's faculty supervisor will be regarded by the campus as the PI/PD who is responsible for ensuring that the terms of the contract are met on behalf of the applicant organization.

Since all applications are submitted and contracts executed by the Research Foundation on behalf of Upstate, the Sponsored Programs Office will obtain the signature of the official authorized to sign on behalf of the RF/Upstate. Although PI/PD and/or department head signatures may be required on grant and contract documents, these individuals are not authorized to sign sponsored program applications or agreements as the institutional official.

A contract between an applicant organization (RF/Upstate) and an granting agency establishes fiscal responsibility for Upstate and the Research Foundation. As an agent of Upstate, the PI/PD and his/her department are responsible for knowing the fiscal policies and limitations that are applicable to each account they are authorized to administer within the applicant organization. All extramural funds are regarded as "institutional funds" and their use is defined by applicable accounting and auditing procedures of Upstate. The PI/PD is obligated to follow additional policy limitations imposed by the funding agency. Those limitations should be considered during the preparation of the budget for application tothe agency. Thus, it is essential that the PI/PD discuss the budget items and agency policies, such as indirect costs, equipment purchases, ownership, and salary support with the Sponsored Programs Office prior to submission of the application. The project must remain in compliance with all of the sponsoring agency's fiscal policies, as well as those of Upstate and the Research Foundation throughout its lifetime. Most sponsored projects require the submission of a final report of expenditures at the conclusion of the project; Upstate and the Research Foundation will be held accountable at that time.

Federal and State Compliance Regulations

Research activities are also governed by a variety of federal and state compliance regulations, including those required for the *protection of human* and *animal subjects*; the *use of radioisotopes*, and the *use of potentially toxic chemicals, human tissues, stem cell research, and recombinant DNA*. Local oversight of each of these activities is by a standing committee at Upstate. Before any project is undertaken, all relevant committees must certify that the research complies with existing institutional policy, standard practices,and all federal and state regulations. All projects, regardless of the funding source, are governed by these guidelines.

In addition, Upstate's policy on Scientific Misconduct is governed by the Office of Research Integrity (ORI), DHHS.

SUNY Upstate Medical University Institutional Review Board for the Protection of Human Subjects (IRB)

All research involving human subjects requires the approval of the *Institutional Review Board for the Protection of Human Subjects*. No project may begin without an IRB approval. The IRB also has general responsibility to oversee institutional policies, practices and reporting of the emergency use of unapproved investigational drugs or devices that would typically require an IND (Investigational New Drug approval) or IDE (Investigational Device Exception). Information and protocol application forms can be obtained *online* or from the IRB office, Room 1254, Weiskotten Hall (phone: 464-4317).

Only persons having a faculty appointment at Upstate may be the Principal Investigator (PI)

on an IRB protocol. Projects taking place at multiple sites (e.g., the VA Medical Center or Crouse Hospital) will require approval by the IRBs at those sites in addition to Upstate. SUNY Upstate Medical University holds a Federal Wide Assurance (FWA00005967). This assurance is Upstate's guarantee that all research conducted at Upstate or by persons paid by Upstate is in full compliance with federal regulations. Failure to adhere to these regulations could result in suspension of all federal funding for research at the campus, even if the project in question is funded through intramural and/or non-federal funds.

Questions regarding IRB policy and requirements should be directed to the IRB Office, room 1254 Weiskotten Hall, 464-4317 (telephone), 464-4318 (fax).

SUNY Upstate Medical University Committee for the Humane Use of Animals (CHUA)

Research involving animals must be approved by the *Committee for the Humane Use of Animals*. Many agencies require a CHUA approval before they will review an application that involves animals and no project may begin, nor any animals procured, without final CHUA approval. Protocol application forms and information can be obtained *online* or from the Department of Laboratory Animal Resources (DLAR), Room 4159 Weiskotten Hall, 464-6563 (telephone).

Only Upstate Medical University faculty may serve as the PI-PD on a CHUA protocol. An Institutional Assurance for the proper use of animals is filed with the Office of Laboratory Animal Welfare, Public Health Service, DHHS. This assurance is Upstate Medical University's guarantee that all research conducted at Upstate, or conducted by persons paid by Upstate, is in full compliance with the Animal Welfare Act and other federal regulations. Failure to adhere to these regulations may mean the suspension of all federal funding for research at the campus, even if the project in question is funded through intramural funds. The campus, including any laboratory using animals, is subject to random inspections from the US Department of Agriculture (USDA).

SUNY Upstate Medical University Radiation Safety Committee (RSC)

The possession and use of radioactive materials or devices producing ionizing radiation at the Upstate Medical University is authorized by licenses, permits, and certificates issued by the New York State Department of Health. The *Radiation Safety Officer* and others delegated by him work closely with the Radiation Safety Committee, the Institutional Review Board for the Protection of Human Subjects (IRB), the Committee for the Humane Use of Animals (CHUA) and appropriate clinical departments and services to ensure the maximum beneficial use of radiation with the minimum practical risk to patients, employees, and the general public. Any PI/PDs wishing to purchase, use and dispose of radioactive materials or devices at Upstate must obtain approval from the Radiation Safety Committee. An application to use radioactive materials may be obtained *online* (upstate.edu/radsafeo) or at the Radiation Safety Office, Room 636 University Hospital, 464-6510 (phone). Direct questions and submit completed applications to the Radiation Safety Office.

SUNY Upstate Medical University Institutional Bio-Safety Committee (IBC)

The *Institutional Bio-Safety Committee* assures that all research protocols using toxic agents, infectious agents, human tissues and recombinant DNA is in compliance with federal and

state regulations. Information regarding bio safety issues can be obtained *online* or from the Research Development Office, Room 1254 Weiskotten Hall, 464-4317 (telephone).

SUNY Upstate Medical University Stem Cell Research Oversight Committee (SCRO)

The Stem Cell Research Oversight (SCRO) Committee provides oversight over all experiments related to human embryonic stem (hES) cell research that involve pre-implantation stages of human development, human embryos or embryonic cells, or that entail incorporating human totipotent or pluripotent cells into animal chimeras. The SCRO committee will evaluate the scientific merit, ethical permissibility, and relevant expertise of investigators for all applicable research proposals.

SUNY Upstate Medical University Research Misconduct

Research at Upstate is governed by the *Institutional Scientific Misconduct Policy* . This policy is reaffirmed annually with the Office of Research Integrity (ORI) at the DHHS and is designed to assure the integrity of scientific data and that ethical standards for conducting research and publishing scientific data are met. The policy pertains to all research conducted at Upstate or by all persons paid by Upstate, regardless of the funding source. It also applies to all personnel performing research, including faculty, students, staff and postdoctoral fellows. All inquiries regarding either the policy or the process for filing allegations of research misconduct may be obtained from the Office of the Vice President for Research, Room 1258 Weiskotten Hall, 464-4515 (telephone).