

Office of Clinical Research (OCR)

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PRINCIPAL INVESTIGATOR RESPONSIBILITY POLICY AND PROCEDURE

1. **PURPOSE:** To outline the scope of the Principal Investigator (PI) responsibilities for research involving humans conducted under the Health Science Center (HSC) policies and its Human Research Protection Program (HRPP).
2. **POLICY:** Principal Investigators are required to conduct studies that comply with applicable federal, state, and local regulations. All PIs are required to complete approved Human Subjects Protections training courses and, as required, additional training as specified by HSC Institutional Review Board (IRB) or Office of Clinical Research (OCR). Instructions to access the training are located on the HSC [OCR website under OCR Training Requirements and Opportunities](#). The scope of the PI's obligations are outlined as follows:
 - a. The PI, regardless of title, is primarily responsible for all aspects of the study, including the protection of the rights, welfare, and safety of each human subject by adequate protocol design and research conduct. The PI will adhere to the institution's HRPP policies, inclusive of applicable policies from the offices overseeing research activities (i.e., Office of Clinical Research, Office of the IRB, Clinical Trials Office, Office of Sponsored Programs, and the Office of Environmental Health and Safety), as well as applicable Handbook of Operations (HOP) policies.
 - b. The PI is required to provide adequate oversight of the study ensuring supervision and training of research staff, resource management, and appropriate medical care or appropriate referral for the subjects and for possible research related injury resulting from study participation. Any responsibility delegated by the PI to member(s) of the Research Team (RT) continues to be performed under the PI's delegation and the PI retains final accountability.
 - c. The PI must ensure that any requirements of contracts, grants, or other legal agreements with a research sponsor and/or funding source are fulfilled.
 - d. Principal Investigators who fail to adhere to their responsibilities and obligations may have their privileges to conduct research suspended or terminated.
3. **RESPONSIBILITY:** The responsibility to protect human subjects is shared by the sponsor, the institution, and the IRB, with the ultimate responsibility for the conduct of the research held by the PI. The department chairperson affirms in the IRB application to the protocol's sound design, to the presence of sufficient resources to protect human subjects, and to the competency of the investigator(s) to conduct the research project. The PI is responsible for all phases of the study including the following:
 - a. Planning and Development
 - (1) Research Team Readiness
 - (a) Establish clear delegation of authority and provide adequate supervision according to policy from the OCR, RT training, qualifications, and delegation of authority.
 - (b) Certify that the RT is adequately qualified to conduct the study as specified on the [HSC Research Scope of Practice for Study Personnel form](#) according to [HOP 7.2.3](#).
 - (c) Ensure the entire RT is trained on study procedures (both study-specific and general operating procedures).

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- (2) Feasibility Assessment: Evaluate the feasibility of the protocol design for scientific, regulatory, and ethical aspects of the study as well as for resource requirements, e.g., staff availability, study documentation, sponsor relationship, study population, procedures and services, safety considerations, and space allocation.
 - (3) Affiliate Planning
 - (a) Coordinate with any affiliate institutions to determine the extent of support necessary for the study as well as the ability to provide the resources in required timelines.
 - (b) Comply with credentialing requirements.
 - (c) Submit the required documentation for the affiliate's approval process.
 - (4) Financial Considerations
 - (a) Identify the type of funding for the study, e.g., industry supported, federal funding, etc.
 - (b) Oversee budget development and billing aspects if any clinical services are provided (HOP 7.7.1).
 - (c) Comply with financial disclosure and conflict of interest for the RT (HOP 10.1.6 and related policies).
 - (5) Document Development
 - (a) [Certificate of Proposal](#) – submit for all externally funded studies.
 - (b) IRB application – complete using IRB checklists and forms, to include a definitive plan for safety monitoring either by the PI or by a third party for studies of greater than minimal risk.
 - (c) Study Documents – protocol, informed consent form, investigational brochure, manual of operations, and/or standard operating procedures.
 - (6) Registration Responsibilities
 - (a) Register any Applicable Clinical Trial in the ClinicalTrials.gov databank when designated as the Responsible Party (Section 801 of the Food and Drug Administration Amendments Act, known as FDAAA 801).
 - (b) Maintain registrations of active Applicable Clinical Trials and report results per required timelines.
 - (c) Maintain registrations of studies which are not Applicable Clinical Trials but which have been opted in to the databank.
- b. Approvals: Research recruitment and enrollment will not be initiated until all required approvals are obtained, including, but not limited to, the following:
- (1) Department
 - (2) Safety committees, as applicable
 - (3) Institutional Review Board
 - (4) Office of Sponsored Programs
 - (5) Office of Clinical Research and/or Affiliate organizations
- c. Study Execution

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- (1) Provide for human subjects protections by ensuring the following:
 - (a) Outreach – equitable recruitment
 - (b) Inclusion/exclusion – confirm each subject’s eligibility
 - (c) Informed consent – obtain and continue during study according to current regulations
 - (d) Medical attention – assess and provide for subjects’ medical needs as related to the clinical trial via HSC medical staff or appropriate referral
 - (e) Protected Health Information (PHI) – assure compliance with regulations to obtain, to use, and to disclose PHI
 - (2) Ensure that the protocol is strictly followed, that the safety of all human subjects is monitored via a safety monitoring plan, and that all regulatory requirements are met.
 - (3) Ensure accurate administration and management of investigational product(s), if applicable, according to OCR policy, “Storage and Control of Investigational Drugs and Devices for Clinical Research.”
 - (4) Assess all reports and provide required information to the IRB/sponsor in a timely manner.
 - (5) Maintain adequate and accurate study records that are readily available for inspection by internal/ external monitors and by regulatory agencies.
 - (6) Manage each research study through active involvement in all aspects of the planning and conduct of the study, which may include the following:
 - (a) Routine meetings to monitor progress, to discuss concerns, and to update staff
 - (b) Internal assessment to verify that process and protocol requirements are followed
 - (c) Processes for corrective action to identify the root cause(s) of issues and prevent future occurrence(s)
 - (7) Routine resource review to evaluate budget (planned versus actual), staffing for study requirements, and time required to complete activities with given resources.
- d. Study Closeout
- (1) Ensure that all applicable guidelines are followed regarding protocol-specific end of study closeout procedures according to sponsor and institutional requirements.
 - (2) Ensure that all financial obligations, encumbrances, and reports are closed.
 - (3) Ensure Applicable Clinical Trials registered in clinicaltrials.gov are finalized. Results reporting, where applicable, should be done within 12 months of primary closeout.
- e. Records Retention
- (1) Ensure that all applicable guidelines are followed regarding protocol-specific end of study records retention procedures according to sponsor and institutional requirements.
 - (2) Follow [HOP 2.2.1](#) List of Research and Grants Retention Schedule.
- f. Publication: Adhere to contract and grant requirements for publication.