

**HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES**

Chapter 7	Research and Sponsored Programs	Effective:	April 2008
Section 7.2	Human Research Protection Program (HRPP)	Revised:	November 2011
<b>Policy 7.2.1</b>	<b>Human Research Protection Program (HRPP) Responsibilities</b>	Responsibility:	Vice President for Research

## **HUMAN RESEARCH PROTECTION PROGRAM RESPONSIBILITIES (HRPP)**

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### **Human Research Protection Program**

The President of Health Science Center has delegated the authority and responsibility to establish, maintain, and advance the Human Research Protection Program (HRPP) to the Vice President for Research (VPR) as the Institutional Official (IO); see *Handbook of Operating Procedures* (HOP), [Section 1.3.7](#), “Vice President for Research”. The HRPP encompasses the entities that contribute to the mission to protect the rights and welfare of participants who take part in Health Science Center research.

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### **HRPP Administration**

The responsibility for the protection of human participants is shared among a number of organizational components that conduct research, as well as those responsible for program administration of the HRPP. To create a cohesive program and support the HRPP mission, the Vice President for Research has established the HRPP Steering Committee. The Steering Committee is responsible for integrating the policies and procedures of the institution and addressing issues across the organizational components; see HOP, [Section 1.6.14](#), “Human Research Protection Program Steering Committee”. The following table identifies the primary organizational components of the HRPP:

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Organizational Components of the Human Research Protection Program (HRPP) Program Responsibility: Vice President for Research Institutional Official (IO)	
Conduct of Research	Program Administration
Principal Investigators Research Teams	<b>HRPP</b> <u>Steering Committee</u> Chair: AVP for Research Operations
Institutional Review Board	<ul style="list-style-type: none"> <li>• VPR Offices                             <ul style="list-style-type: none"> <li>○ Office of the Institutional Review Board (OIRB)</li> <li>○ Office of Clinical Research (OCR)</li> <li>○ Office of Sponsored Programs (OSP)</li> <li>○ Risk Management &amp; Safety</li> </ul> </li> </ul>
Committees as Required (e.g., IBC, Radiation Safety, Radioactive Drug Research, Conflict of Interest)	<ul style="list-style-type: none"> <li>• Office of Regulatory Affairs &amp; Compliance</li> <li>• Chief Legal Officer</li> <li>• CTIC Investigational Drug Services</li> </ul>
Department Chairs, Center or Institute Directors	<ul style="list-style-type: none"> <li>• Representatives:                             <ul style="list-style-type: none"> <li>○ Institute for Integration of Medicine &amp; Science (IIMS)</li> <li>○ IRB Chairs Representative</li> <li>○ Deans of the Five Schools</li> <li>○ Director, Center for Medical Humanities and Ethics</li> <li>○ Affiliate Organizations – STVHCS, UHS, Christus Santa Rosa</li> </ul> </li> </ul>

Each of these organizational components of the HRPP maintains policy for conducting human research relative to their function. The HRPP Steering Committee assures that the essential organizational

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representatives are brought together to address the overall program requirements, and to evaluate the program’s effectiveness. The Steering Committee is chaired by the Assistant Vice President (AVP) for Research Operations. In addition, the Office of the AVP for Research Operations is responsible for the day-to-day operation of the program and disseminating program information.

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**Organizations Covered by the HRPP**

The institution’s HRPP is applicable to the Health Science Center, inclusive of the School of Medicine, the Dental School, the School of Nursing, the Graduate School of Biomedical Sciences, the School of Health Professions, centers, and organized research units.

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**Research Covered by the HRPP**

The HRPP covers activities that are defined as human participant research. Any research involving human participants that is conducted on or off-site by a Health Science Center employee or agent is subject to the Health Science Center HRPP, policies of the institution, and review by a designated Institutional Review Board (IRB). This applies to any investigation and/or data collection for research purposes which involves human subjects regardless of the funding source made to the institution or to an employee of the institution. The federal regulations provide guidance to properly characterize human subject research. It should meet the Department of Health and Human Services (DHHS) definition of both “research” and “human subjects”, or in the case of Food and Drug Administration (FDA) regulated research, it should meet the FDA definition of both “human subject” and “clinical investigation” which are summarized below.

Human research participants covered by the institution’s HRPP may include the following: healthy volunteers, patients, students, children, non-English speaking, pregnant women, prisoners, and the mentally and decisionally impaired, including those who are institutionalized. The term research can pertain to basic and applied investigations, such as bench testing or evaluation, clinical research, product development, and similar activities. The term human subject research or human research participant may be applicable in a variety of activities:

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- Behavioral and social sciences research (e.g., surveys, interviews, observations, and studies of existing records)
  - Clinical trials testing an investigational article
  - Epidemiological research, including surveillance, monitoring, and reporting programs
  - Pilot studies
  - Thesis and dissertation research involving human volunteers
  - Repository research, tissue banking, and databases storing information from individually identifiable, living persons
  - Human genetic research

The institution’s Office of the IRB (OIRB) provides guidance and is responsible for determining whether the project meets the regulatory definitions for human research.

The OIRB provides written policies and procedures for the research community to follow in determining whether activities need IRB review or are exempt from review. The OIRB reviewers for exemption determination may recommend revisions within an exempt project to enhance subjects’ protection. Although proposed research is qualified for exemption, the sponsor or the IRB may require that it receive full or expedited review. Investigators conducting research that is exempt from federal regulations may also incorporate consent and other procedures to maintain human research protections. Investigators may not determine whether research is exempt from the federal regulations, including IRB review.

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**DHHS Definitions**

**RESEARCH:** “Means a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” This may include activities such as demonstration and service programs. (45 CFR 46.102(d))

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**HUMAN SUBJECT:** “Means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.” (45 CFR 46.102(f))

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**FDA Definitions**

**CLINICAL INVESTIGATION:** Involves the use of an investigational article (i.e., drug, device, food substance or biologic) and one or more human subjects. This applies to test articles that require prior submission to the FDA and those that do not. The results of the investigation are intended to be part of an application for a research or marketing permit. It does not include the use of FDA approved devices or drugs in routine medical practice. (21 CFR 56.102(c))

**HUMAN SUBJECT:** “An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.” (21 CFR 56.102(e)) [Drug, Food, Biologic] and “A human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease.” (21 CFR 812.3(p)) [Medical Devices]

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**Ethical & Legal Principles in Conducting Research**

The supporting ethical principles for the institution’s HRPP are set forth in the Belmont Report, entitled “Ethical Principles and Guidelines for the Protection of Human Subjects of Research.” The Belmont Report establishes three guiding principles: the respect for persons, beneficence, and justice. The integrity of the research is also maintained by ensuring that the Principal Investigator and research team members are qualified by education and training to conduct the research and that they adhere to the protocol defining the research.

The HRPP adheres to regulations applicable to protecting the rights of human participants, to include:

- DHHS 45 CFR Part 46 *Federal Policy for Protection of Human Subjects (Common Rule)*

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- DHHS 45 CFR Parts 160 and 164, *Standards for Privacy of Individually Identifiable Health Information (HIPAA Privacy Rule)*
  - FDA 21 CFR Part 50 *Human Subject Protection* and Part 56 *IRBs*

Research involving investigational drugs or biologics falls under FDA regulations to include 21 CFR Part 312, *Investigational New Drug Application*, and Part 314, *Applications for FDA Approval to Market New Drugs*. Research involving investigational devices falls under FDA regulations to include 21 CFR Part 803, *Medical Device Reporting*, Part 812, *Investigational Device Exemptions*, and Part 814, *Pre-market Approval for Medical Devices*. Finally, the applicability of state and local laws must be considered.

Appropriate financial disclosures and conflict of interest considerations in clinical research fall under the FDA 21 CFR Part 54 *Financial Disclosure by Clinical Investigators and U.S. Public Health Service guidelines on Conflict of Interest*.

For research funded by or covered by federal agencies such as the U.S. Department of Education, U.S. Department of Defense, National Science Foundation, or the U.S. Veterans Administration, the institution applies additional regulations/policies on a case-by-case basis as appropriate to the agency or sponsor.

The Office of the Vice President for Research hold the primary responsibility for policies and educational programs communicating the ethical and legal principles to which research personnel must adhere in conducting clinical research. Research must comply with all applicable federal and state laws and regulations. The organizational components of the institution's HRPP shall develop and implement policies and procedures related to human research protection in alignment with this ethical and regulatory framework. The institution maintains memoranda of understanding with affiliates outlining responsibilities regarding human research.

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## **Research Review**

It is institutional policy to review all human subject research conducted by employees, agents of the Health Science Center irrespective of location, source of funding, and exempt status. This review is intended to foster high ethical standards in the conduct of research and to apply criteria to protect the human participants who take part in research. In support of this obligation, the institution has three registered IRBs. With approvals and written agreements, the institution may also occasionally use the IRB of another organization to ensure effective and timely research review. The institution's Federalwide Assurance (FWA) provides that the Health Science Center IRB reviews all human participant research.

The charge to the IRB is given in HOP, [Section 1.6.6](#), "Institutional Review Board". The IRB proceedings and implementation of policies must be free of undue influence or coercion to maintain the reliability and equity of the IRB process. Concerns of undue influence or coercion should be reported to the Director of Research Regulatory Programs, the Office of Regulatory Affairs & Compliance, or the AVP for Research Operations.

The Director of Research Regulatory Programs is responsible for establishing and maintaining policies and procedures to ensure: 1) that all information necessary to adequately review the research is provided by investigators and 2) that the members of the IRB have the guidance and the process requirements necessary to fully evaluate the validity of the research. The OIRB maintains policies and procedures for the HRPP that describe the IRB practices for conducting reviews and approvals of human research in accordance with applicable regulations and institutional policies. These policies include, but are not limited to the following:

Determining whether the proposed research may be expedited, requires convened IRB review, or is exempt in accordance with the federal regulations and guidance; developing informed consent processes and documentation, ethical considerations and policy related to vulnerable populations; research; requirements for data and safety monitoring; policy for emergency use of an investigational drug/device, or humanitarian use

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device; determinations and reporting processes for unanticipated problems involving risks to subjects or others (UPIRSO); and, policies regarding non-compliance, suspensions, or terminations of research approval.

The department Chairs/center Directors are responsible for attesting to: the soundness of the design of research protocols; the competency of the investigator(s) to conduct the project; and, the presence of sufficient resources required for the research and for protecting research participant safety. Processes to support these assurances may include internal review committees or specialized review criteria within departments/ institutes/centers. If the Principal Investigator (PI) fails to meet his/her responsibilities, the department Chair/institute/center Director is the point of contact for correction of deficiencies. The institutional approval process for sponsored research confirms at multiple organizational levels (e.g., department, center, and Dean) that there is agreement on the type and amount of resources required for the research and that it meets the goals and objectives of those organizational levels.

The Office of Clinical Research (OCR) establishes policy and offers education and consultation for Health Science Center researchers conducting FDA regulated and non-FDA regulated human subject research. The OCR conducts quality assessments for continuous improvement efforts and to ensure research best practice and compliance with institutional requirements, federal, state, and local regulations, as applicable [e.g., International Conference on Harmonization (ICH) Good Clinical Practices (GCP); Good Laboratory Practices (GLP); CFR Part 11 requirements for electronic records; Good Manufacturing Practices (GMP); Quality System Regulations (QSR); Centers for Medicare & Medicaid Services (CMS)]. When an investigator takes on sponsor responsibilities and/or is using an investigational article which may require an IND/IDE, the OCR assesses the research operations to ensure the regulatory requirements are supported.

The Biological Safety Division and Radiation Division within Environmental Health & Safety Office provide expertise and consultation

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for human participant research, to include compliance with federal, state and local regulations. As applicable, prior to final IRB approval, these divisions review and approve related human research protocols through the Institutional Biosafety Committee, the Radiation Safety Committee, and the Radioactive Drug Research Committee.

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**Investigator Responsibilities**

PIs are ultimately responsible for protecting the rights and welfare of human participants. The PIs are responsible for ensuring all research personnel are trained and knowledgeable of applicable regulations. All investigators and research staff must be knowledgeable of the HRPP to include applicable regulatory requirements, Health Science Center policies and procedures, as well as IRB, OCR, OSP policies.

Institutional policy requires those engaged in conducting human research to successfully complete and periodically renew mandatory training in the protection of human subjects; this includes those conducting research exempt from federal regulations.

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**Sponsor Agreements**

When human subject research is sponsored by an external sponsor or organization, both the Health Science Center and the sponsor have obligations to protect research participants. The OSP policies and procedures on written agreements with sponsors require the following:

- Affirm that the institution will follow the IRB approved protocol and applicable law
- Address medical care for any research-related injury for participants
- Require timely reporting from sponsor to both Health Science Center and the PI, for the duration of the study and for two years thereafter (or such longer period as may be warranted by circumstances or law), of any findings that may affect the safety of participants or their willingness to continue the study, influence the conduct of the study, or change the IRB's approval of the research

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- Plan for distributing the findings of the research and the procedures for publication
  - Define how to communicate to participants any potential impacts to their safety or medical care which are a direct result of participating in the study
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**Research Participant Interactions**

The IRB and OCR provide policy and guidance on interactions between the research team members and the study participants before, during, and after the conduct of a study (e.g., recruitment, screening, consenting). The research team must provide opportunities for the participant or their designated representative to voice questions, concerns, or complaints regarding the study to either an investigator, research team member, or an informed individual unaffiliated with the research study. These communications must be confidential and supported by processes to ensure that the concerns are handled. Multiple modes of inquiry (e.g., phone, e-mail, hotlines) should be available to current, former, and prospective participants. Various participant outreach efforts should be instructive in nature and designed to communicate effectively to the community being served. The HRPP Steering Committee will conduct periodic review of various outreach efforts to advance quality improvement.

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**Supporting Institutional Programs**

The IO, assisted by the HRPP Steering Committee, is responsible for ensuring integration of these programs in support of the protection of human subjects participating in research.

The Office of Regulatory Affairs & Compliance and Legal Counsel are responsible for multiple aspects of the institution's programs and policies concerning HIPAA, ethics, standards of conduct, and conflict of interest; many of these are global to the institution and some are specific to research.

The Office of Regulatory Affairs & Compliance conducts reviews of human participant research to enhance policies and procedures and assure protection and safety of individual's participating in studies. The results of the reviews are shared with the Director of Research

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Regulatory Programs and the AVP for Research Operations, so that corrective actions in areas of non-compliance are addressed. If the Office of Regulatory Affairs & Compliance receives requests for investigations or reviews for cause, the Vice President for Research as IO, is notified and in turn notifies the Director of Research Regulatory Programs, the AVP for Research Operations, as well as the appropriate Dean and Chair. Also, the Office of Regulatory Affairs & Compliance is responsible for investigating and/or evaluating calls from a confidential hotline which may include complaints or concerns associated with human participant research.

The Vice President for Research is responsible for policy that defines research misconduct and states the institutional processes and consequences for research misconduct that are applicable to those who conduct human participant research under the auspices of the Health Science Center, see HOP, [Section 7.6.1](#), "Policy Statement Relating to Misconduct or Research Misconduct". The HOP, [Chapter 10](#), "Ethics, Standards of Conduct, and Relationships with External Entities", is the responsibility of the Vice President for Research and includes policies related to research conflicts of interest and commitment.

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