Chapter 1	Administration and Organization	Effective:	May 2008
Section 1.6	Administrative Committees	Revised:	May 2016
Policy 1.6.14	**Human Research Protection Program (HRPP) Steering Committee**	Responsibility:	Vice President for Research

HUMAN RESEARCH PROTECTION PROGRAM (HRPP) STEERING COMMITTEE

Members

Members are determined by background and area of expertise. The membership is drawn from the organizational components integral to the Human Research Protection Program (HRPP), as defined in the *Handbook of Operating Procedures* (HOP), Section 7.2.1 "Human Research Protection Program Policy". As the HRPP Institutional Official (IO), the Vice President for Research coordinates with the organizational components to recommend the members who are appointed by the President.

Ex-Officio (with vote)

1. Chair, Assistant Vice President (AVP) for Research Administration
2. Director, Research Protection Programs
3. Director, Office of Sponsored Programs
4. Assistant Vice President for Risk Management & Safety
5. Research Compliance Manager, Office of Regulatory Affairs & Compliance
6. Director of Research Operations for the Cancer Therapy Research Center
7. Director, Office of Clinical Research
8. Director, Center for Medical Humanities and Ethics

Appointed Members (with vote)

The IO appoints one representative from the following organizational components:

1. Affiliate representatives, to include:

    A. University Health System (UHS)

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B. Christus Santa Rosa Health Care

C. South Texas Veterans Health Care System (STVHCS)

D. University of Texas San Antonio (UTSA)

2. Institute for Integration of Medicine & Science (IIMS)

3. IRB Chairs

4. Dean or representative of each School: School of Medicine, Dental School, School of Nursing, Graduate School of Biomedical Sciences, and School of Health Professions.

The number and composition of the appointed members can be expanded beyond the minimum requirements to support the current agenda. Subcommittees may be established as needed.

Charge

To ensure that the Health Science Center's HRPP is in accordance with institutional and federal guidelines (i.e. Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations), as well as applicable state and local laws. To review the HRPP and ensure that its design and administration sufficiently support its mission to protect the rights and welfare of human participants and to promote quality research. To support and promote processes across components and affiliates that are of value and contribute to efficient approval and conduct of research. To establish processes requiring that research involving human participants does not begin until the required approvals are obtained. To evaluate on an annual basis the effectiveness of the program. To support processes for receiving and handling questions, complaints or concerns with the conduct of research. To convey to participants that the institution values the HRPP mission and to ensure adequate sources of information. See HOP, Section 7.2.1, "Human Research Protection Program Policy", which delineates the program requirement and responsibilities.

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Charter

The President of the Health Science Center has delegated the authority and responsibility to establish, maintain, and oversee the HRPP to the Vice President for Research and the IO (see HOP, Section 1.3.7, "Vice President for Research"). The Vice President for Research has established the HRPP Steering Committee to administer the program under the chairship of the AVP for Research Administration.

Committee Responsibilities

The HRPP Steering Committee reviews and approves the HRPP policy and also considers institution-wide policies that affect the HRPP. The scope of the HRPP is defined in the HOP, Section 7.2.1, "Human Research Protection Program Policy". It may recommend changes, policy, etc. to the IO. The HRPP Steering Committee directs program review considering the goals and objectives. The assessment efforts should identify new information, laws and organizational policies or emerging ethical and scientific issues; determine if there are any known risks, problems or exposure areas to address; assess current functions; and, evaluate resources. The review should identify key processes and examine the current performance. Legal counsel is available for consultation to the Committee for any conflicts between federal or national law and other applicable laws. As the level of program performance is defined, ideas for modifying the processes and infrastructure are implemented to achieve improvements in various aspects of the HRPP.

The HRPP Steering Committee should serve to keep faculty and staff who are involved in conducting research aware of the regulations, to recommend best practices in research, to advocate for resources for the HRPP, and most importantly, to increase protections for participants enrolled in research studies. The members of the HRPP Steering Committee are expected to provide counsel on human subject research issues across the Health Science Center and to help make the HRPP an exemplary program. Members will represent the research community in their work on the HRPP Steering Committee and cultivate a dialogue with the research community.

The HRPP Steering Committee identifies the functions, roles and responsibilities, and interfaces of the organizational components supportive to the program. The program review should assess the

individual organizational components, as well as the effectiveness of their interfaces. The HRPP Steering Committee reviews items, such as the following: summaries of program compliance issues addressed; the HRPP documentation of policies and procedures reviewed/initiated; volume and type of studies; resources; satisfaction survey(s); evaluation of participant outreach initiatives; suggestions, comments or concerns from members of the research community; and, quality improvement initiatives. The HRPP Steering Committee forwards recommendations regarding these items to the IO when appropriate. At a minimum, the activities of the HRPP Steering Committee should ensure that the following aspects of the program are appraised and that reports from these components are provided annually:

- Regulatory Affairs & Compliance
- Institutional Review Board
- Sponsored Programs
- Conflict of Interest
- Environmental Health and Safety Committees
- Affiliate Interfaces
- Research Team Operations – IIMS Research Centers
- Center for Medical Humanities and Ethics

Terms

Appointed members serve up to three years with potential for renewal.