

# COMMITTEES FOR THE PROTECTION OF HUMAN SUBJECTS AT THE UNIVERSITY OF HOUSTON

## 2.1 CPHS' Charge

The scope of CPHS' charge is broad. Generally, any University research that involves humans, human tissue, surveys of human subjects, or human subjects' records requires CPHS review and approval, regardless of funding source. This purview extends to all student research projects. The specific charge to the CPHSs is to give consideration to:

- the potential risks to the subjects;
- the anticipated benefits to the subjects and others;
- the importance of the knowledge that may reasonably be expected to result; and
- the informed consent process to be employed.

The basis for the CPHS charge is found in the Code of Federal Regulations (CFR). Although protection of human subjects is a concern of all agencies that sponsor research, regulatory leadership is vested in the Office for Human Research Protection (OHRP) and the Food and Drug Administration (FDA). The OHRP has general responsibility for the protections of humans as subjects in research, and the FDA regulates the use of drugs and medical devices in experiments.

OHRP regulates compliance of institutions primarily through "assurances." A Federalwide Assurance is a legally binding agreement between the institution and the OHRP. The University's assurance outlines our responsibilities and explains the steps the University will take to meet the federal regulations for research on human subjects. The University of Houston's Federalwide Assurance with OHRP states:

This Institution assures that whenever it engages in human subject research conducted or supported by any federal department or agency that has adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule, the Institution will comply with the Terms of The Federalwide Assurance for Institutions. Within the United States, unless the research is otherwise exempt from the requirements of the Common Rule or a department or agency conducting or supporting the research has determined that the research shall be covered by a separate assurance.

This Institution elects to apply the following to its entire human subject research regardless of source of support:

The Common Rule and subparts B, C, and D of the HHS regulations at 45 CFR part 46.

## 2.2 Membership and Structure of the CPHS

The University of Houston has two Committees for the Protection of Human Subjects.

CPHS Committee 1 is responsible for reviewing human subject research in the following colleges and departments:

1. *Gerald D. Hines College of Architecture*
2. *C.T. Bauer College of Business*
3. *College of Education*
4. *Cullen College of Engineering*
5. *Honors College*
6. *Conrad N. Hilton College of Hotel and Restaurant Management*
7. *UH Law Center*

8. *College of Natural Sciences & Mathematics*
9. *College of Optometry*
10. *College of Pharmacy*
11. *Graduate College of Social Work*
12. *College of Technology*

CPHS Committee 2 is responsible for reviewing human subject research in the following colleges and departments:

1. *College of Liberal Arts & Social Sciences including*
  - a. *The Jack J. Valenti School of Communication*
  - b. *Communication Sciences & Disorders*
  - c. *Economics*
  - d. *English*
  - e. *Hispanic Studies*
  - f. *History*
  - g. *Modern & Classical Languages*
  - h. *Moores School of Music*
  - i. *Philosophy*
  - j. *Political science*
  - k. *Psychology*

CPHS Committee 1 is composed of eight members. Included are five faculty members, one community representative, one non-science representative and one graduate student representative. At least one of the faculty members is a medical doctor. CPHS Committee 2 is composed of six members. Included are three faculty members, one community representative, one non-science representative and one graduate student representative. Additional members may be appointed if the required expertise is not available on the CPHS (i.e., the additional membership required to review research involving prisoners).

In accordance with 45 CFR 46.110(b), each CPHS Committee 1 and CPHS Committee 2 have a related subcommittee consisting of the chairman and one other committee member. The subcommittee can only review research activities that fall under one of the expedited categories published in the Federal Register (63 FR 60364-60367, November 9, 1998). The list is also provided on the CPHS web site.

The committees strive for a balance of men and women and representation from diverse ethnic groups. Appointment is based on the expertise required, familiarity with applicable laws, regulations, and relevant standards of professional conduct and practice, and knowledge of vulnerable or special populations. Diversity in experience and expertise enables the CPHS' to evaluate a wide range of research.

## **2.3 The Office of Research Policies, Compliance and Committees (ORPCC)**

The Office of Research Policies, Compliance and Committees is part of the Division of Research and provides administrative support to both CPHS's. The CPHS staff review protocol applications for accuracy and completeness and act as the liaison between the principal investigator and the CPHS members.

## **2.4 CPHS Meetings**

Convened meetings are scheduled monthly, September to August. The schedule is set in the summer for the following academic year and published on the CPHS's web site [[www.research.uh.edu](http://www.research.uh.edu)], under "Human Subjects". The deadline for submission of materials for full CPHS review is two weeks prior to the scheduled meeting. Members are sent applications and other materials for review approximately one week prior to the scheduled meeting. Members are expected to review all materials prior to the meeting.

The CPHS meets in executive session. The Chair may permit persons not affiliated with the CPHS to attend meetings, upon request. Investigators or their collaborators are not permitted to be present at CPHS meetings during deliberations on their research. However, the CPHS may decide to invite investigators to the meetings to answer questions about their research.

## **2.5 CPHS Policies**

The CPHS's policies are drafted by the CPHS chairs, or designees, and approved by a majority of members present at a convened CPHS meeting at which a quorum is present. The policies may be changed or revised as warranted by the majority of the CPHS at a convened meeting.

When warranted and appropriate in specific situations, the CPHS may waive any of its policies and procedures if: (1) the waiver is not inconsistent with federal regulations and (2) the waiver does not increase the risks to participants in research

## **2.6 Conflict of Interest**

No CPHS member may participate in the review of or vote on any initial or continuing application, revision, or other matter involving research in which he or she has a conflict of interest. A conflict of interest is assumed to be present when the member is the Principal Investigator, faculty sponsor, or member of a funded project on any research being reviewed by the CPHS or when the member has a financial interest in the sponsor of research under consideration.

Members shall excuse themselves from discussions at CPHS meetings of an application or other matter in which they have a conflict of interest. This is recorded in the minutes. Members may provide information requested by the CPHS prior to or after formal deliberations.

The Chair excuses him- or herself from reviewing applications for expedited review and revisions or continuations when a conflict of interest is present. The Chair may appoint another CPHS member to act as chair during the review of such applications or research activities. This is noted in meeting minutes indicating the CPHS's actions.

All CPHS members are encouraged to avoid the appearance of a conflict of interest that would compromise their ability to make a fair, impartial, and ethical decision on any CPHS matter and to excuse themselves from decision-making in such instances.