

Memo To: All UH-Downtown/PS Holders
From: Dr. Antonio Tillis, Interim President
Subject: Protection of Human Subjects

UH-Downtown/PS 03.A.23
Issue No. 3
Effective Date: 07/20/2020
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1. PURPOSE

1.1 Charge

The Committee for the Protection of Human Subjects (CPHS) is charged with reviewing and approving all research projects affiliated with or conducted at the University of Houston-Downtown (UHD) involving human subjects. Members of the committee review projects with the goal of ensuring that research is conducted in a manner that is morally and ethically sound to ensure the safety, health, and welfare of research subjects, in a context of compliance with all relevant federal and state laws and regulations.

1.2 Regulatory Requirements

In order to meet the requirements of human subject research review as required by [Title 45 Code of Federal Regulations](#) (CFR), UHD vests this responsibility of human subjects research in the Committee for the Protection of Human Subjects (CPHS) and adopts the rules of the CFR in the establishment of its policies and procedures. Changes to [Title 45 Code of Federal Regulations Part 46, Protection of Human Subjects](#) (45 CFR Part 46) shall constitute a revision to this policy statement as well as to any operating procedures guiding the activities of the CPHS. [Any reference to subsections (§) in this policy refers to the subsections of 45 CFR Part 46 unless otherwise noted.]

2. DEFINITIONS

2.1 The definitions for this policy are those specifically adopted in the “Definitions for purposes of this policy” section of the 45 CFR 46 (46.102), and in the definitions sections of any other relevant federal and state law or regulation.

2.2 Cooperative research projects are those research projects that involve more than one institution.

3. POLICY

3.1 Federal Requirements

According to [Title 45 Code of Federal Regulations Part 46, Protection of Human Subjects](#), the CPHS shall maintain and publish specific policies and procedures that will be followed in the review of research involving human subjects. The policies and procedures of the committee shall be maintained in the committee's Operating Policies and Procedures for the Committee for the Protection of Human Subjects. The CPHS makes these available on its website. The website also provides instruction for faculty who seek approval for research that involves human subjects

3.2 Adjustments to Policies and Procedures

Changes to the committee's policies and procedures must be approved by the majority of the members of the committee while meeting in a quorum.

3.3 Jurisdiction

Any research, scholarly, creative or educational study that involves human subjects in which the data will not be exclusively used or reported for internal purposes only, falls under the jurisdiction of the CPHS. Studies involving human subjects in which the data will be presented externally to UHD, whether by presentation or publication, must obtain CPHS approval prior to initiation of the study and collection of data. Research on human subjects collected for internal purposes may not ever be used for an external purpose unless CPHS approval and informed consent was obtained prior to the collection of data.

If it is unclear whether the proposed research involves human subjects or is subject to review by the CPHS, investigators should seek guidance from the chair of the committee.

The committee shall review all subsequent changes in the approved protocol to ensure compliance with state and federal regulations. Any substantial changes in the protocol, emergence of problems, or development of hazardous conditions involving human subjects must be reported immediately to the CPHS committee chairperson by the responsible investigator.

Investigators do not abdicate ethical and legal responsibility merely by complying with this policy. It is the responsibility of the principal investigator to obtain clearance from the CPHS prior to the initiation of any research activity involving the use of human subjects. Failure to do so may result in charges of research misconduct (as per PS 06.A.07- Misconduct in Research, Scholarly, Creative, and Government Sponsored Activities Policy), institutional restrictions on research activities, as well as potentially endangering all future federal funding to the University.

3.4 Committee Membership

Committee members shall be appointed for three-year terms, starting at the beginning of the academic year, by the Provost. One third of the committee membership shall be appointed each year, so that the committee always has approximately two-thirds of its members with at least one year's service on the committee.

The research enterprise at UHD is not confined to the 9-month, Academic year. CPHS committee responsibilities span the 12-month calendar year. All CPHS committee members are expected to conduct all CPHS activities, including CPHS application reviews, throughout the 12-month calendar year for the duration of their three-year service term.

The committee's faculty membership shall be tenured or tenure-track faculty. Faculty membership on the CPHS shall include two representatives from each academic department.

Non-faculty membership on the committee shall include at least one non-scientific university staff member and one community representative not associated with the university.

Two additional positions on the committee shall include the Director of Sponsored Programs and a representative of the Provost's Office. The representative of the Provost's Office shall serve in an ex-officio capacity and have no voting rights.

The CPHS, in conjunction with the Faculty Senate for faculty appointments and Staff Council for the non-scientific staff appointment, shall advise the Provost at the end of each spring semester of its membership needs and its recommendations as to appointments for the coming academic year. The committee shall also make recommendations to the Provost, in conjunction with the Faculty Senate and Staff Council, on replacement of members who have resigned from the committee. The chair and the chair-elect are elected at the beginning of the academic year if the need exists. The chair must have served at least one year on the CPHS.

3.5 Consultation

The committee may, at its discretion, invite individuals with expertise and competence in special areas to assist in the review of complex research issues.

3.6 Cooperative Research

In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With approval of the CPHS, an institution participating in a cooperative research project may enter into a joint review arrangement, rely upon the formal review of another qualified human subjects committee, or make similar arrangements for avoiding duplication of effort.

Research projects in which the primary investigator is not a current UHD faculty or staff member must obtain a UHD faculty sponsor to serve as a Co-investigator and sponsor for research projects involving human subjects at UHD.

3.7 Records

The University of Houston-Downtown's Committee for the Protection of Human Subjects shall prepare and maintain adequate documentation of the committee's activities, including the following:

- 3.7.1 Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
- 3.7.2 Minutes of the committee meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the committee; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.
- 3.7.3 Records of continuing reviewing activities.
- 3.7.4 Copies of all correspondence between the committee chair acting on behalf of the CPHS and investigators.
- 3.7.5 A list of committee members and their dates of service to the CPHS.
- 3.7.6 Written policies and procedures of the committee outlining the review system (Committee for the Protection of Human Subjects Operating Procedures).
- 3.7.7 Statements of significant new findings provided to subjects. The Committee shall ensure that records are retained in a manner consistent with UH- System, state, and federal regulations.

3.8 University Review

Research covered by this policy that has been approved by the CPHS may be subject to further appropriate review and approval or disapproval by officials at the university (for example, review by the Office of Sponsored Programs). However, officials of the university may not approve research that has been disapproved by the CPHS. (§ 46.112)

4. PROCEDURES

There are no additional procedures for this policy.

5. REVIEW PROCESS

Responsible Party (Reviewer): President

Review: Every three years on or before May 1st.

Signed original on file in Employment Services and Operations.

6. POLICY HISTORY

Issue #1: 06/21/04

Issue #2: 10/28/10

7. REFERENCES

UH System Memorandum 01.A.01

[Title 45 Code of Federal Regulations Part 46, Protection of Human Subjects](#)