

**POLICIES & PROCEDURES
FOR
USE OF HUMAN SUBJECTS COMMITTEE (UHSC)**

A. Implementation - UHSC Designation and Responsibilities

1. The University of Alabama in Huntsville (UAH) has designated and established an Institutional Review Board designated the Use of Human Subjects Committee (UHSC) for the protection of human subjects in research in accordance with the requirements of Title 45, part 46 of the Code of Federal Regulations (CFR), for federally sponsored research, and all other human subject research regardless of sponsorship. UAH subscribes to the ethical principles involving the use of human subjects delineated in the “Belmont Report: Ethical Principles and Guidelines for Protection of Human Subjects of Research.”
2. UHSC review of research
 - a. The UHSC will have the responsibility and authority to review and approve, require modification of, or disapprove all Covered Research involving human subjects. Covered Research is defined as: (1) research sponsored by UAH; (2) research conducted by or under the direction of any employee or agent of UAH; (3) research conducted using any facility of UAH.
 - b. In reviewing research, the UHSC will follow the criteria set forth in 45 CFR 46 and any other applicable UAH policy.

B. Procedures for UHSC Review

1. Submission of research proposals to the UHSC
 - a. The UHSC requires that the investigator for any Covered Research involving human subjects submit to the UHSC an appropriate request for exemption from review, expedited review, or full review.
 - b. All applications seeking review of Covered Research involving human subjects must be accompanied by an approved human subjects application and must be submitted to the UHSC for approval. The application and protocol will be reviewed and presented to the UHSC by the chair of the UHSC as required by this policy.

2. Categories of initial review

Research projects involving human subjects fall in one of three categories for UHSC review: exemption from review, expedited review, or full review.

a. Exemption from review.

- (1) For research to be exempted from review, the investigator must file an exemption request with the UHSC in a form substantially similar to Form 1. This request must accompany a copy of the research proposal (See Form 3). Exemption from review will be granted by the Chair of the UHSC, to research falling within the categories described in 45 CFR 46.101(b). The Chair will confirm the exemption from review by letter to the investigator. Records of all exemption claims will be kept on file in the UHSC office for a minimum of three years. The UHSC Chair may require additional information to determine exemption eligibility or may deny the exemption request.
- (2) When the above review procedure is used, the UHSC Board members shall be informed of research protocols which have been approved under the procedure. Upon the request of any member of the UHSC Board, additional information will be made available by the Chair.

b. Expedited review

- (1) For research to be approved by expedited review, the investigator must file a request for expedited review in a form substantially similar to Form 2. This request must accompany a copy of the research proposal (See Form 3). Expedited review may be carried out by the UHSC Chair or by one or more experienced reviewers designated by the Chair from among the members of the UHSC. In reviewing the research the reviewers may exercise all of the authorities of the UHSC except that the reviewers may not disapprove the research. Expedited review actions shall be reported to the UHSC promptly. This will generally occur by mailing notice to the UHSC of approval by expedited review at least seven days subsequent to any given expedited review action.

(2) The UHSC may use the expedited review procedure only to review either or both of the following:

- Some or all of the research appearing on the expedited review list published by the Secretary of Health and Human Services published in the *Federal Register* (63 FR 60364, November 9, 1998) and found by the reviewer(s) to involve no more than minimal risk,
- or
- Minor changes in previously approved research during the period for which UHSC approval is authorized.

If any UHSC member raises an question concerning the eligibility of a research protocol for review using the expedited procedure the protocol shall be referred to a meeting of the convened UHSC for a decision in the matter.

c. Full UHSC review

(1) When not eligible for exemption or expedited review, each research proposal shall be submitted to the Chair of the UHSC in a form substantially similar to Form 3, attached hereto.

3. Vulnerable subjects

When an investigator seeks approval of any research involving any category of vulnerable subjects (e.g., pregnant women/fetuses, prisoners, children, or individuals with cognitive impairment) the UHSC will comply with the requirements set forth in 45 CFR 46 that provide additional protection for these subjects.

4. Obtaining informed consent from subjects of research

- a. Unless the requirement is waived, the UHSC will require that an investigator obtain informed consent conforming to the requirements of 45 CFR 46.116 prior to participation in research by any human subject. (See Informed Consent Checklist, Appendix A).
- b. The UHSC will require that documentation of informed consent pursuant to the requirements of 45 CFR 46.117 be obtained by the investigator.
- c. The UHSC will require that the investigator keep copies of signed consent documents in a secure location for a minimum of three years after the termination of the UHSC approval period or longer period if required by federal regulations.

- d. The UHSC shall have the authority to observe or have a third party observe the consent process and research.

5. Continuing Review

Every protocol that is approved by the UHSC must undergo continuing review at intervals appropriate to the degree of risk and not less than once in every twelve-month period. At the time of approval of a protocol, the UHSC will designate the date prior to which the protocol must be re-reviewed and approved by the UHSC or be suspended or terminated. Thirty days prior to the renewal date the UHSC will issue a reminder letter informing the investigator of the date by which the protocol must be re-reviewed and approved.

If a protocol has not been re-reviewed and approved by UHSC prior to the required date, the protocol will be suspended or terminated. No human subjects may be enrolled in a suspended or terminated protocol. If the UHSC finds that it is in the best interests of previously enrolled human subjects to continue in the protocol for some brief period of time until the required UHSC re-review and approval occurs, it may authorize such a continuation on a case-by-case basis. Investigators will be notified of each of these actions immediately upon their initiation.

6. Procedures for deferral of UHSC approval when substantive modifications or clarifications are requested by the UHSC

- a. When a convened UHSC determines that protocol or informed consent modifications or clarifications are necessary to the review process for which the UHSC is responsible, the protocol may not be approved and it may not be conditionally approved, except as provided below. The appropriate action in such circumstances is to defer final action pending submission of the required information and distribution to and review by the convened UHSC.
- b. The only exception to the above is when a convened UHSC stipulates *specific revisions requiring no more than simple concurrence by the investigator*. In this case, the UHSC may authorize the Chair or another reviewer to subsequently activate the UHSC's approval of the protocol when the concurrence is received in writing from the investigator. Protocol modifications meeting the conditions and authorized by the UHSC as conditionally approved pending receipt of concurrence, shall be described as such in the UHSC minutes.

7. Procedures for identifying and promptly reporting unanticipated problems involving risks to subjects or others, any series or continuing non-compliance with 45 CFR 46, any UHSC determinations, and any suspension or termination of UHSC approval.

- a. Investigators of activities for which UHSC review and action is required, must report to the UHSC any unanticipated problems involving risks to subjects or others in those activities. Investigators must also report to the UHSC any

proposed changes in approved research, during the period for which UHSC approval has already been given. No such changes may be initiated without UHSC review and approval except when necessary to eliminate apparent immediate hazards to the human subjects of the research activities. At the time of continuing review, all reports of unanticipated problems involving risks to subjects or others will also be summarized in the investigator's progress report for review by the UHSC.

- b. All employees of the institution (other than those legally barred from doing so) must promptly report to the UHSC any information of which they are aware regarding noncompliance with the requirements of these Policies and Procedures and the stipulations of the UHSC.
- c. Upon receipt of any such information, the UHSC will assess the information reported and associated UHSC records and take timely and appropriate actions regarding the information. All such decisions shall be promptly forwarded to the Vice President for Research.
- d. The Vice President for Research will assess all reports, UHSC determinations, actions, and requests for assistance and provide for any institutional intervention necessary to facilitate the action of the UHSC.
- e. The Vice President for Research shall report the decisions and actions of the UHSC, discussed in this section, to appropriate federal officials, pertinent research personnel, the Provost, and other appropriate officials of UAH, as required by law or UAH policy.

C. UHSC Membership

1. Members of the UHSC will be appointed by the Vice President for Research at UAH in accordance with the requirements of 45 CFR 46.107 and applicable UAH policy.
2. The current list of UHSC members, together with information such as earned degrees, representative capacity, and affiliation with UAH, if any, is attached to this document as Appendix B.
3. New appointments to the UHSCs will be made by the Vice President for Research of UAH.
4. The Vice President for Research of UAH, appoints a Chair of the UHSC. The Chair, or in the absence of the Chair, a voting UHSC member designated by the Chair, presides over meetings of the UHSC and certifies decisions reached by the UHSC.

D. UHSC Administration

1. UHSC Office

- a. UAH will maintain suitable space for the UHSC office and for meetings of the UHSC. Necessary equipment and supplies will be furnished. Sufficient staff will be employed to fulfill the administrative responsibilities of the UHSC.
- b. The UHSC office will be responsible for the distribution to all investigators of current information on policies, procedures, and requirements for obtaining UHSC approval.

2. UHSC files

- a. The UHSC will maintain documentation of UHSC activities in accordance with 45 CFR 46.115.
- b. A complete file of each research proposal reviewed, will be maintained in the UHSC office.
- c. Each file will be retained for three years after the last UHSC approval period and the records will be kept under suitable security. Records shall be available for inspection and copying by authorized persons at reasonable times and in a reasonable manner.

3. UHSC meetings

- a. The UHSC will be convened as necessary to consider all research proposals and renewals submitted since the previous meeting and any deferred proposals or appeals. All relevant materials will be furnished prior to each meeting to each UHSC member or alternate scheduled for attendance. Any UHSC member may request a copy of these materials.
- b. A quorum will be four voting members and/or voting alternates, or a combination thereof, and will include at least one person whose concerns are primarily in a non-scientific area.
- c. Research will require approval by a majority of those members present at a convened meeting of the UHSC at which a quorum exists.
- d. UHSC meetings will conform to the requirements of 45 CFR 46.107,108, and 109.

- e. Any member of the UHSC participating in a research activity under review or having a conflict of interest will not be permitted to participate in the initial or continuing review of that project. The Board member will be asked to leave the meeting room during the discussion and vote of the protocol. This information will be noted in the minutes.

4. UHSC Minutes

- a. The UHSC shall maintain minutes of UHSC meetings that shall be in sufficient detail to show attendance at the meetings; actions taken by the UHSC; 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 controverted issues and their resolution. Investigators shall submit and UHSC minutes shall include any statements of significant new findings provided to subjects in accord with applicable informed consent requirements.