

THE UNIVERSITY OF ALABAMA IN HUNTSVILLE
POLICY FOR THE INSTITUTIONAL REVIEW BOARD
FOR HUMAN SUBJECTS RESEARCH

— INTERIM —

Number 07.01.02

Division Vice President for Research and Economic Development

Date July 6, 2016

Purpose Establish consistent policies and procedures for review of all research involving human subjects in accordance with Federal Regulations.

Policy The University of Alabama in Huntsville establishes an Institutional Review Board (hereafter “UAH IRB”) for the protection of human subjects in research in accordance with the requirements of Title 45, part 46 of the Code of Federal Regulations (hereafter “45 CFR 46”). UAH follows the Federal Regulations governing human subjects research and subscribes to the ethical principles related to the use of human subjects delineated in the "Belmont Report: Ethical Principles and Guidelines for Protection of Human Subjects of Research." This policy applies to all human subject research regardless of sponsorship.

- A. UAH IRB Composition.** The UAH IRB will be composed as follows:
1. The members of the UAH IRB will be appointed by the Vice President for Research and Economic Development (VPRED) at UAH. Their terms shall last 4 years. They may be reappointed.
 2. Every nondiscriminatory effort must be made to ensure racial and gender balance on the UAH IRB.
 3. The VRPED shall appoint one member from each Academic College to the UAH IRB. In making these appointments, the VPRED must always include one member whose primary concerns covers scientific matters and one whose primary concerns covers non-scientific manners. Additionally, the VPRED must appoint one non-affiliated member. The UAH IRB can never have fewer than five members.
 4. In addition to the academic members, the UAH IRB will have a representative of the Office of Counsel (non-voting) and the Office of Sponsored Programs (voting) as members.
 5. The Associate VPRED and the Executive Assistant to the VPRED will serve as non-voting members of the UAH IRB.
 6. The VPRED appoints a Chair of the UAH IRB. The Chair (or in the absence of the Chair, a voting UAH IRB member designated

by the Chair) presides over meetings of the UAH IRB and certifies decisions reached by the UAH IRB.

7. The UAH IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the UAH IRB. These individuals may not vote with the UAH IRB.

B. UAH IRB Authority and Charge. In accordance with 45 CFR 46 the UAH IRB

1. Shall review and have authority to approve, require modifications to, or disapprove all human subject research activities as defined in 45 CFR 46.
2. Shall require that information given to subjects as part of informed consent is in accordance with 45 CFR 46.116. The UAH IRB may require that information, in addition to that specifically mentioned in 45 CFR 46.116, be given to the subjects when in the UAH IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.
3. Shall require documentation of informed consent or may waive documentation in accordance with 45 CFR 46.117.
4. Shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure UAH IRB approval of the research activity. If the UAH IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
5. Shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.
6. Shall maintain documentation of UAH IRB activities in accordance with 45 CFR 46.115.
7. Shall follow 45 CFR 46, 107, 108, 109 regarding administrative operations.
8. Shall follow the Federal Assurance policies as set forth in 45 CFR 46.103.

C. Conflict of Interest

Any member of the UAH IRB 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.

D. Procedures for Review and Renewal

The UAH IRB establishes procedures for researchers to file applications and for the UAH IRB to review and renew these applications in accordance with 45 CFR 46. The UAH IRB must make these procedures (and any forms required for application) available to the UAH Campus and post these procedures and forms on the UAH IRB Website. The UAH IRB should regularly review these procedures and forms to help ensure they are current with the regulations stated in 45 CFR 46. These procedures should further be documented in the minutes of UAH IRB meetings as necessary.

E. Research Involving Special Populations. Research involving minors (persons under the age of 18); pregnant women, neonates, and human fetuses; and prisoners is subject to special regulation. The UAH IRB shall make every reasonable effort to comply with these stricter standards and hold researchers to these stricter standards, as set out in 45 CFR 46, Subparts B, C, and D. The UAH IRB shall make these standards and the procedures for following them available to the UAH campus and post these procedures and forms on the UAH IRB Website. The UAH IRB should regularly review these procedures and forms to help ensure they are current with the regulations stated in 45 CFR 46. These procedures should further be documented in the minutes of UAH IRB meetings as necessary.

F. Identifying and Responding to Unanticipated Problems Involving Risks to Subjects. Suspension or Termination of UAH IRB Approval.

1. Primary responsibility for the conduct of research in accordance with UAH IRB approval rests with the researcher. Researchers of activities for which UAH IRB review and action is required must report to the UAH IRB any unanticipated problems involving risks to subjects or to others in those activities. Researchers must also report to the UAH IRB any proposed changes in approved research, during the period for which UAH IRB approval has already been given. No such changes may be initiated without UAH IRB review and approval except when necessary to eliminate apparent immediate hazards to the human subjects of the research activities. Any approval letter to a researcher shall remind the investigator of this obligation, but this obligation cannot be relieved by the absence of such a reminder. At the time of continuing review, all reports of unanticipated problems involving risks to subjects or others must also be summarized in the investigator's progress report for review by the UAH IRB.
2. If deemed necessary by the UAH IRB, verification from sources other than the investigator may be solicited to ensure that no

material changes in the research have occurred since previous UAH IRB review. Reasons for such independent verification include, but are not limited to: (i) complex research projects involving unusual levels or types of risks to subjects; (ii) research projects conducted by investigators who have previously failed to comply with UAH IRB requirements; (iii) research projects where concern about possible material changes without UAH IRB approval has been raised upon information received in investigator reports or from other sources.

3. All employees of the institution (other than those legally barred from doing so) must promptly report to the UAH IRB any information of which they are aware regarding unanticipated problems involving risks to human subjects or others and regarding serious and continuing noncompliance with the requirements of these Policies and Procedures and the stipulations of the UAH IRB.
4. Upon receipt of any such information, the UAH IRB will assess the information reported and associated UAH IRB records and take timely and appropriate actions regarding the information, including suspension of the research pending resolution of the unanticipated problems or noncompliance by the researcher as provided in 45 CFR 46.113. All such decisions shall be promptly forwarded to the VPRED.
5. The VPRED will assess all reports, UAH IRB determinations, actions, and requests for assistance and provide for any appropriate institutional intervention necessary to facilitate the action of the UAH IRB.
6. The VPRED shall report the decisions and actions of the UAH IRB, 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. Such reporting shall take place within seven (7) calendar days from the date of notice to the VPRED.

Review The UAH IRB is responsible for reviewing these policies every 5 years and for making other changes as needed.

Approval

Chief University Counsel

Date

Vice President for Research and Economic Development

Date

Provost and Executive Vice President for Academic Affairs Date

APPROVED:

President Date