

# 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, Revised October 1, 2021

**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 established 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 VPRED shall appoint one faculty member (hereafter also known as Primary IRB Member) from each Academic College with faculty who conduct research 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 matters. Additionally, the VPRED must appoint one member not affiliated with UAH. The UAH IRB can never have fewer than six members excluding external appointments.
  4. The VPRED shall appoint one faculty member from each Academic College that conducts research to serve as an Alternate IRB Member. Alternate IRB Members serve as a substitute for the Academic College's Primary IRB Member who is unable to attend an IRB meeting so that IRB business may

move forward in a timely manner. Alternate IRB Members may attend all IRB meetings and may function as Primary IRB members when they are in attendance with the exception that the Alternate IRB Members may only vote in substitution for an absent Primary IRB Member. Alternate IRB Members have equal responsibilities as Primary IRB Members in terms of required IRB training.

5. In addition to the academic members, the UAH IRB will have a representative from the Office of Sponsored Programs as a (non-voting) member.
6. The Associate VPRED and the Executive Assistant to the VPRED will serve as non-voting members of the UAH IRB.
7. The VPRED appoints a Chair of the UAH IRB. The Chair presides over meetings of the UAH IRB and certifies decisions reached by the UAH IRB.
8. The VPRED appoints a Vice Chair of the UAH IRB. The primary responsibility of the Vice Chair is to preside over IRB meetings in the absence of the Chair or when the Chair has a conflict of interest; the Vice Chair also assists the Chair in the development and implementation of appropriate policies, procedures, and guidelines associated with human subject protection and IRB activities at UAH. The Vice Chair shall be selected from the members of the UAH IRB.
9. 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.
10. All voting members of the IRB must have human subject research training (i.e. IRB Committee Member Training) as provided by VPRED prior to voting on the 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 judgement, 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 as required by law 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 IRB Member shall not be allowed to participate in the review of the project, and the Alternative IRB Member may assume primary duties for the discussion and voting 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: Alabama Code 26-1-1); pregnant women, neonates, and human fetuses; and prisoners are 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 are 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 five (5) years or sooner as circumstances require.