THE UNIVERSITY OF ALABAMA IN HUNTSVILLE

POLICY FOR THE INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH

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Number

involving human subjects in accordance with Federal Regulations.

Policy The University of Alabama in Huntsville established an Institutional Review Board (hereafter "UAH IRB") 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 de

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 investigator

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