CHAPTER 6: IRB APPLICATION & REVIEW PROCEDURES

I. Human Subjects Research Training
All investigators, co-investigators, and lead personnel are required to complete human subjects research training and certification before submission of any IRB applications for review. Collaborative Institutional Training Initiative (CITI) provides HU with online training and certification for faculty, staff, students, and other personnel involved in human subjects research. Review of IRB proposals will take place only after CITI certification of all investigators, co-investigators, and lead personnel is completed.

II. Advance Submission
IRB applications (research proposals) are to be submitted to the IRB Office for review at least 30 days before the planned start-up date for the research. No definitive action such as recruiting participants, expending funds, or submitting a grant proposal to an outside agency may proceed before written approval for the research is obtained.

III. Content of Research Proposal.
Proposals submitted for review shall contain the following: a) a rationale explaining the nature, purpose, and potential benefits of the research; b) a description of the research methods, with particular emphasis on procedures that pose a risk to participants, involve deception, or do not maintain the participant’s anonymity to all parties beyond investigative personnel; c) description of the potential participant pool and the means of recruitment; and d) copies of any written recruitment materials and consent forms, or of information given retroactively to participants.

The following forms will be used to cover the above criteria:
- IRB-1: Full IRB and Expedited Review
- IRB-1A (completed with IRB-1): Drug Device
- IRB-1B (completed with IRB-1): Genetic
- IRB-1C (completed with IRB-1): Treatment
- IRB-2: Reapproval/Completion of Study
- IRB-3: Amendment Review
- IRB-4: Adverse/Unanticipated Events
- IRB-5: Request for Exempt Review
- IRB-6: Protocol Deviation Form
- IRB-7: Research Methods Courses (RMC)
- IRB-8: Reapproval/Completion of RMC/IRB-7
- IRB-9: Ethnographic/Naturalistic Research

IV. Review and Approval of Proposals
All research proposals are first submitted to the IRB office. The IRB Administrator reviews the proposals for completeness, clarity, and eligibility for exempt or non-exempt status. He/she then forwards the proposals to the chairperson of the IRB with either conditional approval as exempt or a recommendation for either expedited or full board review.

A. Requests for Exempt Status
Investigators seeking “exempt” status for research should prepare an IRB-5 form, using
the standard application form on the IRB website. The proposal should clearly explain
why the research is believed to be low risk and should qualify for exempt status.
The IRB Chair will review the proposal. The IRB chairperson will review the submitted
proposal and either approve the exempt status for the research, or designate the proposal
for expedited review or full board review. He/she will forward one copy of the proposal
(with his/her decision regarding the review status) to the Provost office and will retain
the other copy of the proposal for the IRB Office files.

When the IRB-5 is received in the Provost office, the IRB administrative staff will notify
the investigator of the outcome of the review. If the study has been approved with exempt
status, a “Certification for Exemption” will be sent to the investigator. The research may
proceed when the investigator receives the exempt certification. If the IRB chairperson
does not approve the exempt status for the research, the investigator will be advised of
procedures to obtain the required review.

Research studies approved for exempt status are not routinely monitored by the IRB
while the study is in progress. However, the investigator (or supervising faculty member
in the case of student research) is responsible for informing the IRB Office of the
completion date of the approved research study.

Instructors of research methods courses (RMC) that educate students on designing and
executing research should consult the IRB Administrator and/or IRB Chair regarding the
projects their students will be working on in their classes. RMC instructors with projects
that operate in controlled facilities (i.e. public schools), work with protected/vulnerable
populations, or other human subjects activity as deemed by the IRB Administrator and/or
IRB Chair may need to submit an IRB-7 form to the IRB Office. Instructors seeking
RMC reapproval or concluding their courses should complete an IRB-8 form.

B. Expedited Review:
From the viewpoint of the investigator, the procedures for expedited review are the same
as those for full board review. An IRB-1, IRB-7, or IRB-9 (ethnographic/naturalistic
research) application form is completed and submitted with the research proposal and
supporting documents. The proposal shall contain a complete description of the proposed
research or study, including provisions for the adequate protection of the rights and
welfare of prospective human research participants and assurance that the pertinent laws
and regulations are observed. Samples of study materials, communications with
prospective participants and any informed consent forms shall be included.

For studies meeting the eligibility criteria for expedited review, two copies of the
research proposal are submitted to the IRB chairperson. The proposal is read by the IRB
Administrator and/or IRB Chair who takes one of two actions: (i) referral of the proposal
to the full board for review, or (ii) referral to an IRB member (including the Chair) for
expedited review. Note: Reviewers doing expedited reviews cannot disapprove research
proposals.
In the case of stipulations, the approval is conditional, and the investigator must respond to the stipulations in a communication with the IRB Chair. Upon receipt of a satisfactory response to the stipulation(s), the IRB Chair will then give approval. In the case of recommendations, the investigator may proceed without further communication from the IRB. If the IRB Chair judges the proposal to require full board review, the proposal shall be relayed to the full board and the investigator notified in writing to that effect.

C. Full Board Review:
If the unit designate recommends full board review of a submitted proposal, ten copies of the IRB-1, IRB-7, or IRB-9 are to be forwarded to the IRB Administrator and/or IRB Chair. When the application is received, it will first be screened for completeness. If information is missing from the application, the investigator will be contacted and requested to supply the missing information. Applications are assigned to one of the monthly Board meetings for review on a “first come, first served” basis. A week or more before the scheduled meeting, applications are posted on the confidential IRB website for review by board members.

Upon review, the Board shall make one of three determinations:
1. **Approval**
2. **Modifications Needed**: The Board will explain in writing why the proposal, as submitted, needs modification. The investigator may not take any definitive action such as recruiting participants, expending funds, or submitting a grant proposal to any outside agency that requires institutional review board certification until a proposal, with modifications is approved by the IRB.
3. **Disapproval**: If a proposal is not approved, the IRB will in explain, in writing, the rationale for the disapproval and notice of the appeal options under this policy. Without approval the investigator shall not use any university facilities or funds for the research, nor in any way claim university sponsorship. The university will not incur any obligation to protect an investigator who proceeds with the research nevertheless.

V. Approval Timeframes:
Research activities are approved for no longer than a period of one year and may be approved for a shorter period of time commensurate with the level of risk posed by the research and the projected project duration. [45 CFR 46.109]. The approval letter sent to the investigator will specify the time period that research activities may be conducted. No research data may be collected outside of the designated time period. Research projects that cannot be completed in the approved time period will need a continuation approval via an approved IRB-2 form.

When reviewing the initial proposal, the following criteria will be used by the IRB to determine the frequency of study review: 1) the probability or magnitude of anticipated risks to participants, 2) any medical conditions of the proposed participants and their susceptibility to problems as a result of enrollment in the protocol, 3) qualifications of the investigator and other members of the research team, 4) past history of the investigator(s) and research team in adherence to IRB guidelines, 5) specific experience of the
investigator(s) in similar research protocols, 6) the nature and frequency of adverse events in similar research, 7) the general vulnerability of the population being studied, and 8) other factors deemed relevant to the IRB.

VI. Applications for Continuation of Previously Approved Studies
The IRB shall be informed at least annually of the status of all research. As a courtesy to investigators, administrative staff assigned to IRB support functions will send a notice and IRB-2 or IRB-8 form to the investigator one month before the end of a given approval period. An investigator who does not receive such a reminder should contact the IRB Office as soon as possible to request a copy of the Status Report. If the research is proceeding in relation to participants as outlined in the research protocol, the investigator is to note this on the IRB-2 or IRB-8 form. If there are any significantly increased risks to participants, deceptive practices in the research, or if any other changes have occurred (or are expected to occur) that could affect the rights and choices of participants, the investigator shall not wait until the annual status report but shall promptly submit updated information to that effect to the board for its review.

VII. Study Modifications.
It is recognized that changes to a research study and informed consent documents may be required as the research proceeds. However, proposed modifications must be approved by the IRB before they are implemented. The only exception to this requirement is a procedural change that may be necessary to eliminate an apparent immediate hazard to a research participant. If this occurs, the investigator must submit an IRB-3 amendment form or IRB-6 protocol deviation form with the original proposal to make it consistent with the changes. If a research study is completed prior to the end of the approval period, the investigator should submit an IRB-2 form to the IRB Office, noting the date of study closure.

VIII. Appeal Process
If an investigator believes that the IRB review process was not fairly executed and that it resulted in an unduly restrictive decision regarding the proposed research, he/she may appeal the decision. He/she should first discuss the matter with the IRB chairperson, taking care to explain the reasons for believing that the research procedures are in compliance with University policy and federal and state regulations. If the issue cannot be resolved satisfactorily by negotiation, the investigator may appeal the decision of the reviewer(s), in writing, to the Authorized Institutional Official, and then the Provost.

Upon receipt of an appeal the AIO or Provost shall convene an ad hoc committee, constituted so as to fulfill federal requirements, and with the majority of members being past but not current members of the IRB. The ad hoc committee will consider the appeal, and within 60 days, communicate its decision in writing to the Provost, giving its reasoning for the decision. A copy of the decision will be given to the investigator and the current IRB chairperson, and documented in the minutes of the next convened IRB meeting.
Any person who proceeds with collecting or analyzing research data, intentionally disregarding the need for official approval of the IRB for the research, will be in violation of IRB policy and will be subject to administrative sanctions, including the termination of research privileges at the University.