CHAPTER 7: MONITORING THE CONDUCT OF RESEARCH

I. Oversight Responsibilities
Protection of human participants in research is a shared responsibility of many persons in the academic community, including those directly engaged in the conduct of the research (e.g., investigators and study personnel), those with specific review and oversight responsibilities (IRB and AIO), University administrative officers, and the wider academic community.

All persons engaged in the conduct of research are expected to be aware of HU policies regarding human subjects research and are obligated to report observed violations to the IRB. The IRB provides ongoing education on human participant[s] research for the University community through new faculty orientation sessions, online education/training modules, and individual consultations as requested. Members of the IRB and all investigators are required to complete CITI certification training approved by the IRB. Persons engaged in research support roles are also required to complete CITI certification training.

A. Investigator Responsibilities and Reporting Requirements
The primary responsibility for the day-to-day protection and welfare of research subjects lies with the investigator who submitted the IRB application. This person is expected to implement the study in a safe and timely manner, according to the approved proposal, and to keep the IRB informed of any unanticipated problems or adverse events. During the course of the study, and up to three years after completion of a study, he/she must keep detailed records of all research-related activities, (e.g., lists of enrollments, copies of consent and assent forms, minutes of meetings, lists of meetings and attendees), and make the records available for IRB review upon request.

In the case of student research, the student and supervising faculty member share responsibility for monitoring the safety of human participants, and are held accountable for these activities.

B. Unexpected Events and Adverse Reactions
During the course of a research study, unexpected events and adverse reactions may occur to a study participant, other individuals associated with the participant, or to key personnel associated with the research study. An unexpected event is an unanticipated problem associated with any aspect of the research study that may involve risks to the enrolled study participants and/or to other individuals who may or may not be directly associated with the research study. This type of event can happen in both clinical and non-clinical (behavioral or social science) studies. An adverse reaction is an undesirable and unintended, though not necessarily unexpected, result of therapy, study interventions or activities. These generally occur in clinical research and only apply to participants enrolled in the study. Investigators are responsible for ongoing monitoring of their studies for unexpected events and adverse reactions, and reporting these situations to the IRB if they arise using the IRB-4 form.
II. IRB Monitoring of Approved Studies
The IRB tracks all research studies. It also has procedures for systematic monitoring of all non-exempt studies while they are being conducted. If it finds any human subject concerns or violations (or if these are reported to the IRB), it will make every attempt to work collaboratively with the principal investigator to ensure that corrective actions are taken.

A. Routine Monitoring
The following IRB procedures are used for routine monitoring of approved studies:

1. Review of investigators’ credentials and IRB training certifications: Primary Investigators must show evidence of having completed the IRB-approved human participant research training before start-up of a research project. A copy of the CITI training certificate can be attached to the IRB application or sent to the Provost office.

2. Computerized tracking of research studies, with documentation of IRB application approval dates, annual reviews, and notations of any protocol changes or reported human subject concerns;

3. Annual (and other required) Status Reports (IRB-2; IRB-8);

4. Administrative staff assigned to support IRB functions routinely monitor non-exempt research studies in the tracking system for timely submission of Status Reports and any other required documentations from investigators. An alert will be sent to any investigator having a delinquent Status Report, reminding him/her that the approved study period has lapsed and the study may not proceed. If there is no acknowledgement within 10 days, direct contact will be made with the investigator to determine whether the research study has been completed. In the event that the study is still in progress (without the required Status Report), it is in violation of IRB policy, and the investigator will be instructed to desist from all project activities. The violation will also be recorded in the IRB minutes.

Student research projects associated with coursework and must have IRB approval via IRB-7 (if needed) for one or two semesters. The supervising faculty member is responsible for ensuring that the IRB is kept informed of the status of the student project. If the approved project period has lapsed without notification of project completion, the faculty member will be contacted and asked to submit the required status report IRB-8.

1. Random Audits
Random samples of non-exempt studies in progress may be selected for periodic audits. When this occurs, a designated person from the IRB meets with the investigators of the audited studies to discuss the progress of the studies and review the study records. A report is generated for the IRB and feedback is given to the investigators.

2. Unexpected Events/Adverse Reactions
If a report of an unexpected event or adverse reaction is filed with the IRB (IRB-4), an investigation is held to determine the seriousness of the situation and its potential effect on the safety of study participants and other persons (risk/benefit analysis). If the safety concerns can be adequately addressed by modifications of study procedures, the
investigator will be asked to make the modifications and submit an amendment to the original proposal (IRB-3), verifying his/her intent. If risks to the research participants or other persons cannot be adequately addressed by procedural modifications, the research study will be suspended or terminated.

3. Follow-up on reported human subject concerns and/or violations
Any telephone calls or other verbal or written communications that come to the attention of the AIO, IRB Office, or Provost’s office concerning human participant matters in individual studies will be forwarded to the IRB chairperson for follow-up. An investigation of the concern or allegation will be initiated within 10 working days.

B. Additional Monitoring and Verification of Safety and Compliance
There may be situations in which the IRB determines that it needs to do additional monitoring, and/or collect information from sources other than the investigator to verify that no material changes have occurred in the study since previous IRB review or that no other human subject violations have occurred. Situations that may require additional monitoring and/or verification include: a) studies that involve unusual levels or types of risks or that include vulnerable groups as research participants, b) a study conducted by an investigator who has previously failed to comply with IRB or federal regulations, or c) concerns raised about changes occurring in a study, based on information in submitted Status Reports, or d) human participant concerns reported to IRB members or the Provost office.

Various sources may alert the IRB of the need for an independent review of an ongoing study. Inquiries may be submitted from: committees or administrative units within the University; community agencies collaborating on a project; enrolled research participants or family members; the news media; a funding agency; the Office of Research Protections (OHRP) or other federal or state agencies.

In these cases, the IRB will determine whether: 1) an audit of the research study needs to be conducted by the Provost’s office, 2) the research should be suspended, and/or 3) if additional administrative actions need to be taken. If an investigation is required, a designated person from the IRB will meet with the investigator to discuss the reported concerns/violations (without revealing the identity of the person(s) initiating the report). He/she is authorized to review any study documentations, interview study staff and/or study participants, or directly observe the research proceedings to obtain information needed for an impartial assessment of the situation. Needed corrective actions will be discussed with the investigator, and a written report will be given to the IRB and Provost. Additional follow-up visits or contacts may be initiated by the IRB to verify that corrective actions have been taken. Oversight of assigned senior researchers and/or IRB members can be used to ensure that no more violations occur.

C. Federally-Funded Clinical Trials.
Federally-funded research studies that include activities classified as Phase I or Phase II clinical trial research by the National Institutes of Health (NIH) or other federal funding agencies are required to have a “Data and Safety Monitoring Plan” in place to document
safeguards for research participants. The IRB follows and endorses federal policy with regards to the need for additional monitoring for such intervention studies. If an investigator intends to submit a protocol that entails clinical trials research, a preliminary Data and Safety Monitoring Plan should be submitted with the IRB application. The IRB will consult with the investigator on development of the Data Safety and Monitoring Plan or provide advise on external resources. Investigators planning to participate in multi-center collaborative research are encouraged to seek guidance from established clinical trials networks and the DHHS Office of Research Protections (OHRP). This should be done in addition to completing the required IRB-approved human participant research training.

D. Suspension or Termination of Research
The IRB has the authority to suspend or terminate at any time its approval of research that is not being conducted with the IRB’s requirements or that has been associated with unexpected serious harm to subjects [45 CFR 46.113]. Any suspension or termination shall be conveyed promptly to the principal investigator, with reasons for the board action conveyed in writing.

E. IRB Reporting Requirements
The DHHS regulations [45 CFR 46.103(a) and (b) (5)] require that institutions have written procedures to ensure that the following incidents related to nonexempt research conducted under an OHRP-approved assurance are promptly reported to the OHRP:

- any unanticipated problems involving risks to subjects or others;
- any serious or continuing noncompliance with federal policy or requirements or determinations of the IRB;
- any suspension or termination of IRB approval.

Any of the above problems will be promptly reported to appropriate institutional officials, and to the DHHS Office of Research Protections (OHRP) when applicable. Incident reports submitted to the OHRB will include the following information: a) name of the University (HU); b) full title of the research study; c) name of the primary investigator (person currently responsible for conduct of the research); d) number of the study assigned by the IRB (and any number of any applicable federal award, e) a detailed description of the problem, and f) actions the University is taking or plans to take to address the problem.

The Provost or his/her appointed representatives are responsible for communications with the OHRP and/or other governmental or regulatory agencies for compliance purposes. The IRB will cooperate with any compliance investigations initiated by the University or the OHRP.