Section 19. **Investigator Responsibilities**

Principal Investigators are ultimately responsible for the conduct of research for the studies for which they serve as the Principal Investigator. Principal investigators may delegate tasks to appropriately trained and qualified investigators and research staff. However, investigators must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibilities.

19.1 Investigators

The various roles of "Investigators" are differentiated based on their responsibilities in the conduct of research involving human participants.

19.1.1. Principal Investigators (PI)

At the medical school, only individuals with a faculty appointment at the rank of assistant, associate, or full professor are eligible serve as the PI. The medical school may establish more stringent qualifications for individuals to serve as the PI, regardless of a finding by the IRB, whether the medical school IRB or an external IRB. The associate dean for Research or the IRB, either the medical school IRB or an external IRB, may determine that an individual may not serve as PI for any given project based on factors such as expertise, training, experience, licensing, credentials, conflict of interest or commitment, or a history of non-compliance related to research or any medical school policy.

Students, residents, fellows, and others whose status is considered as "in-training" may not serve as a PI but may serve as a sub-investigator. The PI must ensure that the elements of the research protocol conducted in part by trainees has sound research design and that trainees are appropriately supervised at all times.

The IRB recognizes a single individual as the PI for each study. The PI has ultimate responsibility for the research activities.

Studies that require expertise or skills beyond those held by the PI must either be modified or have expertise and skills supplemented by the inclusion of one or more additional qualified sub-investigators.

19.1.2 Sub-Investigators

A sub-investigator is any investigator other than the PI who is involved in the conduct of a research study. Sub-investigators may be faculty appointed at any rank, including at the rank of instructors. Students may not serve as sub-investigators but may serve as research staff. Involvement of sub-investigators could include:

- Obtaining information about living individuals by intervening or interacting with them for research purposes.

- Obtaining identifiable private information about living individuals for research purposes.
- Obtaining the voluntary informed consent of individuals to be subjects in research.
- Studying, interpreting, or analyzing identifiable private information or data for research purposes.

19.2 Responsibilities

In order to satisfy the requirements of the medical school under these policies and procedures, investigators who conduct research involving human subjects must:

- Develop and conduct research that is in accordance with the ethical principles in the Belmont Report.
- Develop a protocol/research plan that is scientifically sound and minimizes risk to the subjects.
- Incorporate into the protocol/research plan steps to ensure the just, fair, and equitable recruitment and selection of subjects.
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence (eg, children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons), include additional safeguards in the study to protect the rights and welfare of these subjects.
- Ensure that the protocol/research plan includes adequate provisions for the monitoring of subjects and data to ensure the safety of subjects.
- Ensure that there are adequate provisions to protect the privacy interests of subjects.
- Ensure that there are adequate provisions to protect data confidentiality and interests of subjects, including an information security plan that considers the collection, storage, maintenance, analysis, and transmission of data and other identifiable information.
- Have sufficient resources necessary to protect human subjects, including:
    - Access to a population that would allow recruitment of the required number of subjects.
    - Sufficient time to conduct and complete the research.
    - Adequate numbers of qualified staff.
    - Adequate facilities.
    - Necessary equipment.
    - A plan to ensure proper supervision of the research including a plan for periods of absence or decreased availability.
    - Availability of medical, psychological, and other support that subjects might require during or as a consequence of their participation in the research.
- Assure that all procedures in a study are performed with the appropriate level of supervision and only by individuals who are licensed or otherwise qualified to perform such under Michigan state law (or the laws where the research is

conducted), and that the policies are followed of the organizations or facilities where the procedures are performed.
- Assure that all study personnel are educated in the regulatory requirements regarding the conduct of research and the ethical principles upon which they are based.
- Assure that all persons assisting with the research are adequately trained and informed about the protocol/research plan and their specific duties and functions.
- Promptly report any changes in, addition to, or departure of investigators or research staff to the IRB for evaluation and approval. (Investigators and staff may not begin work on the research until there is IRB approval.)
- Protect the rights, safety, and welfare of participants.
- Ensure that when protected health information is used, legally effective HIPAA authorization is obtained for each subject unless the Privacy Board or IRB has approved a waiver of the requirement.
- Ensure that the language in the consent form is consistent with that in the protocol/research plan and, if applicable, in the HIPAA authorization.
- Obtain and document informed consent and ensure that no human subject is involved in the research prior to obtaining consent or consent/permission from their legally authorized representative, unless a waiver of the requirement has been approved by the IRB.
- Have a procedure to receive questions, complaints, or requests for additional information from subjects and respond appropriately.
- Ensure that all information provided to the IRB is accurate and complete so that the IRB may fulfill its responsibilities to review the research and make the required determinations.
- Ensure that all research involving human subjects receives IRB review and approval in writing or a determination of exemption before research begins.
- Ensure that all research involving human subjects is reviewed by other experts and organizational components and committees as applicable to the research.
- Comply with all IRB decisions, conditions, and requirements.
- Ensure that studies receive timely continuing IRB review and approval.
- Report unanticipated problems, deviations, complaints, non-compliance, suspensions, terminations, and any other reportable events to the IRB.
- Notify the IRB if information becomes available that indicates a change to the potential risks or benefits of the research.
- Obtain IRB review and approval before changes are made to the research unless a change is necessary eliminate apparent immediate hazards to the subject(s).
- Seek HRPP or IRB assistance when in doubt about whether proposed research requires IRB review.
- Retain records for the time period and in the manner required by applicable regulations, contractual agreements, and medical school policies.

Additional investigator responsibilities, including specific responsibilities for investigators engaged in FDA-regulated research are described elsewhere in the *Human*

Research Protection Program (HRPP) and Institutional Review Board (IRB) Handbook.

19.3 Investigator Records

Investigators must maintain, at a minimum but not limited to, the following research records. If applicable, investigators must also comply with all sponsor and ICH-GCP E6 requirements.

- Study Records
    - Individual subject records or case histories.
    - Materials provided to or completed by subjects.
    - Documentation of the consent process (addressing who, what, when, and how), if applicable.
    - Signed consent forms and HIPAA authorizations, if applicable.
    - Adverse events.
    - Subject complaint reports.
    - Results of all research exams, procedures, and visits.
    - Records of payment or reimbursement.
    - Records related to the withdrawal of subjects, in part or in full.
- Regulatory Records
    - All versions of the IRB-approved protocol/research plan.
    - All versions of IRB-approved consents, parental permission, and assent forms, scripts, or information sheets, if applicable.
    - All versions of the HIPAA authorization form, if applicable.
    - All submissions to and correspondence (ie, approvals, reporting forms and responses) with the IRB.
    - All correspondence with the sponsor and others regarding the study.
    - Investigational product accountability records, if applicable.

Investigator records must be retained in accordance with all applicable regulatory, organizational, and sponsor or grantor requirements. All records must be maintained securely with limited access. Disposal of investigator records must be performed in such a manner that no identifying information can be linked to research data. Information regarding record retention requirements is available from the HRPP and Sponsored Programs Administration.

19.4 Investigator Concerns

As needed, the HRPP director, assistant dean for Research Compliance, and IRB chair are available to address investigators' questions, concerns, and suggestions.

Investigators who have concerns or suggestions regarding the medical school HRPP or IRB(s) that require greater attention should also convey them to the Institutional Official, or to associate dean for Research, assistant dean for Research Compliance, or Research Integrity Officer, who then forward these to the Institutional Official. The Institutional Official considers the issue, and when deemed necessary, seeks additional

information and convenes the appropriate parties to formulate a response for the investigator or make necessary procedural or policy modifications, as warranted.

In addition to these policies and procedures, which are made available on the medical school website for investigators and research staff, investigators are also made aware of the process for expressing their concerns via statement on approval letters, as well as the link on the medical school website for submitting concerns or complaints.