Section 4. **Institutional Review Board**

The medical school has established one or more Institutional Review Boards (IRB) to ensure the protection of human subjects in research conducted, research conducted at, under the auspices of, or using the services or resources of the medical school. All non-exempt human subject research conducted at, under the auspices of, or using the services or resources of the medical school must be reviewed and approved by the medical school IRB prior to the initiation of the research.

The medical school IRB may serve as the IRB of record for research conducted, in part or in full, by other organizations or investigators. A written agreement documenting the acceptance of the medical school IRB as the IRB of record and delineating the responsibilities of each organization or the medical school and the investigator must be executed prior to the medical school IRB accepting such research for review.

The Institutional Official may also authorize use of external IRBs. The authorized external IRBs that serve as the IRB of record for the medical school have the same authority as the medical school IRB and as such all determinations and findings of the external IRBs are binding.

4.1 IRB Authority

The medical school IRB derives its authority from medical school policy, as cited in Section 1.2. Under the federal regulations, IRB has the authority:

- To approve, require modifications to secure approval, or disapprove all human subjects research conducted at, under the auspices of, or using the services or resources of the medical school or for which the medical school IRB serves as the IRB of record.
- To require that informed consent be obtained and documented in accordance with regulatory requirements unless the criteria for the waiver or alteration of such requirements has been satisfied and approved by the IRB. The IRB may require that information, in addition to that specifically mentioned in the regulations, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.
- To conduct continuing review of research at intervals appropriate to the degree of risk of the research, but not less than once per year.
- To suspend or terminate approval of research not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to participants.
- To observe, or have a third party observe, the consent process.
- To observe, or have a third party observe, the conduct of the research.

By medical school policy, the IRB also has the authority to determine, with the assistant dean for Research Compliance, whether data or information involving human subjects but gathered without IRB approval or in association with serious noncompliance may be published or used for research purposes. Both the IRB and the assistant dean for

Research Compliance must approve the publication or use of the data or information under these circumstances.

The IRB functions independently. Attempts to coerce or otherwise unduly influence the actions of the IRB are forbidden by policy, and are to be reported as described in Section 4.7. Similarly, the IRB must remain free from the influence of financial and other organizational interests. No individual with primary responsibility for the business and financial interests of the organization may serve on the IRB.

Research that has been reviewed and approved by the IRB is also subject to review and approval by officials of the medical school or other organizations involved in the research. However, those officials may NOT approve research involving human subjects if it has not been approved or has been disapproved by the IRB. Reviewing officials may strengthen requirements and/or conditions, require modifications to the protocol/research plan, or require approval by an additional committee. Any changes required by reviewing officials or committees after research has been approved by the IRB must be submitted to the IRB and approved by the IRB before initiating the changes unless the change is necessary to eliminate an immediate hazard to human subjects.

4.2 Roles and Responsibilities

4.2.1 Chair of the IRB

The Institutional Official, in consultation with the assistant dean for Research Compliance and HRPP director, appoints a chair and vice chair of the IRB to serve for three-year terms, which may be renewed for a maximum of two terms. Any change in appointment, including reappointment or removal, requires written notification.

The IRB chair should be a highly respected individual fully capable of ensuring that the matters brought before the IRB are managed with fairness and impartiality. The task of making the IRB a respected part of the research community falls largely on the shoulders of the chair. The IRB must be perceived to be fair, impartial, and immune to influence and pressure by administration, the investigators whose research plans/protocols are brought before it, and other committees and professional and nonprofessional offices and entities.

The IRB chair is responsible for conducting IRB meetings, conducting expedited reviews, determining whether research qualifies for exempt status, determining whether proposals are research and whether research involves human subjects, and may serve as signatory for correspondence generated by the IRB.

The IRB chair is authorized to take immediate action to suspend a study or studies if information is presented regarding subject safety or for any other reason where such action would be deemed appropriate. Such action requires subsequent notice to and review by the convened IRB.

The IRB chair may designate other experienced IRB members to perform duties such as expedited reviews and other IRB functions.

The IRB chair advises the Institutional Official and the HRPP director about IRB member performance and competence.

The performance of IRB chair is reviewed annually by the Institutional Official in consultation with the HRPP director and assistant dean for Research Compliance. Feedback from this review is provided to the chair. The Institutional Official may remove the chair if the chair is not acting in accordance with the IRB mission, not following medical school policies and procedures, has an undue number of absences, or not fulfilling the responsibilities of the chair, in the sole discretion of the Institutional Official.

4.2.2 Vice Chair of the IRB

The vice chair serves as the chair of the IRB in the absence of the chair and has the same qualifications, authority, and duties as the chair.

The performance of IRB vice chair is reviewed on an annual basis by the Institutional Official in consultation with the HRPP director, assistant dean for Research Compliance, and IRB chair. Feedback from this review is provided to the vice chair. The Institutional Official may remove the vice chair if the vice chair is not acting in accordance with the IRB mission, not following medical school policies and procedures, has an undue number of absences, or not fulfilling the responsibilities of the vice chair, in the sole discretion of the Institutional Official.

4.2.3 IRB Members

The role of an IRB member is to ensure that human research activities comply with federal regulations, state and local laws, and medical school policies and procedures, by:

- Completing education and training requirements, both initial and ongoing (see Section 3.1).
- Maintaining the confidentiality of IRB deliberations and research reviewed by the IRB.
- Conducting and documenting reviews of assigned research in a timely fashion.
- Attending IRB meetings as scheduled. Members should attend all meetings for which they are scheduled. If a member is unable to attend a scheduled meeting, they should inform HRPP/IRB staff with sufficient time, whenever possible, for the staff to arrange for an alternate member to attend. If an IRB member is to be absent for an extended period of time, he or she must notify HRPP/IRB staff at least 30 days in advance so that an appropriate alternate member can be scheduled to attend. If the member has a designated alternate, the alternate can serve during the primary member's absence.

- Recusing oneself from final deliberations and vote when the IRB member has a conflict of interest or commitment.
- Participating in subcommittees of the IRB if requested and available.
- Conducting themselves in a professional and collegial manner.

Experienced IRB members may be designated by the IRB chair to conduct expedited reviews.

The performance of IRB members is reviewed annually by the IRB chair and the HRPP director. Feedback from this review is provided to IRB members. The Institutional Official may remove an IRB member if an IRB member is not acting in accordance with the IRB mission, not following medical school policies and procedures, has an undue number of absences, or not fulfilling the responsibilities of an IRB member, in the sole discretion of the Institutional Official.

4.2.4 Alternate members

The appointment and function of alternate members is the same as that for primary IRB members. An alternate member's expertise and perspective should be comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate member receives and reviews the same materials prior to the IRB meeting that the primary member received or would have received.

The IRB roster identifies the primary member(s) and class of members (ie, physician scientist) for whom each alternate member may substitute. The alternate member is not be counted toward meeting quorum as a voting member unless the primary member is absent. The IRB minutes must document when an alternate member replaces a primary member.

Experienced alternate members may be designated by the IRB chair to conduct expedited reviews.

4.2.5 Subcommittees of the IRB

The IRB chair, in consultation with the HRPP director and assistant dean for Research Compliance, may designate one or more IRB members to a subcommittee of the IRB to perform duties and undertake IRB functions, and to make recommendations to the IRB (eg, to supplement the IRB initial review, continuing review, review of modifications, and/or review of reports of unanticipated problems or of serious or continuing non-compliance). The IRB chair, in consultation with the HRPP director and assistant dean for Research Compliance, may appoint IRB members to serve on each IRB subcommittee that is created. The number and composition of the IRB subcommittee members shall depend on the scope of duties delegated by the IRB chair to each IRB

subcommittee. No IRB subcommittee can approve research, which requires approval by the IRB at a convened IRB meeting.

4.3 Composition of the IRB

The IRB must promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects; and possess the professional competence necessary to review the research that comes before it.

- The IRB will have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the organization.
- The IRB will be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
- In addition to possessing the professional competence necessary to review specific research activities, the IRB will be able to ascertain the acceptability of proposed research in terms of organizational commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB will therefore include persons knowledgeable in these areas.
- If the IRB regularly reviews research that involves a vulnerable category of subjects (eg, children, prisoners, pregnant women, or handicapped or mentally disabled persons), consideration will be given to the inclusion of one or more individuals on the IRB who are knowledgeable about and experienced in working with these subjects.
- Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, including the organization's consideration of qualified persons of both sexes, so long as no selection is made to the IRB solely on the basis of gender. The IRB shall not consist entirely of members of one profession.
- The IRB includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- The IRB includes at least one member who is not otherwise affiliated with the organization and who is not part of the immediate family of a person who is affiliated with the organization.
- The IRB includes at least one member who represents the general perspective of participants.
- When reviewing nursing research from a facility with Magnet designation by the American Nurses Credentialing Center, the IRB will include at least one nurse representative.

One member may satisfy more than one membership category. The HRPP director and HRPP/IRB staff may be appointed to serve as regular or alternate members of the IRB.

Personnel from the medical school Sponsored Programs Administration, Accounting, and units with primary responsibilities for the business interests of the medical school may not serve as members of the IRB or be involved in the day-to-day operations of the IRB review process. Individuals from these units may provide information to the IRB and attend IRB meetings as invited guests.

On an annual basis, the HRPP director, assistant dean for Research Compliance, and IRB chair shall evaluate the membership and composition of the IRB, and recommend adjustments to the Institutional Official, if needed, to meet regulatory requirements and address organizational needs.

4.3.1 Appointment of Members to the IRB

When a need is identified for a new, replacement, or alternate member for the IRB, the HRPP director, assistant dean for Research Compliance, and IRB chair shall collaborate to identify qualified interested candidates and inform the Institutional Official. Department chairs and others may recommend individuals who may be interested and appropriate for IRB membership by contacting the HRPP director, assistant dean for Research Compliance, or IRB chair. The final decision in selecting a new, replacement or alternate member for the IRB is made by the Institutional Official.

Appointments are made for a renewable three-year term. Any change in appointment, including reappointment or removal before the end of a member's term, requires written notification. Members may resign by written notification to the HRPP director or IRB chair.

4.3.1 IRB Registration Updates

Changes that affect the medical school's federal IRB registration, including changes in IRB membership, must be reported to FDA and OHRP within the following time periods:

- Within 90 days of a change in the IRB membership roster.
- Within 90 days after changes of the IRB chair.
- Within 90 days after changes to the contact person who provided the IRB registration information.
- If an IRB is formed, before the IRB reviews research regulated by the FDA, before the IRB is designated under a FWA, and before the IRB reviews research conducted or supported by DHHS.
- If an IRB is disbanded, within 30 days after permanent cessation of IRB reviews.
- Within 30 days if an IRB decides to review additional types of FDA-regulated products (eg, to review device studies if it only reviewed drug studies previously) or to discontinue reviewing clinical investigations regulated by FDA.

4.4 Use of Consulting Reviewers

The HRPP director or IRB chair may solicit individuals with competence in special areas to assist in the review of issues or research plans/protocols, which require expertise beyond or in addition to that available on the IRB.

Prospective consulting reviewers must complete the conflicts of interest and commitment reporting required by medical school policy GEN04, *Conflicts of Interest and Commitment*. The Research Integrity Officer reviews the conflicts of interest and commitment for prospective consulting reviewers to confirm that they do not have a conflict of interest or commitment prior to review. Individuals who have a conflict or whose spouse or immediate family members have a conflict with the research will not be invited or permitted to provide consulting review.

HRPP/IRB staff ensure that all relevant study materials are provided to the consulting reviewer.

The consulting reviewer's findings are presented either in person or in writing to the convened board for consideration. If in attendance, consulting reviewers may not participate in the vote. For expedited reviews, the consulting reviewer provides documentation of their review for IRB chair, or designee, consideration. The consulting review must be available for discussion if needed.

Written statements from consulting reviewers are kept with IRB records. Key information provided orally by consulting reviewers at meetings must be documented in the minutes or recorded in review notes by the IRB chair, or designee, for expedited reviews.
Ad hoc or informal consultations requested by individual IRB members, rather than the convened board, are managed by the IRB member, or by HRPP/IRB staff at the member's request, in a manner that protects the investigator's confidentiality and is in compliance with the medical school and IRB conflict of interest and commitment policy. Information from consultations is disseminated to other members prior to or during convened IRB reviews, or for expedited reviews, documented in the reviewer's notes.

4.5 Liability Coverage for IRB Members

Medical school professional liability insurance coverage applies to employees and any other person authorized to act on behalf of the medical school, for acts or omissions within the scope of their employment or authorized activity.

4.6 Reporting and Investigation of Allegations of Undue Influence

The medical school Hotline is 269.337.6505.

If the IRB chair, and IRB member, or HRPP/IRB staff person feels that the IRB has been unduly influenced by any party, the individual may make a confidential report to

the HRPP director, assistant dean for Research Compliance, Research Integrity Officer, or Institutional Official. The Institutional Official will ensure that a thorough investigation is conducted and, if the allegation is determined to be valid, that corrective action is taken to prevent additional occurrences. In the event that the allegation is regarding the Institutional Official, the matter will be referred and managed by the assistant dean for Research Complianceand Research Integrity Officer for investigation and any necessary action.

- Undue influence means attempting to interfere with a normal functioning and decision-making of the IRB, or to attempt to influence an IRB member, HRPP/IRB staff, investigator, or research staff outside of established processes or normal and accepted methods in order to obtain a particular result, decision, or action by the IRB or one of its members or HRPP/IRB staff.