

1.6 IRB Composition, Leadership, Qualifications, and Responsibilities

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's requirements for IRB composition, leadership, member qualifications, and responsibilities.

2.0 Policy

It the policy of the Organization that the membership of its IRBs will satisfy requirements of 45 CFR 46.107 and 21 CFR 56.107, and will include an appropriately diverse mixture of backgrounds, gender, and race/ethnicity.

3.0 Composition of the IRBs

- 3.1. Each IRB will have at least five members.
- 3.2. Each IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including 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.

- 3.3. Each IRB shall include persons knowledgeable in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice to be able to ascertain the acceptability of proposed research.
- 3.4. The IRBs will include one or more members who are knowledgeable about or experienced in working with children, pregnant women and fetuses, and decisionally impaired individuals.
 - 3.4.1. The IRB-04 will include a predominance of members who are knowledgeable about and experienced in working with children and neonates.
- 3.5. Every effort will be made to ensure that the IRB does not consist entirely of men or entirely of women. No appointment will be made to the IRB on the basis of gender alone.
- 3.6. The IRB shall not consist entirely of members of one profession.
- 3.7. Each IRB will include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. In order to qualify as a non-scientist member the individual must have little or no scientific training or experience.
- 3.8. Each IRB will include at least one member that is not affiliated with the Institution.
 - 3.8.1. The unaffiliated member should be able to represent the general perspective of research subjects and/or of the community. These members should be particularly cognizant of the need to protect subjects vulnerable to coercion and undue influence.
 - 3.8.2. The unaffiliated member must not have any professional relationship with the Institution as an employee, consultant, faculty (including voluntary faculty), or student, or have an immediate family member who has such a professional relationship with the Institution.
 - 3.8.3. It is expected but not required that at least one unaffiliated member will be present at each meeting of each IRB.
- 3.9. When reviewing community-based participatory research, as necessary, a consultant (or a knowledgeable board member) will supply the IRB with information about the community and how it will be served by the research.
- 3.10. A member of the IRB may fill multiple membership position requirements (for example, an unaffiliated member may also serve as a non-scientist member).
- 3.11. In situations where prisoners will be or are involved in research under IRB review: 1) the majority of the Board (exclusive of the prisoner member) will have no association with the prison(s) involved, apart from their membership on the IRB; and 2) the Board will include a prisoner representative with appropriate background and experience to serve in that capacity. This individual must have a reasonable working knowledge, understanding, and appreciation of prison conditions and be able to act in the best interests of the prisoners who will participate in the research.
- 3.12. Any IRB member with a conflict of interest related to a specific study will be recused from participating in the discussion and vote except to offer information as requested by the IRB. This applies to both full board review and expedited review. A conflict of interest will be determined in accordance with HRPP policy 1.7 (IRB Member, Consultant, Staff COI Identification and Management).
- 3.13. When review of a proposal requires medical or scientific expertise or specific knowledge about vulnerable subjects that is not available on the Board, the IRB will request assistance from an expert consultant. Consultants will provide guidance and information in accordance with the following procedures:

- 3.13.1. Either before or during review of a protocol, the IRB Executive Chair/designee, assigned IRB reviewer, or the IRB itself may determine there is a need for appointment of one or more expert consultants, as per 45 CFR 46.107(e) and 21 CFR 56.107(f).
 - 3.13.2. Consultants may be selected from within or from outside the Organization, based upon the required expertise.
 - 3.13.3. Consultants must certify in writing that they do not have any conflict of interest as described in HRPP policy 1.7 (IRB Member, Consultant, Staff COI Identification and Management).
 - 3.13.4. Consultants will produce written reviews upon request which will be provided to IRB members in advance of, or at the IRB meeting.
 - 3.13.5. Consultants may participate in the IRB's discussion of the protocol but they may not vote and will leave the meeting before a vote is taken.
 - 3.14. IRB alternate members are appointed according to discipline and membership category. They may represent more than one named IRB member. The alternate member's professional specialty, qualifications, and experience must be comparable to those of the primary member to enable them to adequately fulfill the role of the member to be replaced. Alternate members may attend any IRB meeting; however, alternates are not permitted to vote unless the designated regular member is not present. All alternate members have access to IRB review materials regardless of whether or not they attend an IRB meeting.
 - 3.15. Any Organizational representatives responsible for business development are prohibited from serving as an IRB member or in carrying out the day-to-day operations of the IRB review process. Organizational leadership may attend IRB meetings as necessary but will not vote.
 - 3.16. When the IRB membership changes, the HHS/FDA IRB registration will be modified by the IRB Analyst responsible for membership documentation, in accordance with 45 CFR 46.505(b) and FDA regulations.
 - 3.17. A full listing of IRB members will be maintained by the ORA. This list will include for each IRB member: name, earned degrees, scientific status (that is, scientist or non-scientist), representative capacity (for example, children, pregnant women, prisoners), indications of experience (that is, brief descriptors of relevant experiences that describe each member's chief anticipated contributions to IRB), relationship to the organization, affiliation status, office (for example, chair or vice chair), membership status (member, alternate member, or non-voting), and, as applicable, alternate member for and list the members or class of members for whom the alternate member can substitute.
 - 3.17.1. Roster will be updated at least annually.
 - 3.18. The ORA will not release the names of any IRB members except as required by federal regulations or state law. However, the IRB will provide a list of members by specialty and role.
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4.0 IRB Leadership

- 4.1. IRB Executive Chair
 - 4.1.1. The IRB Executive Chair is a senior faculty member and preferably is nationally recognized as an expert in the ethics and regulation of human subject research.
 - 4.1.2. The IO will appoint an IRB Executive Chair to serve for renewable 3-year terms. Any change in appointment, including reappointment or removal, will require written notification.
 - 4.1.3. The IRB Executive Chair reports directly to the IO on all matters pertaining to the IRB and related HRPP issues.
 - 4.1.4. The IRB Executive Chair also has a direct line to the UNMC and UNO Chancellors, as well as Executive Leadership for Nebraska Medicine and Children's Nebraska on all matters as necessary concerning compliance with HRPP policies and procedures.
 - 4.1.5. The IRB Executive Chair performs all the duties of the IRB Chair as described in section 4.2 below.
 - 4.1.6. The IRB Executive Chair is the Chair of the IRB Executive Committee, and may serve on ad hoc IRB subcommittees.
 - 4.1.7. The IRB Executive Chair is a signatory for correspondence in accordance with HRPP policy 1.19 (IRB Signature Authority).
 - 4.1.8. The IRB Executive Chair appoints qualified IRB members to perform expedited review, in accordance with HRPP policy 2.3 (Expedited Review).
 - 4.1.9. The IRB Executive Chair advises the IO, on an on-going basis, about performance and competence of the IRB Chairs, Vice-Chairs, IRB members and ORA staff.
 - 4.1.10. The performance of the IRB Executive Chair will be reviewed in accordance with HRPP policy 1.22 (Assessment of Effectiveness and Efficiency of the HRPP).
 - 4.1.11. The IRB Executive chair must satisfy continuing education requirements per HRPP policy 1.24 (HRPP Training Requirements for IRB Members).
 - 4.1.12. The IRB Executive Chair must keep current with all updates in federal regulations and guidance, as well as attend regional and national conferences in human research subject protections.
- 4.2. IRB Chairs
 - 4.2.1. IRB Chairs are appointed by the IO, in consultation with the IRB Executive Chair, for a renewable 3-year term. The Chair must:
 - 4.2.1.1. Have at least four years of IRB experience.
 - 4.2.1.2. Be knowledgeable about regulatory and institutional requirements for protection of human subjects.
 - 4.2.1.3. Be committed to serving in a leadership role.
 - 4.2.2. The IRB Chair conducts the IRB meetings, performs expedited reviews, reviews adverse events, unanticipated problems involving risk to the subject or others, protocol deviations, noncompliance, provides continuing education of IRB members and investigators, and participates in the development of policies, procedures, IRB forms and checklists.
 - 4.2.3. As needed, the IRB Chair may carry out the duties of an IRB member, as noted in section 4.5.4 below.
 - 4.2.4. If the IRB Chair is an MD (or equivalent) he/she will review requests for emergency use of a test article under 21 CFR 56.104(c)
 - 4.2.5. The IRB Chair is a member of the IRB Executive Committee, and may serve on ad hoc IRB subcommittees.

- 4.2.6. The IRB Chair is a signatory for correspondence in accordance with HRPP policy 1.19 (IRB Signature Authority).
- 4.2.7. The IRB Chair appoints qualified IRB members to perform expedited review, in accordance with HRPP policy 2.3 (Expedited Review).
- 4.2.8. The IRB Chair advises Executive Chair, on an on-going basis, about performance and competence of the IRB Vice-Chairs, IRB members and ORA staff.
- 4.2.9. The performance of the IRB Chair will be reviewed in accordance with HRPP policy 1.22 (Assessment of Effectiveness and Efficiency of the HRPP).
- 4.2.10. The IRB Chair must satisfy continuing education requirements per HRPP policy 1.24 (HRPP Training Requirements for IRB Members).
- 4.2.11. The IRB Chair should keep current with all updates in federal regulations and guidance, as well as attend regional and national conferences in human research subject protections.
- 4.3. IRB Vice Chairs
 - 4.3.1. IRB Vice-Chairs are appointed by the IO, in consultation with the IRB Executive Chair, for a renewable 3-year term. The Vice-Chair must:
 - 4.3.1.1. Have at least two years of IRB experience.
 - 4.3.1.2. Be knowledgeable about regulatory and institutional requirements for protection of human subjects.
 - 4.3.1.3. Be committed to serving in a leadership role.
 - 4.3.2. The IRB Vice-Chair will serve in the capacity as IRB Chair when the Chair is unavailable (or recused).
 - 4.3.3. As needed, the IRB Vice-Chair may carry out the duties of an IRB member, as noted in section 4.5.4 below.
 - 4.3.4. If the IRB Chair is an MD (or equivalent) he/she will review requests for emergency use of a test article under 21 CFR 56.104(c)
 - 4.3.5. The IRB Vice-Chair is a member of the IRB Executive Committee, and may serve on ad hoc IRB subcommittees.
 - 4.3.6. The performance of the Vice-Chair will be reviewed in accordance with HRPP policy 1.22 (Assessment of Effectiveness and Efficiency of the HRPP).
 - 4.3.7. The IRB Vice-Chair must satisfy continuing education requirements per HRPP policy 1.24 (HRPP Training Requirements for IRB Members), section 5.0.
 - 4.3.8. The IRB Vice-Chair should keep current with all updates in federal regulations and guidance, as well as attend regional and national conferences in human research subject protections.
- 4.4. IRB Executive Committee
 - 4.4.1. The IRB Executive Committee is comprised of the IRB Executive Chair, the IRB Chairs and Vice-Chairs, ORA Assistant Director, and Lead IRB Analyst responsible for the Executive Committee operations.
 - 4.4.2. The IRB Executive Committee meets monthly, or more often if needed.
 - 4.4.3. IRB Analysts may attend the IRB Executive Committee meetings as requested by the Committee.
 - 4.4.4. The purpose of the IRB Executive Committee is to:
 - 4.4.4.1. Perform ongoing assessment of the IRBs.
 - 4.4.4.2. Assist in the development of HRPP policies and procedures.
 - 4.4.4.3. Assist in the development of IRB forms.

- 4.4.4.4. Address concerns of any nature which impact the effectiveness of the HRPP in assuring the protection of the rights and welfare of research subjects.
 - 4.4.5. All IRBs will be advised of Executive Committee deliberations that impact the HRPP.
- 4.5. IRB Members
 - 4.5.1. IRB members will normally be identified and recruited by the IRB Executive Chair, IRB Chairs and Vice-Chairs. However, unsolicited nominations may be submitted to the IRB Executive Chair or the ORA at any time.
 - 4.5.2. Prior to appointment to the board, the prospective member will be interviewed by the IRB Executive Chair or designee, to determine the relevant experience of the prospective member that will describe his/her chief anticipated contribution to IRB deliberations (AAHRPP element II.1.A).
 - 4.5.3. IRB members are appointed by the IO, in consultation with the IRB Executive Chair, for a renewable 3-year term.
 - 4.5.4. Each IRB member is expected to be fully engaged in the HRPP and will be involved in carrying out the following responsibilities as assigned:
 - 4.5.4.1. Participate in all assigned IRB meetings and subcommittees with full voting privileges.
 - 4.5.4.2. Serve as a reviewer for new protocols.
 - 4.5.4.3. Serve as a reviewer for applications for continuing review.
 - 4.5.4.4. Serve as an expedited reviewer once they are sufficiently experienced.
 - 4.5.4.5. Serve as a reviewer for unanticipated problems involving risk to the subject or others.
 - 4.5.4.6. Serve as a reviewer for changes in protocol and/or consent documents.
 - 4.5.4.7. Serve as a reviewer for incident reports.
 - 4.5.4.8. Serve on IRB ad hoc subcommittees as needed.
 - 4.5.4.9. Serve on a Post Approval Monitoring assessment team as needed.
 - 4.5.5. IRB members are expected to attend the majority of scheduled meetings, and are required to attend all meetings for which they have been assigned reviews, unless prior arrangements have been made (e.g., written comments sent). IRB member attendance records will be maintained by the ORA in accordance with HRPP policy 1.22 (Assessment of the Effectiveness and Efficiency of the HRPP).
 - 4.5.6. IRB members must satisfy initial and on-going education requirements as per HRPP policy 1.24 (HRPP Training Requirements for IRB Members).
 - 4.5.7. The performance of all IRB members will be reviewed in accordance with HRPP policy 1.22 (Assessment of Effectiveness and Efficiency of the HRPP).
 - 4.5.8. Upon completion of a member's term, the IRB Executive Chair, Chairs and Vice-Chairs, in consultation with the IRB Analysts, and based in part upon the performance evaluation (per HRPP policy 1.22: Assessment of the Effectiveness and Efficiency of the HRPP), will determine whether an additional term is offered.
 - 4.5.9. An IRB Analyst may serve as a voting, or alternate voting, member of the IRB. Analysts are appointed as IRB members or alternate members by the IO, in consultation with the IRB Executive Chair, as noted above.
 - 4.5.9.1. IRB Analysts serving as voting or alternate members will be classified as scientist or non-scientist based on specific degree, education, or experience.
 - 4.5.9.2. IRB Analysts must have at least 2 years-experience with the ORA or another IRB, must be a voting member, and must be approved by the IRB

Executive Chair, before they can act as an expedited reviewer.

- 4.5.9.3. An IRB Analyst serving as a voting or alternate member of the IRB will have the same responsibilities and requirements as noted in section 4.5.4 above, except they may not serve as primary reviewer for a new protocol for which they are the primary Analyst.
- 4.5.9.4. The term of appointment for an IRB Analyst serving as a voting or alternate member of the IRB will be indefinite.
- 4.6. IRB Alternate Members
 - 4.6.1. The appointment, responsibilities, training, evaluation and re-appointment of IRB alternate members is the same as that for regular IRB members.
 - 4.6.2. The alternate member must qualify in terms of expertise and role in order to serve in place of the regular member.
 - 4.6.3. The IRB roster identifies the type of member (for example, non-scientist, physician, oncologist, nurse, etc) for whom each alternate member may substitute.
 - 4.6.4. The alternate member may serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting, or is conflicted.
 - 4.6.5. When an alternate member substitutes for a regular member, the alternate member will receive and review the same materials prior to the IRB meeting that the regular member received or would have received.
 - 4.6.6. The alternate member will not be counted as a voting member unless the regular member is absent or conflicted.
 - 4.6.7. The IRB minutes will document when an alternate member replaces a regular member.
- 4.7. Liability Coverage for IRB Members The Organization's insurance coverage applies to employees and any other person authorized to act on behalf of the Organization within the scope of their employment or authorized activity.

ADMINISTRATIVE APPROVAL: Bruce Gordon, MD IRB EXECUTIVE CHAIR & ASSISTANT VICE CHANCELLOR FOR REGULATORY AFFAIRS Russell McCulloh, MD

DOCUMENT HISTORY:

? Written: 4/11/2016 (Approved: 4/11/2016) - original author not documented

? Revised: 3/27/2018 - revision not documented

? Revised: 7/29/2021 - Removed redundant material; removed references to pre-2019 Common Rule; clarified items included in roster of IRB members; clarified responsibilities of IRB chairs and Vice-Chairs.

? Revised: 4/15/2022 - Clarified that an IRB administrator serving as a voting or alternate member of the IRB may not serve as primary reviewer for a protocol for which he/she primary administrator (section 4.5.9.2). {Approved Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Revised: 7/14/2022 - Revised to clarify that consultants are not officially appointed by EC; removed reference to Compliance Officer as a consultant; clarified that IRB Administrators appointed as IRB members or alternate members by the IO, in consultation with the IRB Executive

Chair; simplified designation of IRB administrators as scientists or non-scientists; specified that IRB administrators must have at least 2 years-experience with the ORA or another IRB, and must be approved by the IRB Executive Chairperson, before they can act as an expedited reviewer. {Approved Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Revised: 10/11/2022 - Clarified that a consultant or a knowledgeable board member may provide information to the IRB regarding Community Based Participatory Research (section 3.9). {Approved Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Board Notified: 11/15/2022

? Revised 4/3/2024 – clarified that assigned analyst may not be the primary reviewer for initial review, but may be for other actions (for example, CR, AE, incident reports) (section 5.4.9.3); deleted reference to “expedited review” in section 4.6.4. {Approved Russell McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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