

Institutional Review Board (IRB) Governance Document for IRB Administrator, IRB Chair, IRB Vice Chair and IRB Members

Roles and Responsibilities of the IRB Administrator

1. Manages the Electronic Management System (e.g., IRBnet.org) to track all active, pending, and terminated protocols.
2. Ensures that IRB submissions are correctly categorized for exempt, expedited, and or full review and identified with other system identifiers (i.e., in-person, remote, etc.).
3. Screens research applications for completeness prior to initiating the IRB review process.
4. Assigns studies to primary and secondary reviewers.
5. Interprets, reviews, and disseminates IRB review outcomes to researchers.
6. Coordinates monthly IRB meetings, prepares agendas and reports, and records and disseminates meeting minutes and notes.
7. Maintains regulatory paperwork including the Federalwide Assurance (<https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwafwas/fwa-protection-of-human-subject/index.html>), IRB membership rosters, and copies of appropriate Federal regulations and guidelines related to human subjects research (<https://www.hhs.gov/ohrp/regulations-and-policy/index.html>).
8. Oversees all IRB record keeping in compliance with Federal regulations.
9. Ensures the prompt reporting to the IRB, appropriate institutional officials, Office of Human Subjects Protection (OHRP), and any sponsoring Federal department or agency administrator of: a) any unanticipated problems involving risk to participants or researchers; b) any serious or continuing noncompliance with the regulations or requirements of the IRB; c) any suspension or termination of IRB approval for research.
10. Sends notices of study suspension or termination (due to serious or continuing non-compliance) to researchers and to appropriate University administrators.
11. Maintains the IRB website.
12. Collaborates with the IRB Chair to provide IRB related guidance and support to faculty, staff, students, and community members.
13. Assists the IRB Chair in providing education and training to IRB members, and to BGSU staff, students, and faculty.
14. Meets monthly with and informs the Vice President for Research and Economic Engagement (VPREE) of IRB proceedings.

Role and Responsibilities of the IRB Chair

1. Ensures that all IRB review of human subjects research is conducted under the purview of 45 CFR 46 (also known as the “Common Rule” or “Final Rule” see: <https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML>).
2. Facilitates Full Board meetings, ensures that Full Board meetings meet Federal regulations for quorum and attendance, and serves as lead reviewer for Full Board Reviews.
3. In conjunction with the IRB Administrator, serves as the point of contact for interaction of the IRB with the BGSU community.
4. Maintains an in-depth knowledge of the regulations and regulatory guidance, and expertise in the review of human subjects research.
5. In partnership with the IRB Administrator and Vice Chair, provides leadership and oversight for the policies, procedures, practices, and function of the IRB and human subjects research.
6. Designs and leads training and orientation for new IRB members with support from the IRB Administrator and Vice Chair; oversees recruitment, retention, and continuing education of IRB members.
7. With the IRB Administrator, provides campus training and outreach for faculty, staff, and students.
8. Oversees the processing and review of faculty research proposals.
9. Ensures that IRB composition meets all membership requirements outlined by OHRP.
10. In consultation with the Vice Chair, lead discussions with investigators and/or administrators to resolve controversial and/or procedural matters relating to research approval and conduct.
11. Signs correspondence communicating and documenting IRB decisions.
12. Drafts notices of study suspension or termination (due to serious or continuing non-compliance) to researchers and to appropriate University administrators.
13. Work with investigators to resolve matters relating to research approval and participate in educational efforts for investigators, research staff, and new IRB members.
14. Invites individuals with competence in specialty areas to assist in the review of IRB submissions that require expertise beyond, or in addition to, those available to the IRB.
15. With the IRB Administrator and Vice Chair, facilitates changes and updates to IRB documents intended for researchers including IRB applications, templates, and other written materials provided to researchers for IRB submission.

Appointment and Retention of the IRB Chair

1. Members of the IRB will recommend a current IRB member to serve as IRB Chair and forward this recommendation to the VPREE. The IRB Chair will be appointed by the Vice President for Research and Economic Engagement.
2. Appointment term will be three years and can be extended at the discretion of the Vice President for Research and Economic Engagement. It is expected that an individual will

not serve as IRB Chair for more than two consecutive terms except under unusual circumstances.

3. Appointment to the position of Chair of the IRB may be terminated before the expiration of the three-year term. The Vice President of Research and Economic Engagement may remove the IRB Chair if they determine that the IRB Chair has failed to perform their duties. When an IRB Chair leaves the university, or is otherwise unable to serve or decides not to serve, the IRB Chair may voluntarily terminate their appointment to IRB.

Roles and Responsibilities of IRB Vice Chair

1. Support the role and responsibilities of the IRB Chair.
2. Assist the Chair in facilitating Full Board meetings.
3. In the absence of the IRB Chair, lead Full Board meetings and ensure that Full Board meetings meet Federal regulations.
4. Assume duties as delegated by the IRB Chair.
5. In consultation with the IRB Chair and IRB Administrator, maintain and update the content for IRB webpages on the BGSU server.

Appointment and Retention of the IRB Vice Chair

1. The IRB Vice Chair will be appointed by the Vice President for Research and Economic Engagement with recommendation by the IRB Chair.
2. Appointment term will be three years and can be extended at the discretion of the Vice President for Research and Economic Engagement. It is expected that an individual will not serve as IRB Vice Chair for more than two consecutive terms except under unusual circumstances.
3. Appointment to the position of Vice Chair of the IRB may be terminated before the expiration of the three-year term. The Vice President of Research and Economic Engagement may remove the IRB Vice Chair if they determine that the IRB Vice Chair failed to perform their duties. When an IRB Vice Chair leaves the university, or is otherwise unable to serve or decides not to serve, the IRB Vice Chair may voluntarily terminate their appointment to IRB.

Roles and Responsibilities of IRB Members

1. Attend IRB meetings and actively participate in the review of research proposals for compliance to human subjects protection.
2. Complete initial training in human subjects protection for IRB members prior to voting on any research, and complete continuing education/training as provided by the Chair of the IRB and/or Office of Research Compliance.
3. Understand and apply the principles of the Belmont Report and all federal regulations related to the protection of human subjects.
4. Providing timely written comments on research undergoing IRB review.
5. Ensure that review of research are performed within the purview and scope of OHRP requirements and University guidelines.
6. Maintain a current knowledge of and compliance with relevant regulations, laws, and policies related to the protection of human subjects.
7. Participate in the discussion of issues affecting the human research protection program and contribute to policy development, as appropriate.
8. Review and approve research by exempt and expedited procedures as assigned.

Appointment and Retention of IRB Members

1. Individuals wishing to serve on the IRB should self-nominate by submitting a curriculum vitae and brief (one paragraph) statement expressing their interest in serving on the IRB to the Chair of the IRB.
2. The Chair of the IRB and Vice Chair of the IRB will review applications and make recommendations to the Vice President for Research and Economic Engagement (VPREE). Recommendations for appointment to the board shall take into account area(s) of need, diversity and composition of the board, and all Federal and OHRP regulations.
3. The Vice President for Research and Economic Engagement shall appoint members to the IRB based upon this recommendation and/or in consultation with the IRB Chair, Vice Chair, and/or IRB Administrator. The IRB Chair will review the nature and demands of IRB service with the candidate. Upon agreement by all parties, the Vice President for Research and Economic Engagement will generate the official letter of appointment.
4. IRB members are appointed for a three-year term, with the first year serving as a probationary year. Following the probationary year, the board member will continue for the remaining two years upon the recommendation of the IRB Chair and IRB Vice Chair and approval by the VPREE. Terms of appointment may be renewed at the discretion of the Vice President for Research and Economic Engagement. It is expected that an individual will not serve more than two consecutive terms on IRB except under unusual circumstances.
5. All appointments to the IRB will be reported to the Office for Human Research Protections (OHRP).
6. Appointment to the IRB may be terminated before the expiration of the three-year term. The Institutional Official may remove an IRB member if the Institutional Official, in consultation with the IRB Chair or other parties, determines that the member failed to perform member duties. When an IRB member leaves the university, or is otherwise

unable to serve or decides not to serve, the IRB member may voluntarily terminate their appointment to the IRB.

Drawn from Governance and Operating Procedures: Northern Iowa University, Ohio University, Miami University, and Ohio State University