Institutional Review Board
irb@bgsu.edu
(419) 372-7716

IRB PROCEDURE STATEMENT

Procedure: Initial Review of IRB Applications – Full Board Projects

Procedure ID: 2022-09

Effective: November 6, 2002
Revised: January 17, 2019; May 2022

A. Background

BGSU policy requires review of all research involving human participants if a project meets the Federal definitions of:

"Research" as defined by United States Department of Health and Human Services (HHS) *Subpart A - Basic HHS Policy for Protection of Human Research Subjects* at 45 CFR 46.102(l): "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." and

"Human subject" as defined by HHS *Subpart A - Basic HHS Policy for Protection of Human Research Subjects* at 45 CFR 46.102(e(1)), "means a living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, or analyzes, the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens." **BGSU's IRB is responsible for the review of research projects involving human participants.**

The review is guided by the ethical principles regarding all research involving humans as participants, as set forth in the report: *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (***The Belmont Report***) regardless of whether the research is subject to Federal regulation with whom the research is conducted or source of research support. These principles are as follows:

- Respect for persons – Participants are given the opportunity to decide, based upon information provided to them by the researcher, whether or not they will voluntarily participate in a project.
- Beneficence – Researchers are obliged to give forethought to the maximization of benefits and the reduction of risks associated with participation in a project.
- Justice - No group should be expected to bear the risks of participating in research when the benefits of the research are more broadly applicable beyond the group itself.

This review and approval must occur before any participants can be recruited or data collected and includes the following considerations from the Federal regulations (45 CFR 46.111(a) (1-8) and (b):

- Risks to participants are minimized.
- Risks to participants are reasonable in relation to anticipated benefits.
- Selection of participants is equitable.
- Proper informed consent will be sought from each participant or their legally authorized representative.
- Informed consent will be appropriately documented.
- Adequate provision is provided for monitoring data collected to ensure safety to participants, when appropriate.
- Adequate provision is provided to protect the privacy of participants and to maintain the confidentiality of the data, when appropriate.
- A limited IRB review can be made if "Broad consent" applies as defined in [45 CFR 46.104 (d)(7)].
- If project involves vulnerable populations such as children, prisoners, individuals with impaired decision-making capacity or economically or educationally disadvantaged persons, additional safeguards have been included to protect them from coercion or undue influence and so their rights and welfare are protected.

Many IRB Applications receive Expedited Review or are in an Exempt category that may receive Administrative or limited IRB review, while some require a Full Board review. If any Expedited/Exempt reviewer requests that a project be referred to the Full Board for review, that request is honored.

Some characteristics of studies requiring Full Board review are:

- More than minimal risks
- Research with prisoners
- Certain types of research with children
- Invasive procedures
- Survey research involving sensitive questions or questions that are likely to be stressful to the participant

B. Procedure

1. The researcher must complete the IRB Application Form – Expedited/Full Board, which includes indicating the Full Board Review category on the first page of the application form. The completed application and all relevant materials (e.g., survey, consent document, debriefing form, advertisement) must be submitted electronically for IRB review using IRBNet at least seven days prior to the date of the scheduled meeting (the IRB meeting schedule and associated deadlines for submission can be found at the "About the IRB" webpage.

2. The IRB Administrator and staff reviews the application for completeness, checks to make sure that the principal investigator (PI) and project advisor (if applicable) have electronically signed the submission, and checks to make sure the PI and project advisor (if applicable) have had the CITI human subjects training. If training is required or the application is incomplete the PI will be contacted, and the application held from the review process until training has been acquired and/or required materials/ information are provided.

If the application does not indicate that the project requires Full Board review, but an IRB member determines, during the expedited review process that Full Board review is required, the IRB Administrator changes the review type for the project in IRBNet. The IRB Administrator will submit the application and relevant materials for review at the next monthly IRB Full Board meeting.

3. Project applications, with all relevant materials, are shared with IRB members five to seven days prior to the monthly meeting.

4. The Full Board meets, discusses the application within the context of the review considerations identified above, and determines a review outcome. Possible outcomes are:
    a. Approved as submitted.
    b. Deferred or Information Required: The Board does not have sufficient information to make a decision. Additional information is required from the researcher before the request can be reviewed again by the Board and a decision rendered.
    c. Modifications Required: Researcher must make changes or provide clarifications before final approval can be given.
    d. Disapprove: The project cannot be conducted. Substantial changes must be made before the project can be re-submitted for review by the Full Board.

5. The IRB notifies the PI, and the PI's advisor (if applicable), of the review outcome via IRBNet. The notification letter and other applicable document(s) can be found in the "Board Documents" section under the "Reviews" tab of the relevant project in IRBNet.