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IRB PROCEDURE STATEMENT

Procedure: Initial Review of IRB Applications – Full Board Review

Procedure ID: 02-11-003

Effective: November 6, 2002
Revised: January 17, 2019

A. Background

BGSU policy requires review of all research involving human participants. Research, as defined by Department of Health and Human Services (DHHS) Policy for the Protection of Human Subjects at 45 CFR 46.106(l), is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." A human subject, as defined by DHHS Policy for the Protection of Human Subjects at 45 CFR 46.102(e(1)), is "a living individual about whom an investigator (whether professional or student) conducting research (1) 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, 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 of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (entitled: 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 of with whom conducted or source of 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)):

- 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
- Appropriately documented informed consent
- Adequate provision is provided for monitoring data collected to ensure safety to participants, if appropriate
- Adequate provision is provided to protect the privacy of participants and to maintain the confidentiality of the data
- If project involves vulnerable populations, additional safeguards have been included to protect their rights and welfare

The majority of IRB applications receive Expedited review or are in an Exempt category that may receive 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, 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, which includes indicating the full Board review category on the cover page of the application. The completed application and all relevant materials (e.g., survey, consent documents, debriefing forms) 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 http://www.bgsu.edu/offices/orc/IRB/page44843.html).

2. The Office of Research Compliance (ORC) reviews the application for completeness, checks to make sure that the principal investigator (P.I.) and project advisor (if applicable) have electronically signed the submission, and checks to make sure the P.I. and project advisor (if applicable) have had human subjects training. If training is required or the application is incomplete the P.I. will be contacted, and the application held from the review process until training has been acquired and/or required materials/information is 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 ORC changes the review type for the project in IRBNet. The ORC will submit the application and relevant materials for review at the next monthly Board meeting.

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

4. The 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. Modifications Required: Researcher must make changes or provide clarifications before final approval can be given
   c. 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 will be reviewed by the Board.
   d. Disapprove: The project cannot be conducted. Substantial changes must be made before the project can be re-submitted for review by the Board.

5. The ORC notifies the P.I., and the P.I.'s advisor (if applicable), of the review outcome via IRBNet. The notification letter and other applicable document(s) can be located in the "Board Documents" section of the relevant project in IRBNet.