



HSRB POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Initial Review of HSRB Applications – Full Board Review

Policy/Procedure ID: 02-11-003

Effective: November 6, 2002

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 46.102(d), is “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” A human participant, as defined by HHS Policy for the Protection of Human Subjects at 45 CFR 46.102(f), is “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. BGSU’s HSRB 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

Initial Review of HSRB Applications – Full Board Review

- 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 Human Subject applications receive expedited review, but some require a full Board review. Some characteristics of studies requiring full Board review are:

- More than minimal risks
- Research with prisoners
- Certain types of research with children
- Invasive procedures
- Experimental drugs and devices
- Survey research involving sensitive questions or questions that are likely to be stressful to the participant
- Studies seeking federal funding
- Studies seeking grant funding where the funding agency requires IRB review of the proposed activities

B. Procedure

1. The researcher completes an HSRB application.
2. If the application indicates the project requires full Board review, the researcher submits 13 copies (the original plus 12 copies) of the completed application (signed, dated, and with advisor's signature if the P.I. is a student) and all relevant materials (e.g., survey, consent documents, debriefing forms) to the Office of Research Compliance (ORC) at least seven days prior to the date of the scheduled meeting (the HSRB meeting schedule and associated deadlines for submission can be found at http://www.bgsu.edu/offices/orc/hsrb/hsrb_review_schedule.html).
 - The ORC reviews the application for completeness and checks to make sure the principal investigator (P.I.) and project advisor (if applicable) have had human subjects training. If training is required or the application is incomplete (e.g., signatures, instruments or consent documents missing) 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 HSRB member determines, during the expedited review process that full Board review is required, the ORC notifies the P.I. and advisor (if applicable), in writing, of this referral. The ORC makes copies of the application and relevant materials for the next monthly Board meeting.

3. The ORC assigns a project identification number and logs the project information into the database.

Initial Review of HSRB Applications – Full Board Review

4. Project application packets, with all of the relevant materials, are assembled and distributed to HSRB members seven days prior to the monthly meeting.
5. 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. Conditionally approved- researcher must make changes or provide clarifications before final approval can be given
 - c. Deferred- the Board does not have sufficient information to make a decision. Additional information is required from the researcher before the Board will review the application.
 - d. Denied- the project cannot be conducted. Substantial changes must be made before the project can be re-submitted for review by the Board.
6. The ORC notifies the P.I. and the P.I.'s advisor (if applicable), in writing, of the Board's decision.