



HSRB POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Class Research Project Guidelines

Policy/Procedure ID: 02-10-002 **Effective:** October 2, 2002

A. GENERAL PHILOSOPHY

Bowling Green State University's Human Subjects Review Board (HSRB) recognizes that many instructors require projects that involve research with human participants to fulfill course requirements. The instructors must have completed human subjects training before assigning those projects.

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 DHHS 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.

Such research may entail certain risks to the participants involved in the research. Because students vary in expertise regarding research procedures designed to protect the rights of human participants, the HSRB has developed the following guidelines regarding classroom-based projects. These guidelines are intended to clarify and simplify the process for obtaining HSRB approval. Please note – this policy supercedes the prior policy on class projects.

Whether or not HSRB review and approval of a class project is required, the student researcher and the instructor are obligated to ensure ethical treatment of the human participants involved in the project. In all cases of student research associated with class projects, the instructor has ultimate responsibility for the ethical conduct of the project and adherence to the guidelines.

B. CONDITIONS UNDER WHICH HSRB APPROVAL IS REQUIRED FOR STUDENT RESEARCH PROJECTS INVOLVING HUMAN PARTICIPANTS

The HSRB strongly encourages inclusion of a discussion of the ethical treatment of human participants in the curriculum in those courses for which research projects involving human subjects will be conducted. This discussion should include, at a minimum, the principles of human participant protection. To do less would be a disservice to the students and the general public that trusts the University and faculty to train students both to respect the rights

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of people who participate in research and to use the proper procedures for conducting research with human participants.

1. Any project that would identify the interviewee or respondent either by name or by the responses to specific questions and/or recorded behaviors requires HSRB approval.
2. Any project that systematically selects subjects from a potentially vulnerable or sensitive group (e.g., prisoners, pregnant women, children who are gifted and talented, alcoholics, sexual minorities, people with disabilities, people with cognitive impairment, people unable to give informed consent) and asks questions regarding their opinion, behavior or experiences requires HSRB approval.
3. Any project that systematically collects private or protected information about individuals (e.g., school records, medical records, criminal records, membership or participation in self-help organizations) requires HSRB approval.
4. Any project that proposes to investigate opinions, behaviors, and/or experiences regarding the following sensitive topic areas requires HSRB approval:
 - sexual orientation
 - AIDS or HIV status or related behavior
 - incest, rape or date rape, sexual molestation
 - substance use and/or abuse
 - eating disorders or behaviors
 - contraception, pregnancy or abortion
 - questions dealing with subjects' mental health
 - religious orientation and /or views
 - veteran or wartime experiences
 - illegal activities
5. Any project in which participants are asked to engage in behavior that carries greater than minimal risk requires HSRB approval. As defined by DHHS policy for the Protection of Human Subjects at 45 CFR 46.102(i), minimal risk means that “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”
6. Any project which has the potential to become a thesis or dissertation project requires HSRB approval.
7. If there is reasonable expectation that the study will be externally funded (regardless of the source), published and/or presented outside the course for which the project was originally conducted, HSRB approval must be obtained.

C. CONDITIONS UNDER WHICH HSRB APPROVAL IS NOT REQUIRED FOR STUDENT PROJECTS INVOLVING HUMAN PARTICIPANTS

Students who wish to collect data from human participants as part of the requirements for a specific class may conduct the project without obtaining HSRB approval as long as the participants are not identified by name or description and the information is not of the type listed in section B above. Examples of this type of project are:

- Opinions of political candidates or issues.
- Opinions regarding American made vs. foreign made products.
- Opinions regarding the participant’s favorite television show, preferred vacation spot, musical preference, etc.

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- Evaluations of various programs for which the results will be used to make improvements to the program in question.
- Projects that are designed to teach students how to do research (e.g., in research methods courses). However, participants must be informed that the purpose of the work is to learn how to do research and that none of the information collected will be disseminated.
- Observation of public behavior where the observer does not actively manipulate others or the environment in any way.
- Observations of classroom behavior or behavior in a natural learning environment for purposes of evaluation or for learning about teaching and learning.

The key factor is that such projects do not require participants to reveal their identity or anything about sensitive personal experiences or behaviors, such as those listed in point 4 above in section B. This would guarantee that participants are not placed at more than minimal risk by their participation. In these cases, HSRB approval for individual projects is not required.

Even though HSRB approval is not required, ethical considerations require that potential participants be informed regarding the purpose of the research and how data will be used. The instructor is responsible to familiarize students with these considerations.

If there is any doubt as to whether a project or set of projects should be reviewed by the HSRB, please contact the Chair or the Administrator of the HSRB for assistance. They may be reached at the Office of Research Compliance at 372-7716.

D. PRACTICAL ASPECTS OF HSRB APPLICATION SUBMISSION FOR CLASS PROJECTS

Before an HSRB application will be considered for review, the instructor must have completed human subjects training. The HSRB web page (www.bgsu.edu/offices/orc/hsrb) contains information regarding scheduled training dates and alternatives.

When HSRB review is required (such as situations specified in section B above), the instructor is required to submit an HSRB application setting forth the parameters of the research projects being conducted by the students. The instructor should describe the types of research projects to be undertaken by the students, the nature of the participants to be used, and the kind of procedures to be used in the research projects (e.g., interviews, questionnaires, performance of physical activities). Supporting material associated with the application should include:

- Description of the guidance to be provided to students relative to informed consent
- Template consent documents appropriate to the particular type(s) of research data collection procedures to be performed. These consent documents should include the elements of informed consent (see the Informed Consent Checklist on the HSRB web page).
- A list of the subject matter / topics to be addressed

Individual HSRB applications are not to be filled out by each student researcher as long as the research project falls within the parameters described in the “umbrella” form. Any

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research project not within the described parameters requires separate approval. Possible outcomes of review of these “umbrella” applications are:

- The HSRB determines that the proposed project falls within the types of projects listed in C above and does not require review.
- The HSRB determines the proposed project(s) is research involving human participants, that it requires review, and that it is acceptable.
- The HSRB determines that risks could be substantial, and the individual projects will require review.

Instructors are responsible for screening individual research projects and determining whether the project either falls within the parameters of the approved “umbrella” HSRB application or requires independent review and approval by the HSRB.

The “umbrella” application can be renewed on an annual basis via the normal continuing review procedure. Likewise, changes to the application relative to changes of topics and/or procedures resulting from adjustments to the curriculum can be handled via the normal modification/addendum request process (using the Request for Modification form – available on the HSRB web page).