IRB PROCEDURE STATEMENT

Procedure: Initial Review of IRB Applications - Exempt Projects
Procedure ID: 13-07-001       Effective: July 1, 2013

A. Background

Bowling Green State University policy requires all research involving human participants meeting or appearing to meet one of the exempt categories to be submitted to the Institutional Review Board (IRB) for review. The review of all projects is guided by the ethical principles regarding all research involving humans as participants, as set forth in the Belmont Report. The 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.

All research determined to be exempt must, at a minimum, meet the principles outlined in the Belmont Report. The IRB Chairperson, or designee, may require additional protections to meet these principles, such ensuring the informed consent process is appropriate to the research or requiring a full Board review of the project.

Exempt research must pose no more than minimal risk to participants, have a sound research design, and be conducted ethically. Research involving, or potentially involving, prisoners may not be classified as exempt. Any project indicated as requiring a full Board review by the most current version of the IRB application will not be eligible for exempt review.

B. Exempt Research Categories (45 CFR 46.101)

Research activities in which the only involvement of human subjects will be in one or more of the following categories can be approved as exempt by the IRB:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
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(i) research on regular and special education instructional strategies, or
(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Note that this category may be applied to research involving children.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Note that survey and interview research involving children is not exempt. However, this category may apply to research involving observation of public behavior of children, when the investigator does not participate in that activity.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2 above, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or
(ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. The following statements apply to this category:

(i) Data, documents, records, or specimens must be in existence before the project begins. The Investigator must describe where the information exists.
(ii) An Investigator, which proper institutional authorization, may inspect identifiable records, but can only record information in such a manner that the investigator cannot subsequently access or obtain direct or indirect identifiers that are linked to the subjects. The Investigator must describe how the information will be obtained, what data elements will be records, and whether any links to identifiers will be recorded.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
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(i) public benefit or service programs; this exemption is for federally supported projects and is invoked with authorization or concurrence by the funding agency. The following criteria must be met:
   a. The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).
   b. The research or demonstration project must be conducted pursuant to specific federal statutory authority.
   c. There must be no statutory requirement that the project be reviewed by an Institutional Review Board.
   d. The project must not involve significant physical invasions or intrusions upon the privacy of participants.

(ii) procedures for obtaining benefits or services under those programs;
(iii) sensible changes in or alternatives to those programs or procedures; or
(iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies if:
   (i) if wholesome foods without additives are consumed or
   (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

C. Procedure

   a. The researcher must complete the IRB application, which includes indicating which exempt category s/he believes that project is eligible for. The complete application will be submitted electronically for IRB review using IRBNet.

   b. The Office of Research Compliance (ORC) 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 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 is provided.

   c. One member of the IRB will be assigned to review the application. IRB members will make the following determinations (as applicable) to ensure the protection of potential participants:
      i. The research involves no more than minimal risk,
      ii. Selection of subjects is equitable,
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iii. When identification is to be recorded, there are adequate provisions in place to maintain the confidentiality of data,
iv. There are adequate provisions in place to maintain the privacy interests of participants,
v. When there are to be interactions with participants, informed consent will be obtained by a process that will disclose adequate information, including that the activity includes research, the purpose, the extent of confidentiality, participation is voluntary, a description of the procedures, and investigator contact information.

d. The member will determine a review outcome. Outcomes include:
i. Not Research – the project does not meet the federal definitions of “research” and “human subject”. Therefore the project does not require IRB review or approval.
ii. Exempt – the project methods falls under an exempt category, the principals in the Belmont Report are being followed, and the research can begin.
iii. Information Required – additional information is required from the P.I. before the review can be completed.
iv. Modifications Required – (1) the project materials must be revised so that the principals in the Belmont Report are being followed, or (2) it is believed that the project is not exempt. If the project cannot be categorized as exempt, in addition to conducting a review of the project, a comment indicating this must be made so that the ORC staff can route the submission accordingly. The procedures for reviewing expedited or full Board projects will be followed.

e. The member will state the category and state why the project can be categorized as such.

f. The ORC notifies the P.I. and the P.I.’s advisor (if applicable) through IRBNet of the outcome of the review. The review type and category will be documented on the exemption letter.

g. Exempt research activities may not begin until the investigator receives notification of the exempt determination from the Office of Research Compliance, in writing. IRB members and institutional officials are notified of all research that is determined to be exempt.

D. Amendment Request

An amendment may not be made to exempt research because of the possibility that proposed changes may change the research in such a way that it is no longer meets the criteria for exemption. A new application for exempt determination must be submitted and reviewed prior to modifying the research activity, unless the researcher believes that the change must be made to protect participants. In this case, the researcher must report the change to the Office of Research Compliance as soon as practicable.