Bowling Green State University

Institutional Review Board
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IRB PROCEDURE STATEMENT

Procedure: Initial Review of Exempt Projects

Procedure ID: 2002-04 **Effective:** January 17, 2019
Revised: May 2022

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 46.104(d)(1)-(8)]

Research activities in which the only involvement of human subjects will be in one or more of the following categories (designated by the revised Common Rule effective January 21, 2019) can be approved as Exempt by the IRB. Depending on risks pertaining to privacy of subjects and confidentiality of data, many Exempt projects are required by BGSU's IRB policy to undergo review, and or may be recategorized as Expedited review.

From: 45 CFR 46.104(d)(1)-(8)

“Exempt Categories:

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **or**

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

(3)

(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think

the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those

programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(6) Taste and food quality evaluation and consumer acceptance studies:

(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.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results."

C. Procedure

1. These Exempt categories listed above are abbreviated and shown on the IRB Application Form – Exempt Review. The researcher must complete the IRB Application Form – Exempt Review, which includes indicating the one Exempt category that the project represents. The completed application should be submitted electronically for IRB review using IRBNet.

2. The IRB Administrator 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.

3. One or two members of the IRB will be assigned to review the application, depending on whether the IRB determines that the project warrants "limited IRB review." IRB members will make the following determinations (as applicable) to ensure the protection of potential participants:
   a. The research involves no more than minimal risk,
   b. Selection of subjects is equitable,
   c. When identification is to be recorded, there are adequate provisions in place to maintain the confidentiality of data,
   d. There are adequate provisions in place to maintain the privacy interests of participants,
   e. 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, the voluntary nature of participation, a description of the procedures, and investigator contact information.

4. The IRB member(s) will determine a review outcome. Outcomes include:

   a. **Exempt and approved**. The project methods fall under an Exempt category, the principles in *The Belmont Report* are being followed, and the research can begin.

   b. **Information Required** – additional information is required from the PI before the review can be completed.

   c. **Modifications Required** – (1) the project materials must be revised so that the principles 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 IRB Staff can route the submission accordingly. The procedures for reviewing Expedited or Full Board IRB projects should be followed.

5. The member(s) will state the category and state why the project should be categorized as such.

6. The IRB Administrator notifies the PI and the PI's advisor (if applicable) through IRBNet of the outcome of the review. The review type and category will be documented on the exemption letter.

7. Exempt research activities may not begin until the PI receives notification of the Exempt determination from the IRB, in writing. IRB members and institutional officials are notified of all research that is determined to be Exempt.

D. Amendment Request for the Project

An amendment (i.e., change to a project initiated by the PI) can be made to an Exempt research project that has been determined *not* to warrant limited and continuing review by submitting the Amendment Request form to the IRB via IRBNet. The Amendment Request Form is found under the "Forms and Templates" tab at IRBNet.