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IRB PROCEDURE STATEMENT

Procedure: Initial Review of IRB Applications - Exempt Projects

Procedure ID: **13-07-001** **Effective:** **January 17, 2019**

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)

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, although depending on

risks pertaining to privacy of subjects and confidentiality of data, many Exempt projects are required by BGSU's IRB policy to undergo "limited IRB review," which is similar to Expedited review:

(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 non-research 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.

(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.

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 or two members of the IRB will be assigned to review the application, depending on whether the ORC determines that the project warrants "limited IRB review." 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,
   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, the voluntary nature of participation, a description of the procedures, and investigator contact information.

d. The member(s) will determine a review outcome. Outcomes include:
   i. Exempt – the project methods falls under an exempt category, the principles in the Belmont Report are being followed, and the research can begin.
   ii. Information Required – additional information is required from the P.I. before the review can be completed.
   iii. 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 ORC staff can route the submission accordingly. The procedures for reviewing expedited or full Board projects will be followed.

e. The member(s) 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 can be made to an Exempt research project that has been determined *not* to warrant limited and continuing review by submitting a form to the Office of Research Compliance which can approve it administratively (Procedure 01-12-001). For all other Exempt projects (those undergoing limited and continuing review) P.I.s must follow the same procedures described in IRB Procedure 02-12-008, "Review of Amendment Requests - Expedited Review."