Institutional Review Board
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IRB PROCEDURE STATEMENT

Procedure: Initial Review of IRB Applications – Expedited Projects

Procedure ID: 2022-06

Effective: January 17, 2019
Revised: May 2022

A. Background

BGSU policy requires review of all research involving human subjects if a project meets the Federal definitions of:

"Research" as defined by United States Department of Health and Human Services (HHS) *Subpart A - Basic HHS Policy for Protection of Human Research Subjects* at 45 CFR 46.102(l): "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." and

"Human subject" as defined by HHS *Subpart A - Basic HHS Policy for Protection of Human Research Subjects* at 45 CFR 46.102(e(1)), "means a living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, or analyzes, the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens." **BGSU's IRB is responsible for the review of research projects involving human participants.**

The Federal regulations provide for certain types of research to be reviewed by a means other than the Full IRB, such as **Expedited Review**. A description of the types of projects can be categorized as Expedited can found in section B. of this document.

Regardless of the category, 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 regulations regardless of who conducts the research or source of support for the research.

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 IRB 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)):

(1) Risks to participants are minimized.
(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
(3) Selection of participants is equitable.
(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, § 46.116.
(5) Informed consent will be appropriately documented or appropriately waived in accordance with § 46.117.
(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
(8) For purposes of conducting the limited IRB review required by § 46.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations:

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

(ii) Broad consent is appropriately documented, or waiver of documentation is appropriate, in accordance with § 46.117; and

(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. "

B. Expedited Research Categories (45 CFR 46.110) as explained by OHRP as "Expedited Review: Categories of Research that may be Reviewed Through an Expedited Review Procedure (1998).

Note:
"1) An **expedited review procedure** consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

2) **Children are defined in the HHS regulations as** "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a)."

"Expedited Categories:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

   (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

   (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   b. from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared

medical devices for new indications.)
Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:
   a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   b. where no subjects have been enrolled and no additional risks have been identified; or
   c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified."

C. Procedure

1. The researcher must complete the **IRB Application Form – Expedited and Full Board Review**, which includes indicating which Expedited Category the project is eligible for on the first page of the application. The completed IRB Application Form – Expedited and Full Board Review and all relevant materials (e.g., consent document(s), survey,

recruitment script, debriefing form) 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. Two members of the IRB will be assigned to review the Expedited IRB Application, affirm the project review category, and determine a review outcome. Review outcomes include:
   a. **Approved** as submitted.
   b. **Information Required** – the IRB Reviewers do not have sufficient information to make a decision. Additional information is required from the researcher before the request will be reviewed.
   c. **Modifications Required** – the researcher must make changes or provide clarifications before final approval can be given.
   d. **Project requires Full Board Review** – The IRB Administrator changes the review type for the project in IRBNet. The IRB Administrator will make the IRB Application and relevant materials available for review at the next IRB Full Board meeting.

4. The IRB Administrator notifies the PI, and the PI's advisor (if applicable), of the review outcome via email. The notification letter and other applicable document(s) can be found in the "Board Documents" section under the "Reviews" tab of the relevant project in IRBNet.