303: Expedited Reviews

1. POLICY: The Secretary of the Department of Health and Human Services and the Food and Drug Administration have established and published in the Federal Register a list of categories of research that may be reviewed by the IRB through an expedited review procedure. (See Section 5 below for links to the current list of expedited review categories.) An IRB may use the expedited review procedure to review either or both of the following:

1.1. Some or all of the research appearing on the list, unless the reviewer determines that the study involves more than minimal risk. (If the reviewer determines that the study involves more than minimal risk, the reviewer's rationale for this determination shall be documented in accordance with applicable HRPP policies. See SOP 203: Documentation and Records Management.)

1.2. Minor changes in previously approved research appearing on the list during the period for which approval is authorized.

2. DEFINITIONS

2.1. ***Minimal Risk.*** Level of risk in which 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 of a normal healthy person living in a safeenvironment or during the performance of routine physical or psychological examinations or tests.

2.2. ***Minor Change:*** A change that does not introduce new risks to the subject population or negatively alter the risk/benefit analysis. Minor changes may be reviewed using expedited procedures. Examples: revision of project title, alteration of recruitment media, reduction of subject interventions or interactions that do not change the risk/benefit ratio of the study as originally reviewed by the IRB.

3. PROCEDURES

3.1. The Researcher submits the IRB protocol in the electronic system by the Researcher, where it is be routed to the faculty member working with the student, or the employee's supervisor. The faculty/supervisor will verify that the Investigator has submitted all of the necessary paperwork and supporting documents and ensures that all required elements are complete. If it is determined that the submitted documents are not adequate, the Researchers may be required to submit additional information, answer questions and/or explain the details of the study. Incomplete submissions will not be routed for IRB review.

3.2. After the faculty member/supervisor approves the proposal in the electronic system, it will be routed to an IRB member for review.

3.3. The assigned Expedited Reviewer will determine if the protocol qualifies for Expedited Review under any of the following categories for Initial Review:

3.3.1. **Categories 1 to 3: not applicable to applied research at Purdue Global but are listed for reference**

3.3.1.1. **Category 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. 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

3.3.1.2. **Category 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, as defined in 45 CFR 46.402(a), 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.

3.3.1.3. **Category 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.

3.3.2. **Category 4:** Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving xrays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Example:

3.3.2.1.1. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

3.3.3. **Category 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).

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

3.3.5. **Category 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.

3.3.6. **Categories 8 and 9:** not applicable to applied research at Purdue Global

3.4. If the proposal is determined to fit the expedited criteria by the IRB member, it is automatically routed to two additional IRB reviewers for approval/denial.

3.4.1. If the two independent reviewers do not reach a consensus, the IRB Chair will make a determination.

3.5. The Expedited Reviewer can choose to consult with another IRB Member, including the Chair, with appropriate expertise. The Expedited Reviewer must have experience in terms of professional competence related to human research protections or conduct of research with human subjects.

3.6. The Expedited Reviewer will conduct a review of the research which includes, but is not limited to the criteria outlined in 45 CFR 46.111 and/or 21 CFR 56.111:

3.6.1. A determination that risks to participants are minimized;

3.6.2. A determination that risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result;

3.6.3. A determination that selection of participants is equitable;

3.6.4. A determination that informed consent will be sought from each prospective participant or the participant's legally authorized

representative, in accordance with and to the extent required by 46 CFR 46.116 and/or 21 CFR 50;

3.6.5. A determination that informed consent will be appropriately documented, in accordance with and to the extent required by 46.117 and/or 21 CFR 50.27;

3.6.6. A determination that when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;

3.6.7. A determination that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; A determination that when some or all subjects are likely to be vulnerable to coercion or undue influence (such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons), additional safeguards have been included in the study to protect the rights and welfare of subjects;

3.6.8. and A determination of the scientific or scholarly validity of the research.

3.6.8.1. Such validity is determined by the experience of an Investigator, a review by a funding agency, a separate peer review process, or by a thesis/ dissertation committee (in the case of graduate student research).

3.6.8.1.1. These processes help to ensure that:

3.6.8.1.1.1. The research procedures are consistent with sound research design;

3.6.8.1.1.2. The research design is sound enough to reasonably expect the research to answer its proposed question;

3.6.8.1.1.3. and The knowledge expected to result from the research is of importance to the scientific or scholarly discipline.

3.6.8.1.2. Should IRB Reviewers disagree with the scientific or scholarly validity assessment, the application should be reviewed either by an IRB Member with appropriate expertise or a consultant whose expertise is germane to the research.

3.6.9. Once approved, an email confirmation is automatically generated and sent to the Researcher, and the Researcher can proceed.

4. RESPONSIBILITY

Researchers must accept overall responsibility for directing and overseeing the research and adhering to University policies, federal and state regulations, IRB SOPs, and approved IRB protocols.

The faculty working with the student/employee supervisor is responsible for reviewing

the submitted protocol and ensuring all documentation is in order.

IRB Members are responsible for participating in the review of protocol application submissions.

The IRB Chair or his/her designee is responsible for providing consultation on the evaluation of protocol application submissions and for making a determination on expedited reviews if the two IRB members do not reach consensus.

5. APPLICABLE REGULATIONS AND GUIDELINES

- 45 CFR 46.109; 45 CFR 46.111
- 21 CFR 56.109; 21 CFR 56.111

6. REFERENCES TO OTHER APPLICABLE SOPs

- 303 Expedited Review
- 320 Informed Consent Requirements