FRANKLIN UNIVERSITY

EXEMPT REVIEW

Research procedures that meet the categories set forth by the federal regulations [45 CFR 46.104(d)] may qualify for exemption. The IRB Manager reviews and approves all exemptions claimed for research conducted at Franklin University. Research activities are exempt from the human research protection regulations when the only involvement of human subjects falls within one or more categories [45 CFR 46.104(d)]. The categories are as follows:

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, such as:

- 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:

- 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;
- 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
- 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:

- 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;
- 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
- 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:

- The identifiable private information or identifiable biospecimens are publicly available;
- 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;
- 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
- 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:

- 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.
- [Reserved]

6. Taste and food quality evaluation and consumer acceptance studies:

- If wholesome foods without additives are consumed, or
- 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:

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

The IRB Office reviews research in categories that are exempt from the federal human research requirements to determine whether an exemption is appropriate.

PROCEDURES

Assigning Reviewers

1. The IRB Manager reviews exempt protocols. If the IRB Manager is not available to conduct the review or has a conflict of interest, the IRB Chair may review the protocol or assign another IRB member.

Submission and Screening

1. The PI makes a preliminary determination that a protocol is eligible for exempt review based on an assessment of the protocol establishing that it falls into one or more of the categories specified in the

federal regulations. The IRB Manager makes the final determination regarding whether a protocol is eligible for exemption.

2. The PI submits a completed exempt review application. Instructions for preparing the application are available on the IRB website. The investigator may contact the IRB Office with questions.

3. Upon receipt of the application, designated IRB staff screen the application, including the informed consent process and documentation, for completeness and accuracy. The designated IRB staff review the PI's exempt category selection for appropriateness. If it is clear to the designated IRB staff that the application does not meet the criteria for exempt review, the designated IRB staff contact the PI and recommends that he/she consider resubmitting either an expedited or full review application.

4. Based on the screening, IRB staff contact the PI for any additional information needed for a thorough review.

IRB Exempt Review

1. The reviewer for exempt protocols receives the following:

- Completed exemption application;
- Research proposal;
- Data collection instruments (if applicable);
- Grant/contract proposal (if applicable);
- Consent form or requests for waiver of informed consent or a waiver of documentation of informed consent;
- Any additional information IRB staff may have requested from the PI (usually via email).

2. The reviewer is responsible for reviewing the application upon receipt to determine that all of the research procedures fit one or more of the exemption categories specified in the federal regulations. The reviewer ensures that the research meets ethical principles and standards for protecting research subjects.

3. The reviewer contacts the PI for any clarification and documents the issues discussed with the PI.

4. If the reviewer is unable to respond within approximately 10 days, IRB staff send up to two reminders. If the reviewer is still unable to respond, IRB staff forward the protocol to another reviewer.

REVIEW OUTCOME(S)

1. The reviewer makes one of the following determinations as the review is completed, if possible, no later than 10 days from receipt:

- Additional information needed to determine exempt status;
- Required revisions needed to qualify study for exemption;
- Disapproved of exempt status with rationale for disapproval and recommendations for submission of expedited or full review application;
- Approved (general comments or suggestions may be included but not required for approval).

2. The reviewer can also recommend that the activities do not fall under IRB purview. In these cases, the IRB handles the review using procedures outlined in the Description of Activities That Need IRB Review SOP.

3. IRB staff forward the reviewer's recommendation in writing to the PI.

4. The PI is responsible for submitting any requested revisions to the IRB Office. The IRB Office forwards the revisions to the reviewer for review and approval if appropriate. The reviewer determines whether the revisions are sufficient for approval of exempt status, and, if so, IRB staff send an approval letter to the PI.

5. If the reviewer determines the revisions are inappropriate or insufficient, he/she may request that the PI make further revisions. This review and revision process continues until the research is either approved or disapproved as exempt.

6. If the IRB disapproves the exemption request, the PI may submit the research proposal as an expedited study if the study meets the criteria for an expedited review. If the study does not meet the criteria for an expedited review, the PI submits a full review application and requests that the IRB Office schedule a full review.

7. IRB records for all exempt determinations include the citation of the specific category justifying the exemption.

8. When the IRB has certified a research study as exempt, the IRB does not require continuing reviews.

9. If the PI has concerns regarding the IRB decision/recommendations in the study, the PI may submit a written appeal that includes a justification for changing the IRB decision to the reviewer and/or the IRB Chair for final resolution. The appeal determination is final. If the investigator is still dissatisfied with the IRB decision, the PI may submit the study to the full IRB for review.