University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
Revision #10	**TITLE: Exempt Review**		**Page 1 of 9**
Approved By: ORI Director	Signature	Date	Date First Effective: 05-10-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date: 05-21-2023

OBJECTIVE

To describe the policies and procedures for the exempt review process

GENERAL DESCRIPTION

Research procedures that meet the categories set forth in 45 CFR 46.104(d); 21 CFR 56.104(d) may qualify for exemption. An Institutional Review Board (IRB) member reviews and provides a determination for all exemptions claimed for research conducted at the University of Kentucky (UK) or by employees or agents of UK facilities. Research activities are exempt from the human research protection regulations when the only involvement of human subjects falls within one or more of the exempt categories. 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. This includes most research on regular and special education instruction strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

   This category does not apply to Food and Drug Administration (FDA) regulated research.

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 45 CFR 46.111(a)(7).

The first two criteria of this category (i and ii) may not be applied to research with minors when involving surveys and/or interviews. They may only be applied to research with minors when involving educational tests or the observation of public behavior and the investigators do not participate in those activities. The third criteria of this exemption (iii) may not be applied to research with minors.

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 45 CFR 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. UK defines brief duration for an intervention (not including data collection, unless intertwined) as lasting no longer than a few minutes to a few hours on a single day. 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.

Research involving minors is not eligible for this category of exemption.

This category does not apply to FDA regulated research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens that have been or will be collected for a non-related primary or initial activity, 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*.

   Note: This fourth criteria is unlikely to be used. If you feel that it is applicable, please contact the Office of Research Integrity (ORI) for Assistance.

   This category may not be applied to research involving primary collection from subjects; collection must be performed for a non-related purpose. Collection can be either prospective or retrospective.

   This category does not apply to FDA regulated research.

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 website 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 FDA 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 45 CFR 46.111(a)(8).

   Research category 7 is not an option at the University of Kentucky at this time.

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 45 CFR 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 45 CFR 46.117;
   (iii) An IRB conducts a limited IRB review and makes the determination required by 45 CFR 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.

Research category 8 is not an option at the University of Kentucky at this time.

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

RESPONSIBILITY

Execution of SOP: IRB Members, Office of Research Integrity (ORI) Staff, ORI Research Privacy Specialist (RPS), and Principal Investigator (PI)/Study Personnel

PROCEDURES

Assigning Reviewers

1. ORI staff currently assigned as alternate IRB members are the primary reviewers tasked with making exemption determinations and conducting limited IRB review, if required. These ORI staff may assign submissions to the IRB Chair or another IRB member to assist with or conduct the exemption review as needed or if specific expertise is required. ORI staff members who have a conflict of interest related to a specific application, as outlined in the IRB Member and Consultant Conflict of Interest SOP, assign the application to another reviewer.

2. IRB Chairs and other IRB members assigned as reviewers of exempt protocols are responsible for notifying ORI staff if they are not able/available to conduct the review. An assigned reviewer is also responsible for notifying ORI staff if they have a conflict of interest as outlined in the IRB Member and Consultant Conflict of Interest SOP.

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 is eligible for one or more of the exemption categories specified in the federal regulations. The IRB member makes the final determination regarding whether a protocol is eligible for exemption.

2. The PI submits an exempt IRB application.

3. Upon receipt of the application, designated ORI staff screen the application for completeness and accuracy. The designated ORI staff member reviews the PI's exempt category selection for appropriateness. The designated ORI staff member either assigns themselves as the reviewer or provides screening comments to another IRB member. The comments include recommendations for the appropriate exempt category(ies) and justification for the chosen category(ies). If it is clear to the designated ORI staff member the application does not meet the criteria for exempt review, the designated ORI staff member contacts the PI and

recommends that they consider withdrawing the exempt application and resubmitting as either an expedited or full review application.

4. ORI staff contact the PI during the application screening process to request any additional information needed for a thorough review.

5. ORI staff also screen for Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and/or Family Educational Rights to Privacy Act (FERPA) concerns. If there is a HIPAA or FERPA concern, ORI staff forward the application to the ORI Research Privacy Specialist (RPS) or designee for review. The RPS or designee reviews the application and submits comments and the IRB reviewer takes them into consideration and makes the final determination.

IRB Exempt Review

1. The IRB reviewer is responsible for reviewing the application upon receipt to determine whether all of the proposed 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. If required by the exempt category(ies), the reviewer performs and documents the determinations of a limited IRB review, applying the criteria at 45 CFR 46.111(a)(7).

2. The IRB reviewer ensures the research does not include any of the following:
   - Targeted enrollment of prisoners as they are excluded from the exemption categories (however, research aimed at involving a broader subject population that only incidentally includes prisoners may be allowed);
   - Survey or interview procedures which include children as subjects (exemption category #2 only);
   - The administration of educational tests to children and/or observation of public behavior involving children where the investigator directly participates in the activities being administered and/or observed (exemption category #2 only);
   - FDA-regulated research (exemption categories #1-5).

3. The IRB reviewer may contact the PI for any clarification needed and documents the issues discussed with the PI.

4. If the IRB reviewer is unable to respond within approximately ten (10) days, ORI staff send up to two (2) reminders. If the reviewer is still unable to respond, ORI staff forward the protocol to another reviewer.

Review Outcome(s)

1. The IRB reviewer makes one of the following recommendations:
   - APPROVED: IRB approval indicates that the IRB reviewer(s) concluded the research and consent forms meet the federal criteria for approval. An approval determination verifies the IRB agrees with the assessment of the protocol and/or specific findings as described by the PI in the application. ORI staff process the determination and the PI is provided with an approval letter and, when applicable, stamped informed consent/assent documents.
   - REVISIONS and/or ADDITIONAL INFORMATION REQUIRED: The IRB reviewer(s) withhold approval pending submission of revisions/additional information. ORI staff return the protocol to the PI to address concerns/questions provided by the reviewer(s). The PI responds and re-submits the application to the ORI within 90 days of receiving the requested revisions. ORI staff assign the PI's response to the IRB reviewer who made the initial determination. Barring extenuating circumstances, if a PI does not respond to requested revisions in the 90-day time-period, the application is administratively withdrawn, and a new protocol submission is required.
   - EXPEDITED or FULL REVIEW REQUIRED: The IRB reviewer may determine the protocol requires expedited or full review by the IRB.

2. The IRB 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 Determination of Activities that Need IRB Review SOP.

3. ORI staff forward the IRB reviewer's recommendation to the PI in accordance with ORI Customer Service Standards.

4. The PI is responsible for submitting any requested revisions.

5. ORI staff approve directive requested revisions made in response to the IRB's review as an administrative change. This includes, for example:

   - addition of a letter of support from a non-UK research site;
   - addition or minor modifications to recruitment materials, advertisements;
   - changes to study duration or schedule, (e.g., extending end date of study, adding an additional semester of the same data collection activities);
   - minor changes to study population in non-therapeutic studies (e.g., raising inclusion criteria from age 20 to 30);
   - small changes to incentives (e.g., $25 instead of $15 gift card); and
   - minor changes to data collection instruments in non-limited review protocols.

Minor changes are limited to directive revisions such as grammatical edits, new dates, expanding a Likert scale, clarifying an item, or adding questions that would not change the subject matter or overall time commitment. Revisions that are substantive, ambiguous, open-ended, or involve sensitive topics are not minor.

6. For substantive requested revisions, the IRB reviewer determines whether the revisions are sufficient for an exempt determination and, if so, ORI staff issue an exemption certification to the PI.

7. If the reviewer determines the revisions are inappropriate or insufficient, they may request that the PI make further revisions. This review and revision process continues until the research is either approved or the IRB reviewer determines the study is not eligible for exemption.

8. If the IRB reviewer determines that the study is not eligible for an exemption, the PI may submit the research proposal as an expedited study if the study meets the criteria for expedited review. If the study does not meet the criteria for expedited review, the PI submits a full review application.

9. If the PI has concerns regarding the IRB decision/recommendations for changes in the study, they may submit the concerns via a written appeal, including a justification for changing the IRB decision. The PI sends the request to the ORI. The reviewer and/or the IRB Chair/Vice Chair or the full convened IRB reviews the appeal in conjunction with a separate party (e.g., chair/vice chair from a different committee, consultant, etc.) to assist in adjudicating the appeal. The appeal determination is final.

10. IRB records for all exempt determinations include the citation of the specific category(ies), justifying the exemption.

11. When the IRB has certified a research study as exempt, the IRB does not require continuation or annual administrative reviews. The exemption approval is in effect for a six-year period. Approximately three months prior to the end of the six-year period, the ORI notifies the PI that the exemption will expire and that they must submit a new exemption application if the project is to continue.

Exempt studies certified prior to implementation of the Revised Common Rule (approved prior to January 21, 2019)

For studies receiving an exempt determination prior to the implementation of the Revised Common Rule, the previous regulations will apply. No action is required on the part of the investigator as these studies will be “grandfathered in” under the previous regulations. Investigators are still expected to submit modification requests that may affect the exempt determination. For information regarding the regulations applicable to these studies, please see

archived Exempt Review SOP Revision #8.

REFERENCES

45 CFR 46.104(d)
21 CFR 56.104(d)

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