

<b>University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures</b>			
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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: 07/08/2011

## **OBJECTIVE**

To describe the policies and procedures for the exempt review process

## **GENERAL DESCRIPTION**

Research procedures that meet the categories set forth by the federal regulations [45 CFR 46.101(b); 21 CFR 56.104(d); 38 CFR 16.102(b)] may qualify for exemption. The Institutional Review Board (IRB) must review and approve 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 of more categories. The categories are as follows:

1. Research conducted in established or commonly accepted educational settings, involving normal education practices, such as:
  - Research on regular or special educational instructional strategies, **or**
  - 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 involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  - Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and**
  - Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability; **or**
  - Be damaging to the subjects' financial standing, employability, or reputation.

**This category does not apply to FDA regulated research.**

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3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category (b) of this section, if:
- The human subjects are elected or appointed public officials or candidates for public office; **or**
  - Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

**This category does not apply to FDA regulated research.**

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

**This category does not apply to FDA regulated research.**

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
- The projects conducted pursuant to specific federal statutory authority such as programs under the Social Security Act, or other federal statutory public benefit or services programs;
  - 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.
  - Projects for which there is no statutory requirement for IRB review;
  - Projects that do not involve significant physical invasions or intrusions upon the privacy interests of subjects;
  - Authorization or concurrence by funding agencies that exemption from IRB review is acceptable.

**This category does not apply to FDA regulated research.**

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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

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The IRB must review 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. Each year, after finalizing the list of IRB members, ORI staff select members from each IRB to serve as either a primary reviewer or a secondary reviewer for monthly rotating terms. ORI staff forward this schedule, designed to appoint reviewers based on familiarity with IRB issues, to the IRB Chair for his/her review and approval. After the IRB Chair approves the schedule, ORI staff forward it to the IRB members.
2. The IRB member who serves on both Nonmedical IRB and the Psychology Department Subjects Use and Research Ethics Committee (SURE) may review Nonmedical IRB exempt studies that require approval from both the IRB and SURE Committee.
3. Each reviewer (whether primary or secondary) is responsible for notifying the ORI staff if he/she is not able or available to conduct the review during the period assigned. The reviewer is also responsible for notifying ORI staff if he/she has a conflict of interest as outlined in the IRB Member and Consultant Conflict of Interest SOP. ORI staff document who served as exemption reviewer on the assigned line at the top of the applicable reviewer form (i.e., IRB Exemption Certificate Signature Page).

#### *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 makes the final determination regarding whether a protocol is eligible for exemption.
2. The PI submits a completed Exemption Certification Form to the ORI. Instructions for preparing the application are available in the IRB Survival Handbook and on the ORI website. The investigator may call the ORI with questions.

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3. Upon receipt of the application, designated ORI staff screen the application including the informed consent process and documentation for completeness and accuracy. The designated ORI staff reviews the PI's exempt category selection for appropriateness. The designated ORI staff completes and sends to the exempt reviewer an "Exemption Comment Form" which offers recommendations for the appropriate exempt category(s) and justification for the chosen category(s). If it is clear to the designated ORI staff the application does not meet the criteria for exempt review, the designated ORI staff contacts the PI and recommends that he/she consider resubmitting either an expedited or full review application.
4. In addition, ORI staff screen for Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and/or Family Educational Rights to Privacy Act (FERPA) concerns. If the PI includes a HIPAA form or checks "HIPAA" in the application or if there is a HIPAA or FERPA concern, ORI staff forward the application to the ORI Research Privacy Specialist (RPS) for review. The RPS reviews the application and submits suggestions in writing, and ORI staff forward them to the exemption reviewer, who then makes the final determination.
5. ORI staff screen the application to see whether the investigator for the study is a Registered Nurse (RN). If the PI is an RN, an RN IRB member is assigned to serve as the exemption reviewer.
6. Based on the screening, ORI staff contact the PI for any additional information needed for a thorough review.
7. ORI staff enter the application into the ORI computerized tracking system. The tracking system assigns a number to the application and, for reporting purposes, places it on an agenda.
8. After screening the application, ORI staff retain the original application in the ORI and forward a copy of the application to a primary reviewer (or to a secondary reviewer in the absence of the primary reviewer or in the event of a conflict of interest).

#### *IRB Exempt Review*

1. The reviewer for exempt protocols receives the following:
  - Completed exemption application
  - "Issues to be Addressed When Conducting Exempt Review" (guidance to reviewers)
  - 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 applicable HIPAA forms

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- IRB Exemption Certification Signature Page
  - Any additional information ORI staff may have requested from the PI (usually via email) or ORI recommendations to reviewer
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. During review, the reviewer ensures that the research does not include any of the following:
    - Prisoners;
    - Survey or interview techniques which include children as subjects (this applies to exemption category #2 only);
    - The observation of children where the investigator participates in the activities being observed (this applies to exemption category #2 only);
    - FDA-regulated research (this applies to exemption categories #1-5).
  4. The reviewer contacts the PI for any clarification needed and documents the issues discussed with the PI on the IRB Exemption Certificate Signature Page.
  5. If the reviewer is unable to respond within approximately 10 days, ORI staff send up to two reminders. If the reviewer is still unable to respond, ORI staff forward the protocol to another reviewer.

*Review Outcome(s)*

1. The reviewer makes one of the following recommendations by completing the IRB Exemption Certificate Signature Page and returning it to the ORI as soon as the review is completed but, 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. ORI staff forward the reviewer's recommendation in writing to the PI in accord with ORI Customer Service Standards.
3. The PI is responsible for submitting any requested revisions to the ORI. The ORI forwards the revisions to the reviewer for review and approval if appropriate. The reviewer determines

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whether the revisions are sufficient for approval of exempt status, and, if so, ORI staff send an approval letter to the PI.

4. 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.
5. 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 ORI schedule a full review.
6. IRB records for all exempt determinations include the citation of the specific category justifying the exemption.
7. When the IRB has certified a research study as exempt, the IRB does not require continuation 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 in writing that the exemption will expire and that he/she must submit a new exemption application if the project is to continue.
8. If the PI has concerns regarding the IRB decision/recommendations for changes in the study, he/she may submit the concerns to the IRB in writing, including a justification for changing the IRB decision. The PI may send the request to the reviewer and/or the IRB Chair or Vice Chair for final resolution. If the investigator is still dissatisfied with IRB decision, he/she may send the study to the full IRB for review.

## **REFERENCES**

- 45 CFR 46.101(b)
- 45 CFR 46.102(i)
- 21 CFR 56.104(d)