

<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: 02-15-19

## **OBJECTIVE**

To describe the policies and procedures for conducting expedited initial review

## **GENERAL DESCRIPTION**

The Institutional Review Board (IRB) uses an expedited review process to review studies that meet the categories adopted by the Department of Health and Human Services (HHS) or the Food and Drug Administration (FDA) that involve no greater than “minimal risk.” The expedited applicability criteria, including the definition of “minimal risk” and federally mandated categories are attached. Expedited review procedures allow the IRB to review and approve studies that meet the criteria in the attached document without convening a meeting of the full IRB. The IRB Chair and/or one or more experienced reviewers from among the IRB membership (regular and alternate members) conducts expedited initial review.

Expedited reviewers only approve research that meets the federal criteria for approval as specified in [45 CFR 46.111](#) and [21 CFR 56.111](#). Also, expedited reviewers ensure that the study’s informed consent process and documentation meet the requirements as specified in [45 CFR 46.116](#) and [21 CFR 50.25](#) unless the IRB waives the requirements in accord with federal regulations. (See Informed Consent SOP.)

Expedited reviewers exercise all the authority of the IRB except that the reviewers may not disapprove the research. The IRB only disapproves a research activity in accordance with non-expedited procedures set forth in the HHS and FDA regulations.

The IRB agenda for convened meetings advises the IRB of research studies approved using expedited review procedures. Any member can request to review an IRB expedited study submission.

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## **RESPONSIBILITY**

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

## **PROCEDURES**

### *Assigning Reviewers*

1. Each year, after finalizing the list of IRB members, ORI staff select and recommend experienced members from the IRB roster to serve as expedited reviewers for monthly rotating terms. Members who have served on an IRB for three months or have completed orientation and attended at least one convened meeting, an expedited review training, and reviewed two instructional ORI videos qualify as an experienced member.
2. ORI staff make initial IRB reviewer assignments based on the member's familiarity with IRB issues and his/her experience and expertise. For Medical expedited review assignments, ORI staff assign the submission to one experienced member for review. For Nonmedical expedited review assignments, ORI staff assign the submission to the Chair and he/she may work in conjunction with one or two other assigned expedited reviewers.
3. Expedited reviewers notify ORI staff if they are unable to conduct an expedited review during the assigned time period or have a conflict of interest on any protocol as outlined in the IRB Member and Consultant Conflict of Interest SOP. Another reviewer is selected by ORI staff.

### *Submission and Screening*

1. The PI makes a preliminary determination that a protocol is eligible for expedited review based on the criteria in the attached document. The IRB makes the final determination regarding whether a protocol is eligible for expedited review.
2. Upon receipt of the application, ORI staff screen it for accuracy and make a preliminary determination whether the application meets the criteria for expedited review, including minimal risk, and identify the research categories. If the application does not meet the criteria for expedited review, ORI staff either return the IRB application to the PI and instruct the PI to change the submission type to "Full" or instruct the PI to withdraw the submission and re-submit for exempt review.
3. ORI staff follow the screening procedures outlined in the Initial Full Review SOP (e.g., screening for: coordination with other University review committees; vulnerable subjects or federally mandated specific findings; waiver of informed consent or documentation requests;

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completion of mandatory training requirements; or need of additional expertise or prisoner representative review). See the Initial Full Review SOP for a detailed description of ORI staff procedures.

4. ORI staff note, during the screening process, whether the submission involves areas of research requiring federally mandated specific findings.
5. ORI staff screen for Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and/or Family Educational Rights and Privacy Act (FERPA) concerns. If the PI includes a HIPAA form, checks "HIPAA" in the application, or if there are any HIPAA or FERPA concerns, ORI staff assign an ORI Research Privacy Specialist (RPS) as an additional reviewer. The RPS reviews the application and provides feedback via comments to the PI, ORI staff, and expedited reviewer.
6. After screening the application, ORI staff assign a primary reviewer to the application. For Nonmedical protocols, the Chair is the reviewer and he/she may work in conjunction with one or two other assigned reviewers. Additional reviewers are added as needed for necessary expertise. The reviewer(s) receive notification by email that a protocol has been assigned for to their review.

#### *IRB Expedited Review Process*

1. Expedited reviewers conduct expedited reviews outside of a convened meeting in accordance with 45 CFR 46.110. If an expedited reviewer is not available or has a conflict of interest, ORI staff contact another reviewer to conduct the review.
2. ORI staff assign Medical IRB protocols to a single primary expedited reviewer and Nonmedical IRB protocols to the Chair as the primary reviewer who may work in conjunction with one or two additional assigned reviewers, depending on the research topic. Assigned reviewers have access to all IRB protocol materials provided by the PI. If a reviewer is unable to complete his/her review within approximately ten (10) business days, ORI staff send the reviewer up to two reminders. If the expedited reviewer still does not respond, ORI staff reassign the protocol.
3. The primary expedited reviewer, with input from other assigned reviewers as applicable, provides feedback for any clarification needed and documents the issues discussed on the Expedited Reviewer Signature Page. The expedited reviewer utilizes the Criteria for IRB Approval: Reviewer Checklist to document that the research meets the federal criteria for IRB approval. The expedited reviewer makes determinations for specific findings using the information from the IRB application and records his/her determinations on the Expedited Reviewer Signature Page. The reviewer documents any issues pertaining to specific findings (e.g., requests for a waiver of informed consent or documentation of informed consent,

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and/or Subpart B, C, D findings) in the materials submitted by the PI and the expedited reviewer's final approval of the application.

*Review Outcomes*

1. Both Medical and Nonmedical primary expedited reviewers make the final determination as to whether research activities meet the expedited review criteria outlined in the attached document.
2. The primary reviewer determines whether the research meets the federal criteria for approval as outlined in [45 CFR 46.111](#) and [21 CFR 56.111](#).
3. Primary expedited reviewers ensure that the investigator describes the informed consent process and how to obtain documentation of informed consent, as specified in [45 CFR 46.116](#) and [117](#) and [21 CFR 50.25](#) unless the primary expedited reviewer waives the requirements in accord with federal regulations. (See Informed Consent SOP.)
4. Expedited reviewers only raise controverted issues or request changes that they have determined do not meet the federal criteria for approval or UK IRB policies.
5. The primary expedited reviewer documents on the Expedited Reviewer Signature Page his/her determinations regarding expedited eligibility, applicable expedited category (or categories), rationale for conducting continuation review (if applicable), and whether the research meets the federal criteria for approval.
6. The primary expedited reviewer makes one of the following three determinations:
  - **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. Upon request, ORI staff send the PI a funding agency Certification of Approval form.
  - **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 primary expedited 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.
  - **FULL REVIEW REQUIRED:** The primary expedited reviewer may determine the protocol requires full review by the IRB at a convened meeting.

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7. The primary expedited reviewer can determine that the research is eligible for a less stringent mechanism of review (i.e., the project is eligible for exemption or the activities do not fall under the purview of the IRB). If the protocol is determined to be eligible for exemption, the PI withdraws the IRB submission and submits a new exempt application. If the activities do not fall under the purview of the IRB, the IRB handles the review using procedures outlined in the Determination of Activities That Need IRB Review SOP.
8. The ORI procedures for notifying the PI of the review outcome, obtaining follow-up correspondence, and issuing approval letters outlined in the Initial Full Review SOP which also applies to expedited review. See Initial Full Review SOP for details.
9. The date the primary expedited reviewer signs off for final approval of the study is the date the approval period starts. The primary expedited reviewer must document rationale for requiring an annual continuation review, if applicable. Otherwise, the protocol requires an annual administrative review. See Continuation Review SOP for details.
10. If the PI has concerns regarding the primary expedited reviewer's decision/recommendations, he/she may submit his/her concerns via a written appeal. The PI sends the request to the ORI and the appropriate primary expedited reviewer or the convened IRB reviews the appeal. The appeal determination is final.

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

Studies that are IRB approved prior to the implementation of the Revised Common Rule, the previous Common Rule regulations will apply. No action is required on the part of the investigator as these studies will be "grandfathered in" the previous regulations. Investigators are still expected to submit modification requests and annual continuing reviews. See Modification, Deviations, and Exceptions SOP and Continuation Review SOP. For more information regarding the regulations applicable to these studies, please see archived Expedited SOP Revision #10.

## **REFERENCES**

[21 CFR 56.102\(i\)](#)  
[21 CFR 56.110](#)  
[45 CFR 46.108\(b\)](#)  
[45 CFR 46.110](#)  
[45 CFR 46.115](#)  
[63 FR 60364-60367;](#)

## **Federally Mandated Expedited Review Criteria – Effective November 9, 1998 – Definition of Minimal Risk Guidance to PI and Reviewers**

Expedited procedures can only be used to review a study if the only involvement of human subjects fits one or more of the categories specified in the federal regulations and if all the procedures present no greater than “minimal risk.”

The IRB reviewer confirms that **all the research activities** fit in one or more of the expedited categories. If the research includes activities that do not fit in the categories, the study is not eligible for expedited review even if the research involves “minimal risk.”

The Department of Health and Human Services defines *minimal risk* to mean “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 or during the performance of routine physical or psychological examinations or tests.” [45 CFR 46.102(j)]

Investigators are asked to provide a risk assessment, but it is the IRB reviewer’s responsibility to determine whether the research meets the federal definition.

The IRB reviewer must consider two questions:

- ◆ Is the probability of the harm or discomfort anticipated in the proposed research greater than that encountered ordinarily in daily life or during the performance of routine physical or psychological examinations or tests? OR
- ◆ Is the magnitude of the harm or discomfort greater than that encountered ordinarily in daily life or during the performance of routine physical or psychological examinations or tests?

If the answer is “yes” to either of these questions, then the research does not meet the definition of minimal risk. The IRB policy on risk assessment is included in the UK Assessing the Research Risk document, which is on the ORI website and in the IRB Survival Handbook.

### **Federal Expedited Review Applicability and Categories**

- (A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
- (B) The categories in this list apply regardless of the age of subjects, except as noted.
- (C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

- (D) The expedited review procedure may not be used for classified research involving human subjects.
- (E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.
- (F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

### Research 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<sup>1</sup> 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 non-disfiguring 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 non-research purposes (such as medical treatment or diagnosis) as well as research involving existing information or specimens that were previously collected for research purposes—provided they were not collected for the currently proposed research. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.104(d)(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 46.104(d). 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.