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 (DHHS) 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, one or more experienced reviewers from among the Medical IRB membership (regular and alternate members) or the Nonmedical IRB Expedited Review Subcommittee conducts expedited initial review.

The 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 meets 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 of the authority of the IRB except that the reviewers may not disapprove the research. The IRB only disapproves a research activity in accord with non-expedited procedures set forth in the DHHS 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 the entire file of an expedited study.
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 three convened meetings qualify as an experienced member.

2. ORI staff make initial Medical IRB reviewer and Nonmedical IRB reviewer assignments based on the member’s familiarity with IRB issues, experience, and expertise and forward the proposed assignments to the respective IRB Chair for review and approval. ORI staff assign the approved list of expedited reviewers to the IRB members.

3. The expedited reviewer notifies ORI staff if he/she is not available to conduct expedited review during the assigned time period or has a conflict of interest as outlined in the IRB Member and Consultant Conflict of Interest SOP. ORI staff document who served as expedited reviewer on the applicable reviewer form (i.e., Expedited Reviewer Signature Page).

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. The PI submits a completed expedited review application. Instructions for preparing the application are available on the ORI website. The investigator may call the ORI with questions.

3. Upon receipt of the application, ORI staff screen it for completeness and accuracy and make a preliminary determination whether the application meets the criteria for expedited review, including minimal risk, and identifies the research categories. If the application fails to meet the criteria for expedited review, ORI staff advise the PI to resubmit the study for full or exempt review.
4. 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; 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.

5. ORI staff note during the screening process whether the proposal involves areas of research requiring federally mandated specific findings. ORI staff use the checklist of specific findings in the Expedited Reviewer Signature Page to alert the expedited reviewer(s) of the areas requiring determinations.

6. 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 HIPAA information or checks “HIPAA” in the application or if there are any HIPAA or FERPA concerns, ORI staff assign the application to the ORI Research Privacy Specialist or designee for review. The RPS reviews the application and submits suggestions in writing. These suggestions are included with the materials available to the IRB Chair, the Medical Expedited reviewer, or the Nonmedical IRB Expedited Reviewer(s) for a final determination.

7. The researcher enters information in the study application and submits it to the ORI for screening. Once submitted, an IRB number is assigned to the application for tracking purposes.

8. After screening the application, ORI staff assign a primary reviewer. The reviewer(s) receive(s) notification that a review has been requested, and access to the application is provided so documentation of a determination can be made. In the event an assigned reviewer has a conflict of interest, ORI staff will re-assign the application for review.

9. The IRB Chair and/or one or more experienced reviewers from among the Medical IRB membership (regular and alternate members) or the regular Nonmedical IRB membership conduct(s) Expedited Initial Review. Unless otherwise noted, the IRB agrees with ORI screening comments/revisions.

Nonmedical IRB Expedited Review Process

1. A Nonmedical IRB Expedited Review comprises of the IRB Chair and, when applicable, designee(s) who have been granted access to the protocol application, conduct the expedited review outside of a convened IRB meeting.
2. With assistance from ORI staff as needed, the IRB Chair or designee documents federally mandated specific findings (e.g., Subpart B, C, D, or waiver of informed consent or documentation) by completing the Expedited Reviewer Signature Page. In conducting the initial review of the proposed research, the reviewer utilizes the Criteria for IRB Approval: Reviewer Checklist.

Medical IRB Expedited Review Process

1. For the Medical IRB, the primary expedited reviewer conducts expedited reviews outside of a convened meeting. The designated ORI staff person assigns the application materials to the primary expedited reviewer. If the assigned reviewer is not available or has a conflict of interest, the ORI contacts another reviewer to act as the primary reviewer and conduct the review.

2. The designated ORI staff person provides the reviewer with recommendations for the appropriate expedited category along with justification for the category(ies) chosen.

3. If the reviewer is unable to respond within approximately 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 to another reviewer.

4. The expedited reviewer makes comments on the application to gain clarification needed from the PI 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 documents any issues pertaining to and makes determinations for specific findings (e.g., requests for waiver of informed consent, documentation, and/or Subpart B, C, D findings) using the information from the IRB application and records his/her determinations on the Expedited Reviewer Signature Page.

Medical and Nonmedical IRB Reviewers have access to the following material

1. Both the medical and nonmedical expedited reviewers receive the following application information, when applicable:
   - Protocol Type
   - Project Information
   - PI Contact Information
   - Risk Level
   - Subject Demographics
   - Informed Consent
   - Study Personnel
   - Research Description
2. Expedited reviewers review all information in the application in enough depth to be familiar with the protocol, to determine whether the research is eligible for expedited review, and to determine whether the research meets the regulatory criteria for approval.

**Review Outcomes**

1. Both medical and nonmedical expedited reviewers make the final determination as to whether research activities meet the expedited review criteria outlined in the attached document.

2. Reviewers can 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. Reviewers determine whether the research meets the federal criteria for approval as outlined in 45 CFR 46.111 and 21 CFR 56.111.

4. Expedited reviewers ensure that the investigator will conduct the informed consent process and obtain documentation of informed consent, as specified in 45 CFR 46.116 and 117 and 21 CFR 50.25, unless the IRB waives the requirements in accord with federal regulations. (See Informed Consent SOP.)

5. The expedited reviewers only raise controverted issues or request changes they have determined do not meet the federal criteria for approval or UK IRB policies.
6. The expedited reviewers document on the Expedited Reviewer Signature Page their determinations regarding expedited eligibility, applicable expedited category(ies), and whether the research meets the federal criteria for approval.

7. The medical and nonmedical expedited reviewers makes one of the following three determinations:

- **APPROVED:** IRB approval indicates that the IRB reviewer(s) concluded that the research and consent forms meet the federal criteria for approval. An IRB approval vote verifies that the IRB agrees with the assessment of the protocol and/or specific findings as described by the PI in the application. ORI staff send the investigator an approval letter according to the guidelines in the ORI Customer Service Standard, accompanied by an informed consent/assent document with the affixed "IRB Approval" validation stamp which includes the valid date of IRB approval. Upon PI request, ORI staff include 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 send the investigator notification according to the guidelines in the ORI Customer Service Standards, describing the revisions requested by the IRB expedited reviewers. The PI responds to the revisions requested by the IRB and sends the response to the ORI. ORI staff notify the expedited reviewer of the response and requests further review.

- **FULL REVIEW REQUIRED:** The IRB expedited reviewers may determine the protocol requires full review by the IRB at a convened meeting.

8. The medical and nonmedical expedited reviewer(s) can determine the research is eligible for a less stringent mechanism of review (i.e., the project is exempt from requirements for review or the activities do not fall under the purview of the IRB). In these cases, ORI staff are notified of the rationale for determining that the activities either meet exempt categories or do not meet the federal definitions of research, clinical investigation, or human subject. ORI staff then notify the PI accordingly and either have the PI withdraw the application (if it does not meet the federal definitions) or request that the PI submit an application under the applicable exempt category.

9. 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 apply for expedited review as well. See Initial Full Review SOP for details.

10. Once the IRB reviewer(s) approves the study, he/she/they assign(s) the approval period at an interval appropriate to the degree of risk, but not less than once per year. The date the
expedited reviewer signs off on final approval of the study is the date the approval period starts. ORI staff document the approval period dates in the approval letter to the PI.

11. If the PI has concerns regarding the IRB decision/recommendations for changes in the study, he/she may submit his/her concerns via a written appeal that includes justification for changing the IRB decision. The PI sends the request to the ORI. The appropriate reviewer or, if need be, convened IRB review the appeal. The appeal determination final.

REFERENCES

21 CFR 56.102(i)
21 CFR 56.110
45 CFR 46.102(i)
45 CFR 46.110
63 FR 60364-60367; 63 FR 60353 – 60356 DHHS-FDA list published in Federal Register November 9, 1998
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 of the procedures present no greater than “minimal risk.”

The IRB reviewer confirms that all of 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(2)(i)].

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 the 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 children1 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 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.

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, electoretinography, 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 nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(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 46.101(b)(2) and (b)(3). 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.