

<b>SOP: RR 401</b> <b>Version No: 2</b> <b>Effective Date: 01/01/07</b>	<b>EXPEDITED REVIEW</b>	<b>Supersedes Document</b> <b>Dated: 10/01/04</b>
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## 1. POLICY

An expedited review procedure consists of a review of research involving human subjects by the Chairperson of each IRB or by one or more experienced reviewers designated by the Chairperson from among members of the IRB. 45 CFR 46.402(a).

The categories of research that may be reviewed by the IRB through an expedited review procedure include research activities that (1) present no more than minimal risk<sup>1</sup> to human subjects, and (2) involve only procedures listed in one or more of the specific categories listed in the regulations at Federal Register Volume 63, CRF 216, No 216, November 9, 1008, pages 60353-60356 (detailed in **Specific Categories** below).

### Specific Categories

1. **Clinical studies of drugs and medical devices only when** (a) research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. 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. **Or** (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) 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 adults and children<sup>2</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 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, 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). (NOTE: some research in this category may be exempt from the DHHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4) – see *Research Exempt from IRB Review* policy, category #4 – FO 302. 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, identify, 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 DHHS regulations or the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3) – see *Research Exempt from IRB Review* policy, category #2 – FO 302. 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 #2 through #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.

## **Specific Policies**

### **1.1 Definition of Minimal Risk<sup>1</sup>**

Minimal risk is defined as "...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(i). [NOTE: in the process of determining what determines risk, only those risks that may result from research, as distinguished from those associated with therapies subjects would undergo even if not participating in research, should be considered. It is possible for the risks of the study to be minimal when the procedure itself is more than minimal.]

### **1.2 Definition of Children<sup>2</sup>**

Children are defined in the DHHS regulations as "...persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

### **1.3 Cautions**

1.2.1 The activities listed should not be deemed to be of minimal risk simply because they are included on the list of eligible research. 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.

1.2.2 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. Furthermore, the expedited review procedure may not be used for classified research involving human subjects.

### **1.3 Authority of the IRB Chairperson**

The IRB Chairperson (or designated reviewer) may exercise all of the authorities of the IRB, except that he/she may not disapprove the research. A research proposal may be disapproved only after review by the full IRB.

### **1.4 Notification of the IRB**

When the expedited review procedure is used, all regular members shall be informed of actions taken by the IRB at the next convened meeting.

### **1.5 Documentation**

If the study qualifies for expedited review, the IRB Chairperson or designee will document his/her determination of risk.

The minutes will include documentation of the studies that were reviewed via expedited review and any issues resolved relating to questions that IRB members had concerning the research reviewed.

## **1.6 Additional Items That May be Reviewed by the Chairperson or Designee**

1.6.1 Conditional approval pending minor revisions, clarification: Revisions to consent documents and other documentation or clarifications submitted as a result of full IRB review and as a condition to final approval may be reviewed by the IRB Chairperson or his/her designee. Final approval will be issued providing the revisions, documentation or clarifications do not indicate or result in a change to the study or change the risk/benefit ratio.

1.6.2 Continuing review:

- The IRB Chairperson may use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. Any protocol revision that entails more than a minimal risk to the subjects must be reviewed by the full IRB at a convened meeting.
- Revisions to informed consent documents: Minor changes to informed consent documents that do not affect the rights and welfare of study subjects, or do not involve increased risk or significant changes in study procedures may be reviewed and approved by the Chairperson/designee.
- Serious / Unexpected adverse event and safety reports: A qualified staff person will triage serious adverse event reports (including IND safety reports) according to pre-established criteria. The Chairperson will review those reports deemed significant. If the Chairperson feels that action is needed to protect the safety of research subjects due to the nature or frequency of reported adverse events, he/she may take such action to the full IRB or designated subcommittee, which will review the adverse events and study in question to determine action, if any, by the IRB. The IRB Chairperson acting for the IRB will review summaries of safety reports and serious adverse events as soon as possible.
- Should the serious / unexpected adverse event(s) be such that the seriousness of the risk to patients is so significant that the Chairperson in consultation with a physician member of the IRB or Vice President for Medical Affairs (IO), may suspend a project until the next meeting of the IRB.
- Advertisements: The IRB Chairperson, or his/her designee may approve new or revised recruitment advertisements or scripts.

1.6.3 Administrative/Editorial changes to protocol and/or consent documents: Minor changes to the protocol, including: amendments/addendums, investigative brochure or package inserts, safety updates, interim reporting, data monitoring reports, and advertising, and informed consent documents that do not affect the rights and welfare of study subjects, or do not involve increased risk or significant changes in study procedures may be reviewed and approved by the Chairperson or the IRB Administrator.

1.6.4 Translations: Translations of consent documents will also be submitted for IRB approval and will be reviewed in an expedited manner. There are two options available to obtain approval of translated consent forms.

- Option #1: The IRB-approved consent form will be translated by the Sponsor or site and submitted to the IRB. Verification of the translator's qualifications will be reviewed by the IRB prior to acceptance of the translated consent form. The translation must match the English version.
- Option #2: The Investigator (or Sponsor) may submit the IRB-approved version of the consent to an IRB-approved, certified translator.

## **2. SCOPE**

These policies and procedures apply to all research submitted to the IRB(s) that qualifies for expedited review.

## **3. RESPONSIBILITY**

IRB Administrator is responsible for identifying submissions that qualify for expedited review.

IRB Administrator is responsible for providing a summary of expedited review performed to IRB members at convened meetings.

IRB Chairperson (or designee) is responsible for conducting expedited review.

IRB Coordinator is responsible for notifying IRB members of expedited review via inclusion in the IRB Agenda and Minutes.

## **4. APPLICABLE REGULATIONS AND GUIDELINES**

Minimal Risk: 45 CFR 46.102  
21 CFR 56.102

Expedited Review: 45 CFR 46.110  
21 CFR 56.110  
FDA Information Sheets, 1998  
OHRP IRB Guidebook

## **5. REFERENCES TO OTHER APPLICABLE SOPs**

This SOP affects all other SOPs.

## **6. ATTACHMENTS**

RR 401-A Determination of Qualifications for Expedited Review  
RR 401-B Guidance – Expedited Review  
RR 401-C Expedited Review Determination

## **7. PROCESS OVERVIEW**

The IRB Chairperson (or designee) or IRB Administrator will review any research project requesting expedited review or deemed able to be expedited using the criteria of the Determination of Qualification for Expedited Review (RR 401-A). The IRB Chairperson or designated IRB member will document which criteria is being used to expedite a project using the Expedited Review Determination (RR 401-C). Once determination to expedite a project is made, the form shall be signed and

returned to the OROC staff for processing. If the Chairperson or designee determines that the study does not meet the Expedited Review criteria, the reasons for disapproval will be documented, and the study will go to full board review at the next scheduled IRB meeting.

## 8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

### A. Expedited Review - New Study

Who	Task	Tool
<i>IRB Administrator</i>	Make initial determination regarding qualification for expedited review. Refer to Guidance as needed.	RR 401-A Determination of Qualifications for Expedited Review RR 401-B Guidance – Expedited Review
<i>IRB Administrator or IRB Coordinator</i>	If the study qualifies for expedited review, assemble reviewer's material and place on schedule for review by the designated IRB member. Notify IRB member by e-mail that a new study is ready to be reviewed.	
<i>IRB Chairperson or Designated IRB Member</i>	Perform primary review; using all the appropriate worksheets. Document result of review using Determination of Qualification for Expedited Review	RR 401-C Determination of Qualification for Expedited Review
<i>IRB Coordinator</i>	Upon completion of the review, add the study to the upcoming IRB Agenda as activities occurring since the last meeting (Announce Only), and indicate the outcome.	

### B. Expedited Review - Renewal

Who	Task	Tool
<i>IRB Administrator</i>	Make initial determination regarding qualification for expedited review. Refer to Guidance as needed.	RR 401-A Determination of Qualifications for Expedited Review RR 401-B Guidance – Expedited Review
<i>IRB Administrator or IRB Coordinator</i>	If the study renewal qualifies for expedited review, assemble reviewer's material and place on schedule for review by the designated IRB member. Notify IRB member by e-mail that a previously reviewed study is ready to be reviewed for renewal.	
<i>IRB Chairperson or Designated IRB Member</i>	Perform primary review; using all the appropriate worksheets. Document result of review using Expedited Review Determination form	RR 401-C Expedited Review Determination

<i>IRB Coordinator</i>	Upon completion of the review, add the study to the upcoming IRB Agenda as activities since last meeting (Announce Only), and indicate the outcome.	
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**C. Expedited Review - Amendments**

<b>Who</b>	<b>Task</b>	<b>Tool</b>
<i>IRB Administrator</i>	Review Revision and/or Amendment form and make initial determination regarding qualification for expedited review. Refer to Guidance as needed.	RR 403-B Revision and/or Amendment form RR 401-B Guidance – Expedited Review
<i>IRB Coordinator</i>	If the amendment qualifies for expedited review, assemble reviewer's material and place on schedule for review by the designated IRB Member. Notify IRB Member by e-mail that a new amendment is ready to be reviewed.	
<i>IRB Chairperson or Designated IRB Member</i>	Perform primary review Document result of review using Expedited Review Determination form. ??	RR 401-C Expedited Review Determination
<i>IRB Coordinator</i>	Upon completion of the review, add the amendment to the upcoming IRB Agenda as activities occurring since last meeting (Announce Only), and indicate the outcome.	