

<b>SOP: RR 401</b> <b>Version No.: 06</b> <b>Effective Date: 7/7/11</b>	<b>EXPEDITED REVIEW</b>	<b>Supersedes Document</b> <b>Dated: 12/2/10</b>
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Steering Committee approved 9/19/11

## 1. POLICY

An expedited review procedure consists of a review of research involving human subjects by an IRB Chair or by one or more experienced reviewers designated by the IRB Chair from among members of the IRB.

Federal regulations permit an IRB to review research through an expedited review procedure only when those research activities: (1) present no more than minimal risk to human subjects; and (2) involve only procedures listed in one or more of the specific categories listed in the-Federal Register, Volume 63, No. 216, pages 60362-67, which may change from time to time. A link to the most current categories can be found on the RSPP web site.

### Specific Policies

Terms used in this policy, but not defined herein shall have the meanings set forth in the Glossary.

**“Minimal risk”** (as it applies to the research procedure or the investigational article) means that “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”

**“Minimal risk”** (as it applies to the risk of violating the subject’s privacy rights) means that the investigator has provided (1) an adequate plan to protect the subject’s identifiers from improper use or disclosure; (2) an adequate plan to destroy the identifiers at the earliest possible opportunity consistent with the conduct of research, unless there is a health or research justification for retaining the identifiers or retention is otherwise required by law; and (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except for those individuals or entities who are also conducting the research studies or are disclosed in the authorization, as required by law, or for authorized oversight of the research study.

#### 1.1. Authority of the IRB Chair

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

The designated reviewer will be an Aurora IRB committee member with two or more years of experience serving on an Aurora IRB, and meets one or more of the following criteria:

- Has certification as an IRB professional or manager;

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- Has, in the Chair’s opinion, demonstrated extensive knowledge of the ethical principles, federal regulations and applicable laws governing human subject research;

The individual must be designated in writing by the Senior IRB Chair in a memo to RSP staff to be approved to conduct review using the expedited procedure.

**1.2. Changes to research that are proposed after the IRB has approved the research with Conditional Approval**

After research has been approved with conditions by the IRB, additional changes are sometimes proposed by the investigator or recommended by designated reviewers before all conditions have been satisfied and the protocol documents have been finalized. The process for handling such changes is the same as for any change that is proposed during the period for which IRB approval has already been given.

Protocol corrections that are only administrative in nature (e.g., correction of typographical and spelling errors in the protocol) would not need additional IRB review because Aurora IRB does not consider such corrections to be changes to the research.

Changes to the research that are “minor” may be reviewed by the IRB Chair or designee, and documented using Form RR 401-C. All members of the IRB will be advised of any such minor changes that are approved under an expedited review procedure in accordance with section 1.8.

Changes to the research that are more than minor would require further review by the IRB at a convened meeting.

**1.3. Review of Newly Submitted Research Via Expedited Review**

Research studies to be reviewed will be those submitted in accordance with Policy FO 301. Based on the categories of research eligible for expedited review referenced in 45 CFR 46.110 and 21 CFR 56.110, and the definition of minimal risk, as outlined above, the Senior IRB Chair or individual designated to conduct expedited review will determine whether the research study qualifies for an expedited review procedure. At times, individuals with specific expertise may be asked to provide a recommendation. If the study qualifies for expedited review, the Senior IRB Chair or individual designated to conduct expedited review will document his/her final determination that the research meets applicable approval criteria and falls into one or more categories allowing expedited review. Such determinations will be documented through completion of the checklist for Review Using the Expedited Procedure (RR 401-A) and the Reviewer Checklist (Form RR 402-A).

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#### **1.4. Categories Of Revisions To An Approved Protocol**

Revisions to an approved protocol and associated documents can be categorized as minor or major revisions.

1.4.1. Minor revisions are defined as changes that do not involve an increase in risk that is more than minimal, do not change the risk/potential benefit relationship of the study, do not affect the rights and welfare of subjects, and in which all added procedures fall into categories (1) – (7) of research that can be reviewed using the expedited procedure [45 CFR 46.110(a)].

1.4.2. Major revisions are revisions that are not minor revisions.

#### **1.5. Additional Items That Pose No More Than Minimal Risk That May be Reviewed by the IRB Chair or Designee**

1.5.1. Conditional approval pending specific revisions requested by the IRB: 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 RSPM Manager (or other IRB member designated by the IRB) provided that such revisions or clarifications require only “simple concurrence” by the Investigator. Final approval will be issued provided that the revisions, documentation, or clarifications do not indicate or result in a change to the study or change the risk/benefit ratio.

1.5.2. Review of minor revisions to research previously approved by a fully convened IRB during the period for which approval is authorized. Some examples might be:

- Minor revisions in approved research or informed consent documents. Examples of minor changes include: basic informational revisions (changes in telephone numbers or contact persons on the consent form, addition or deletion of associates or staff, a change in the number of research participants anticipated to be enrolled at the local site, or the deletion of questions in a questionnaire); changing the amount of blood that is drawn or the frequency provided it remains within the expedited category limitations; adding nonsensitive questions to a questionnaire; revising the format of the consent form or other minor changes to the consent form; adding a standardized test; in certain circumstances, decreasing the drug dosage or the frequency of drug administration; changing the recruitment plan; adding a standard quality of life questionnaire; extending the time period of the study to include follow-up with the research participants; in some circumstances, revising eligibility to include or exclude study participants; adding a research site; changing the principal investigator; or changing the consent form to include a newly identified side-effect or

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adverse event related to the study provided the new risk information has been reviewed by the full committee. The key determining factor is whether the risk to the study participant is increased or changed based on the definition of minimal risk.

Any revision that entails more than a minimal risk to the subjects must be reviewed by the full IRB at a convened meeting. Examples of a major revision include a change of the study drug or the addition of a research arm to the study.

For changes to research involving a study in which an already enrolled subject becomes a prisoner but the focus of the study does not involve a prison population, expedited review of changes to the approved protocol may be appropriate.

- **Recruitment Materials:** Advertisements submitted with the initial protocol are reviewed by the fully convened IRB. When appropriate, the IRB Chair, or designated reviewer, may approve new or revised recruitment materials, advertisements or scripts. (See Policy RR 406)–Recruitment materials that are submitted after a study is approved may receive expedited approval when such advertisements are easily compared to the information contained in the approved consent document.

1.5.3. The Senior IRB Chair, at his/her discretion, may ask another IRB member (e.g. the original Primary Reviewer, or a drug/device specialist) to also review the protocol modification. Upon completion of their review, the designated reviewer will be asked to provide a recommendation to the Senior IRB Chair as to whether the modification is a minor revision. If the designee’s recommendation is that the changes are a minor revision, and the Senior IRB Chair concurs with the designee’s recommendation, the Senior IRB Chair will consider whether the research meets the regulatory criteria for approval, and if so, approve the modification. If the designee indicated that the revision is not a minor modification, the modification will be placed on a future IRB meeting agenda.

1.5.4. **Translations:** Translations of IRB approved consent documents will also be submitted for IRB approval and may 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 is translated by the Sponsor or site and submitted to the IRB. The IRB will have the Aurora Interpreter/Translation Services department review the translated document for accuracy. The Aurora Interpreter/Translation Services department will provide the RSPP office with documentation that the translated document is substantially similar to the English version.

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Option #2: The IRB will accept the consent translated by a certified translator when the consent is accompanied by appropriate documentation.

## **1.6. Continuing Review of Research Previously Approved at Convened IRB Meeting**

Federal regulations allow the IRB to use the expedited review procedure to provide continuing review of research previously approved by the full Board. In order for the reviewer to approve the continuing review of research by expedited review, the reviewer must ensure that the research has met the applicability criteria set forth in 45 CFR 46.110(a) (categories (8) or (9)) and 45 CFR 46.110(b).

### **1.7. Cautions**

1.7.1. Requirements related to informed consent apply regardless of whether the expedited review procedure or the fully-convened IRB review procedure is utilized.

1.7.2. Expedited review is not appropriate for the initial review of a Humanitarian Use Device (HUD) opened for the first time within any Facility, or studies using an investigational device.

### **1.8. Notification of the IRB**

When the expedited review procedure is used for any activity, all members shall be informed of actions taken by the IRB at a subsequent meeting by documentation on the IRB meeting agenda.

### **1.9. Documentation**

The agenda will include documentation of any studies (initial review) or research activities (e.g. modification, continuing review) that were reviewed via expedited review.

## **2. SCOPE**

These policies and procedures apply to all materials submitted to the IRB that qualify for expedited review.

## **3. APPLICABLE REGULATIONS, GUIDELINES, AND STANDARDS**

Minimal Risk: 45 CFR 46.102

21 CFR 56.102

Expedited Review: 45 CFR 46.110

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21 CFR 56.110

Federal Register Volume 63, No. 216, pp. 60364-67

FDA Information Sheets, 1998

OHRP Guidance on Written IRB Procedures (January 15, 2007)

OHRP IRB Guidebook

OHRP Guidance on Continuing Review (January 15, 2007)

OHRP Guidance on the Use of Expedited Review Procedures  
(August 11, 2003)

AAHRPP Element II.E.2.

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

SOP 301

SOP 401

SOP 402

SOP 403

SOP 404

SOP 406