AAH RSPP GUIDANCE
Expedited Review

PURPOSE
The purpose of this document is to describe when the IRB may review new applications, modifications, and continuing review reports by an expedited procedure; as well as requirements for the expedited review process. The AAH IRB permits the use of expedited review procedures for eligible human subject research activities, as defined by federal regulations.

Definitions of *Italicized words* can be found in the AAH RSPP Glossary.

GUIDANCE

Who can conduct expedited review?
- An expedited review will be performed by the IRB Chair or by an IRB member designated by the IRB Chair.
- Reviewers may receive assistance from a consultant to the IRB.

The IRB Chair may designate an individual as an expedited reviewer if he/she meets the following criteria:

- an Aurora IRB member;
- AND at least one of the following criteria:
  - Certification as an IRB professional (CIP); OR
  - Has, in the Chair’s opinion, demonstrated extensive knowledge of the ethical principles, federal regulations and applicable laws governing human subject research.

What types of research/research activities is eligible for review by an expedited procedure?
The IRB may use an expedited review procedure to review any of the following:

- New submissions - Research that involves no more than *minimal risk* and which appears on the list of expedited review categories (1-7) at 45 CFR 46.110 and 21 CFR 56.110.
- Continuing review of expedited research as deemed necessary by the IRB, or a study approved by the convened board that meets the criteria of expedited categories 8 or 9 at 45 CFR 46.110 and 21 CFR 56.110.
- Minor Changes (see below for examples) in already approved research during the period for which approval is authorized. Changes that are greater than minor must be reviewed by the convened IRB.
• **Limited Review** in exempt research - Research for which limited IRB review is a condition of exemption under 45 CFR 46.104(d)(2)(iii), or (d)(3)(i)(C).

**In general, how is expedited review conducted?**

- Expedited reviewers have access to and review the same materials that are available for primary reviewers in convened IRB review.
- The regulatory criteria for approval of research (45 CFR 46.111) using an expedited procedure are the same as those for review of research by a convened IRB.
- Expedited reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research.
  - A research activity may only be disapproved after convened IRB review.
- The expedited reviewer will make one of the following determinations regarding the application:
  - Approve as minimal risk research
  - Revisions and/or additional information are required (conditional approval).
  - Forward to convened IRB.
- Documentation of the review, action taken by the reviewer, and any specific findings required by federal regulations will be documented on the Change form or appropriate expedited review checklist.

In all cases the expedited reviewer may refer any review action to an individual with specific expertise (a ‘consultant’ to the IRB), another IRB member and/or to the Convened IRB. The rationale for referral/deferral will be documented on the expedited review checklist and may include, but is not limited to, assessment that the research is potentially greater than minimal risk.

**What is the process for conducting expedited review of the different types of research activities?**

**New submissions**

- PI will submit to the IRB using the IRB application found in IRB Net.
- Upon acceptance in the RSPP office, a Research Compliance Analyst in the RSPP office, a qualified IRB member, will check the application for completeness and determine if the research activity meets the criteria for expedited review.
- An IRB Chair or designed expedited reviewer will review all submitted materials.
- At times, individuals with specific expertise (‘consultant’) may be asked to provide a recommendation as to the minimal risk nature of the study. These individuals may not provide expedited approval of the research study.
- The expedited reviewer will determine whether the study meets applicable regulatory criteria for approval [45 CFR 46.111], and falls into one or more expedited review categories allowed for by the federal regulations.
- The expedited reviewer may request revisions to the submitted materials.
• The expedited reviewer will document his/her decisions on the New Submission Expedited Review checklist and the Primary Reviewer Checklist. The completed checklists will be added to the study file.

• The revised Common Rule does not require continuing review of any research that falls into one of the expedited review categories. However, IRBs are provided the latitude to require continuing review if determined necessary. The expedited reviewer will determine/document if continuing review of the study is needed.

• An approval letter will be issued to the PI once IRB review using the expedited procedure has been finalized and all administrative requirements are completed. The approval letter will note the approval category and requirements of continuing review as appropriate.

Continuing Review
Under the revised Common Rule most research approved as no greater than minimal risk (‘expedited’) does not require continuing review. However, the revised Common Rule does allow the IRB the latitude to determine that continuing review of expedited research is necessary. This decision will be made during initial review or at subsequent continuing review.

If the research was initially granted approval under one of the federal expedited approval categories of research, any future continuing review may also be conducted via expedited review. The continuing review checklist and form will document the expedited review category provided for continuing review.

Federal regulations also allow the IRB to use the expedited review procedure for continuing review of research previously approved by the convened IRB. 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 applicable criteria set forth in 45 CFR 46.110(a) (categories (8) or (9)) and 45 CFR 46.110(b).

Minor Changes in already approved research
Minor changes to already approved research are defined as changes that do not involve an increase in risk that is more than minimal, do not affect the regulatory criteria for approval, 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)].

The process for submission of Changes to already approved research are outlined in RSPP Guidance entitled ‘Changes to Already Approved Research’.

Limited IRB in exempt research
Some types of exempt research require ‘limited IRB review’ as a condition of exemption under 45 CFR 46.104(d)(2)(iii), or (d)(3)(i)(C). Limited review is conducted as an expedited action as outlined in RSPP Guidance entitled ‘Exempt Research’.
What are examples of minor changes in previously approved research that may be approved via expedited review?

Minor changes in previously approved research are defined as changes that do not involve an increase in risk that is more than minimal, do not affect the regulatory criteria for approval, 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)].

Examples of minor changes to already approved research may include, but are not limited to: 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); Non-English translations of an IRB approved consent document as long as a the translation is accompanied by a Certificate of Accuracy, as well as the qualifications of the translator; changing the amount of blood that is drawn or the frequency of the blood draws provided it remains within the expedited category limitations; adding non-sensitive questions to a questionnaire; changing 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; new or revised recruitment materials, advertisements or scripts; 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 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 based on the definition of minimal risk.

Note that for changes to research to a research 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.

How are IRB members made aware of actions conducted under expedited review?

Members are notified of all actions conducted under expedited review via the IRB meeting agenda. Each meeting agenda includes a list of the expedited review actions conducted since the last convened board meeting.

REQUIREMENTS

Include the regulations/requirements related to the guidance document. To include, but not limited to:

Minimal Risk: 45 CFR 46.102
21 CFR 56.102
Expedited Review: 45 CFR 46.110
21 CFR 56.110
Criteria for approval: 45 CFR 46.111
FDA Information Sheets, 1998
OHRP Guidance on Written IRB Procedures (January 15, 2007)
OHRP Guidance on Continuing Review (January 15, 2007)
AAHRPP Element II.E.2.
Exempt research: 45 CFR 46.104
RSPP SOPs: 5, 6, 7, 8
RSPP Guidance: Changes to Already Approved Research; Exemptions