Final Rule Material:
Updates to Expedited Review Procedures

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CITI Program Final Rule Materials

- We invite you to use this presentation to introduce those involved in the research enterprise to federal Common Rule changes, which are a result of the U.S. Department of Health and Human Services (HHS) Final Rule published in 2017.
- This presentation will review changes to expedited review procedures under the revised Common Rule (the Final Rule).
- All CITI Program Final Rule materials are available on the "Resources" tab of the CITI Program website, www.citiprogram.org/en/resources.

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Introduction

- For consistency and clarity, this presentation uses citations to 45 CFR 46, Subpart A, version of the Common Rule.
- The regulations themselves should be read and understood before implementing changes.
  - *Note - the Final Rule's preamble is a good source for further explanation.*
- **Note**: These resources are based on the Final Rule issued by the U.S. Department of Health and Human Services (HHS) at 45 CFR 46, Subpart A - "Federal Policy for the Protection of Human Subjects" (the Common Rule) on 19 January 2017. These resources have been updated to reflect the 19 June 2018 Final Rule. The general compliance date is now 21 January 2019.

What is expedited review?

Expedited review is review of research by an Institutional Review Board (IRB) Chair or IRB member using an expedited review procedure. The expedited review procedure is a complete and thorough IRB review, just not at a convened IRB meeting.

The expedited reviewer:

- *May only approve or require modifications in (to secure approval) the research.*
- *May not disapprove research.*

The expedited reviewer must be an IRB member.

Expedited Review Categories

A list of **expedited review categories** is published by the Secretary of HHS.

For research to be reviewed using the expedited review procedure, it must:

- *Present no more than minimal risk to subjects.*
- *Involve only procedures listed in one or more of the expedited categories.*

No Changes to Expedited Categories

As of the date of this resource, the categories of research eligible for expedited review are still those published in the *Federal Register* in 1998.

Changes Coming?

The Final Rule stipulates in 46.110(a) that the list of categories will be reviewed every eight years.

Updates to Expedited Review Procedures

Minor updates to expedited review procedure include:

- New documentation requirements at 46.115(a)(3) and 46.115(a)(8).
- Additional statement added to 46.110(b) about limited IRB review.
- Elimination of continuing review for research initially approved through expedited review.

The general compliance date for the Final Rule revisions to expedited review is 21 January 2019.

New Documentation Requirement at 46.115(a)(8)

- Under the Final Rule, a study is presumed to be minimal risk if it meets one of the categories of the HHS Secretary's list.
- If the expedited reviewer determines that the study involves more than minimal risk, the reviewer can override that presumption, but the review has to document his/her rationale.

Elimination of Continuing Review

- When the research involves no more than minimal risk, the regulations no longer specify that continuing review must occur.
- Continuing review no longer required for:
  - *Research initially approved under expedited review.*
  - *Ongoing research approved by a convened IRB (when only certain specified activities are all that remain for the study).*
  - *Research reviewed in accordance with limited IRB review.*

Use of Burden-Reducing Provision

During the delay period of 19 July 2018 – 20 January 2019, institutions may (but are not required to) apply three burden-reducing provisions from the 2018 requirements of the Common Rule, including the provision listed in 46.109 (f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) for certain research (HHS 2018).

New Documentation Requirement at 46.115(a)(3)

- If an IRB chooses to conduct continuing review even when it is not required by the regulation (as described in 46.109(f)(1)), the rationale for doing so must be documented.
  - *Expedited review procedures may still be used for optional continuing review.*
  - *Optional administrative review does not need to occur within any specified period of time, and institutions have the option to decide that re-review after initial approval is not required at all.*

Updates to 46.110(b)

The pre-2018 rule described two general uses of the expedited review process.

1. *Review some or all of the research appearing on the HHS Secretary's list.*
2. *Review minor changes in previously approved research during the period for which approval is authorized.*

The Final Rule added a third.

3. *Review research for which limited IRB review is a condition of exemption.*

What is limited IRB review?

- Limited IRB is a new concept added by the Final Rule and is relevant to certain new exemptions (Categories 2, 3, 7, and 8).
  - *In a limited IRB review, an IRB must conduct a review and make certain determinations as a condition of exemption. For example, that "there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data" (46.111(a)(7)).*
  - *Limited review for Categories 2, 3, and 8 invokes criteria at 46.111(a)(7), however, limited review for Category 7 invokes criteria at 46.111(a)(8).*

Can expedited review be used for limited IRB review?

- The expedited review procedure may be used to conduct limited IRB review.
- The fact that expedited review may be used for categories of review eligible for exemption is a departure from the pre-2018 regulations that required no IRB determinations or involvement regarding how exemption decisions are made.

No Update to Authorities of IRB Members Conducting Expedited Review

- The authorities of an expedited reviewer and the stipulation that the reviewer may not disapprove a submission (46.110(b)(2)) are unchanged by the Final Rule.

No Update for Reporting to the IRB

- The requirement that each IRB using an expedited review procedure shall continue to adopt a method for keeping all members advised of research proposals that have been approved under the procedure (46.110(c)) is unchanged by the Final Rule.

No Update for the Use of Expedited Review Procedure

- Expedited review procedures are not required by the regulation, which is unchanged. Section 46.110(d) remains the same and states that "The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure."

Ongoing Research is Grandfathered to Pre-2018 Rule

- Ongoing research studies initially approved prior to the general compliance date are not required to comply with the revised Common Rule, unless institutional policy requires it.
- According to the preamble, this should minimize burdens associated with research being subject to two sets of rules during the lifetime of the research (HHS 2017).

References

- U.S. Department of Health and Human Services (HHS). 2017. "Federal Policy for the Protection of Human Subjects." *Federal Register* 82(12):7149-274.
- U.S. Department of Health and Human Services (HHS). 2018. "Federal Policy for the Protection of Human Subjects: Six Month Delay of the General Compliance Date of Revisions While Allowing the Use of Three Burden-Reducing Provisions During the Delay Period." *Federal Register* 83(118):28497-520.