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# Final Rule Material:
# Updates to Expedited Review Procedures

## Content Author

Lorna Hicks, MS
Duke University

## Introduction

On 19 January 2017, the U.S. Department of Health and Human Services (HHS) and 15 other federal departments and agencies issued a Final Rule to update the current regulations at 45 CFR 46, Subpart A - "Federal Policy for the Protection of Human Subjects" (the Common Rule) in the *Federal Register*. Changes affect research institutions, Institutional Review Boards (IRBs), and investigators.

This material will cover the updates to expedited review that institutions, IRBs, and investigators should be aware of to conduct research after the Final Rule's general compliance date. The general compliance date for the Final Rule revisions to expedited review is 21 January 2018 (HHS 2018).

This material will use the terms "pre-2018 rule" to refer to the current Common Rule and "Final Rule" or "revised rule" when referring to the rule as published in the *Federal Register* on 19 January 2017. For consistency and clarity, this material will use citations to the HHS 45 CFR 46, Subpart A version of the Final Rule.

***Grandfathered Research***

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).

## Uses of Expedited Review

The revised Common Rule changes affect expedited review procedures. The changes will be reviewed by examining the revisions to section 46.110 ("Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research").

*Section 46.110(a)*

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

*Section 46.110(b)*

| Pre-2018 Rule 46.110(b) | Final Rule 46.110(b) |
| --- | --- |
| An IRB may use the expedited review procedure to review either or both of the following:<br><br>(1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,<br><br>(2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized. | An IRB may use the expedited review procedure to review the following:<br><br>(1) Some or all of the research appearing on the list described in paragraph (a) of this section, unless the reviewer determines that the study involves more than minimal risk;<br><br>(2) Minor changes in previously approved research during the period for which approval is authorized; or<br><br>(3) Research for which limited IRB review is a condition of exemption under § __.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8). |

There are two general statements about the use of expedited review in the pre-2018 rule. The revisions to the Common Rule added a third.

Under the Final Rule, an IRB may use the expedited review procedure to review the following:

UPDATED Some or all of the research appearing on the HHS Secretary's list

Under the Final Rule, a study is presumed to be minimal risk if it meets one of the categories of the Secretary's list. If the expedited reviewer determines that the study involves more than minimal risk, the reviewer can override that presumption, but they have to document their rationale. The documentation requirement is at 46.115(a)(8).

UPDATED Minor changes in previously approved research during the period for which approval is authorized

The Final Rule modified the second statement from the pre-2018 rule to be consistent with the new regulation, so that the parenthetical comment defining the review period "(of one year or less)" has been removed.

***Final Rule Update***

Continuing review for research initially approved using expedited review procedures no longer needs to occur.

NEW Research for which limited IRB review is a condition of exemption

The Final Rule also added a third statement about the use of expedited review for 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 which are the exceptions to mandated continuing review for certain research (HHS 2018).

*Section 46.110(c)*

This section was revised to change "which" to "that" in two instances, and these changes should not affect expedited review procedures.

*Section 46.110(d)*

This section was not revised.

## 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) added by the Final Rule.

The exemptions subject to limited IRB review requirements are (HHS 2017):

The exemption for research that includes only interactions involving educational tests, survey procedures, interview procedures, or observations of public behavior regardless of the identifiability or sensitivity of the information collected/recorded (§ __.104(d)(2)(iii))

The exemption for the storage or maintenance of identifiable private information or identifiable biospecimens for which broad consent is required, when there is a change specific to the research activity in how the identifiable private information or identifiable biospecimens are stored and maintained (§ __.104(d)(7))

The exemption for research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses or video recording (regardless of the identifiability or sensitivity of the information collected/recorded (§ __.104(d)(3)(i)(C))

The exemption for the secondary research use of identifiable private information or identified biospecimens for which broad consent is required (§ __.104(d)(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)). The limited IRB review can be conducted through the expedited review procedure.

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).

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

## Authorities of IRB Members Conducting Expedited Review

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

## Reporting to the IRB

Also unchanged is 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 using the procedure (46.110(c)).

### *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."

## 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.*