

What's New With Continuing Review for Expedited Research?

Continuing review requirements under the Final Rule remain the same for research approved by a convened IRB. However, requirements have changed for research approved via expedited review.

Continuing Review No Longer Required For:

Expedited Research

All studies that undergo expedited review, unless the reviewer explicitly justifies why continuing review would enhance protection of research subjects and documents it according to 46.115(a)(3).

Certain Convened Research

For studies initially reviewed by a convened IRB, when only certain specified activities are all that remain for the study, including:

- Research eligible for expedited review in accordance with § __.110; or
- Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
 - a) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
 - b) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

Exempt Research Requiring Limited IRB Review

Research reviewed in accordance with limited IRB review.

Final Rule Revisions to Continuing Review for Expedited Research

When the research involves no more than minimal risk, the regulations no longer specify that the review must occur one year or less after the approval date.

However, expedited review procedures may still be used for optional continuing review (but rationale for review of research that would not otherwise require continuing review must be documented).

This means that there is no regulatory requirement for 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.

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).

New Final Rule Records Requirement

The IRB may conduct continuing review for research that otherwise would not require continuing review under 46.109(f)(1), but these continuing review activities must be documented and rationale for this review provided under 46.115(a)(3).

Pre-2018 Rule Expedited Research Requires Continuing Review

Ongoing research studies initially approved prior to the effective date are not required to comply with the revised Common Rule, unless institutional policy requires it.

This means that research approved via expedited review and governed by the pre-2018 rule still requires continuing review.

--- What should institutions do? ---

Create policies that reflect the new regulations. Some institutions may need to use some kind of annual or administrative review to ensure that the institution's tracking system accurately reflects what research is active.

However, institutions that have been following OHRP guidance regarding expedited review (essentially a review of the protocol) may wish to adopt a very simple review process to relieve the burden on both reviewers and investigators.

The general compliance date for the revised Common Rule is 21 January 2019.

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