CITI PROGRAM
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New Documentation Requirements for Expedited Review

Documentation Requirement at 46.115(a)(3)

The Final Rule eliminates continuing review for many minimal risk studies.

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.

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 reviewer has to document his/her rationale.

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

Are expedited categories staying the same?

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