

---

Minimal-risk research that falls under one of nine categories defined in federal policy and guidance may undergo expedited IRB review. In an expedited review procedure, an IRB Chair—or one or more experienced IRB members designated by the Chair—reviews the application and may approve it without a vote by the convened board at an IRB meeting. Federal regulations governing expedited review are located at 45 CFR 46.110 and, for research subject to FDA oversight, at 21 CFR 56.110.

Research category 5, as defined in HHS and FDA notices published in the Federal Register, is “research involving materials (data, documents, records, or specimens) that have been collected, or will be collected, solely for non-research purposes (such as medical treatment or diagnosis).” Since some research in this category may be exempt from HHS human subjects research regulations, the notices clarify that the listing refers only to non-exempt research.

HHS later clarified the scope of category 5. The clarification states that category 5 “was intended to and should include research involving existing information or specimens that were previously collected for research purposes, provided that they were not collected for the purposes of the current research.” This means that research materials or data gathered in the past for either research or non-research purposes may be eligible for an expedited review procedure. Research involving materials or data that have not yet been collected, on the other hand, may qualify for expedited review only if they will be collected for non-research purposes.

The notices outline the applicability of the expedited review regulations.

- A. Research eligible for expedited review must
  - (1) present no more than minimal risk
  - (2) fall under one of nine categories defined in the notices
- B. The categories apply regardless of subject age, except where noted
- C. An expedited procedure is not permitted if identification of subjects would place them at risk of criminal or civil liability or could damage their
  - a. financial standing
  - b. employability
  - c. insurability
  - d. reputation,

unless measures to protect subjects’ privacy and confidentiality are sufficient to place them at no more than minimal risk of invasion of privacy or breach of confidentiality

## **U-MIC TRANSCRIPT Expedited Category 5**

- D. An expedited review procedure may not be used for classified research
- E. Requirements for informed consent (or waivers or alterations of consent) apply regardless of whether a study undergoes a standard or expedited review process
- F. All but two categories defined in the notice may undergo expedited review for both initial and continuing IRB review

Contact the IRB for more information about expedited review and research category 5.

*Posted: 3/19/2014*