STATEMENT OF PRACTICE
Interpretation of
Expedited Category (5)

I. STATEMENT OF PRACTICE

IRBMED may apply Expedited Category (5) to research projects (or elements thereof) involving data/materials that either have been collected previously for research or non-research purposes *and/or* will be collected solely for non-research purpose; when the general Applicability criteria in the published list of 1998 are met, including:

- Research activities present no more than minimal risk to human subjects
- Research is not classified
- Identification of the subjects and/or their responses would **not** reasonably place them at risk of criminal or civil liability or be damaging to the subjects; **or** reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal

II. BACKGROUND

Following regulations issued by OHRP 45CFR46.110 and FDA 21CFR56.110, IRBMED commonly uses 'expedited review' procedures for initial and continuing review, and review of proposed changes, for research described by one or more categories on the 1998 list of Expedited Categories published at 63 FR 60364.

Category (5) applies to *Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).*

This can be read to suggest that the category covers only materials generated for non-research purposes, whether retrospective or prospective.

However, OHRP issued in 2007 a **clarification of the scope of Expedited Category (5)** at 72 FR 60849: *OHRP has concluded that expedited review category 5 was intended to, and should, include … research involving existing information or specimens that were previously collected for research purposes---provided they were not collected for the currently proposed research.*

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III. RESOURCES

1. 45 CFR 46.110
   http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.110
2. 21 CFR 56.110
   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.110
3. OHRP, Categories of Research That May Be Reviewed …through an Expedited Review Procedure, http://www.hhs.gov/ohrp/policy/expedited98.html
4. Federal Register, 72 FR 60849, https://federalregister.gov/a/E7-21126
5. UMIC: Expedited Review, Category 5