

Statement of Practice Interpretation of Expedited Category (8)

I. STATEMENT

IRBMED may apply **Expedited Category (8)** to continuing review of research with any previously determined risk level. When the research meets criteria for category 8(a) or 8(c), the IRB member performing expedited review should determine that the ongoing and future research activity involves No More Than Minimal risk.

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 (8) applies to *Continuing review of research previously approved by the convened IRB as follows:*

- a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or*
- b. where no subjects have been enrolled and no additional risks have been identified; or*
- c. where the remaining research activities are limited to data analysis.*

[63 FR 60364](#) also clarifies that *Category eight (8) identifies three situations in which research that is greater than minimal risk and has been initially reviewed by the convened IRB, could undergo subsequent continuing review by the expedited review procedure.*

OHRP Guidance on Continuing Review 2010 ([section E.2](#)) states, *Under expedited review category (8)(a), OHRP interprets "long-term follow-up" to include:*

- Research interactions that involve no more than minimal risk to subjects (e.g., quality of life surveys); and*
- Collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice*

OHRP Guidance on Continuing Review 2010 ([section E.2](#)) also states, *Under expedited review category 8(c), an IRB may use an expedited review procedure to conduct continuing review when the only remaining human subjects research activity is the analysis of data that includes identifiable private information and the IRB chairperson (or another experienced IRB member designated by the chairperson) determines that this activity involves no more than minimal risk.*

FDA Guidance on Continuing Review 2012 ([section D.1](#)) does *not* suggest a stricter interpretation of 8(c).

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III. IMPLEMENTATION

IRBMED regulatory staff may assign Expedited Category 8 reviews to qualified reviewers, per IRBMED [Standard Operating Procedures](#) (Part 3, III, C) and other applicable P&G documents. For 8(a) or 8(c), when the assigned reviewer determines ongoing research activities pose no more than minimal risk, staff may change the overall study risk level as part of finalization, per [IRBMED Staff Edit Rights](#) P&G (PG.300).

In some cases, Expedited 8 is not appropriate. For instance, if the Board determined a study poses ongoing risk during long-term follow-up (*e.g.* for an implanted device), Full-Board review should continue. This can be documented as a Board intent in [Manage Action Items](#). At reviewer request, any SCR may be referred to Full Board (for example, to discuss risk level).

IV. 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, 63 FR 60364, <https://federalregister.gov/a/98-29749>
5. OHRP, Guidance on Continuing Review 2010,
<http://www.hhs.gov/ohrp/policy/continuingreview2010.html>
6. FDA, Guidance on Continuing Review 2012,
<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf>
7. IRBMED Practice and Guidance
 - PG.300 - IRBMED Staff Edit Rights
 - PG.403 - Expedited Review of SCRs by SARAs and JARAs