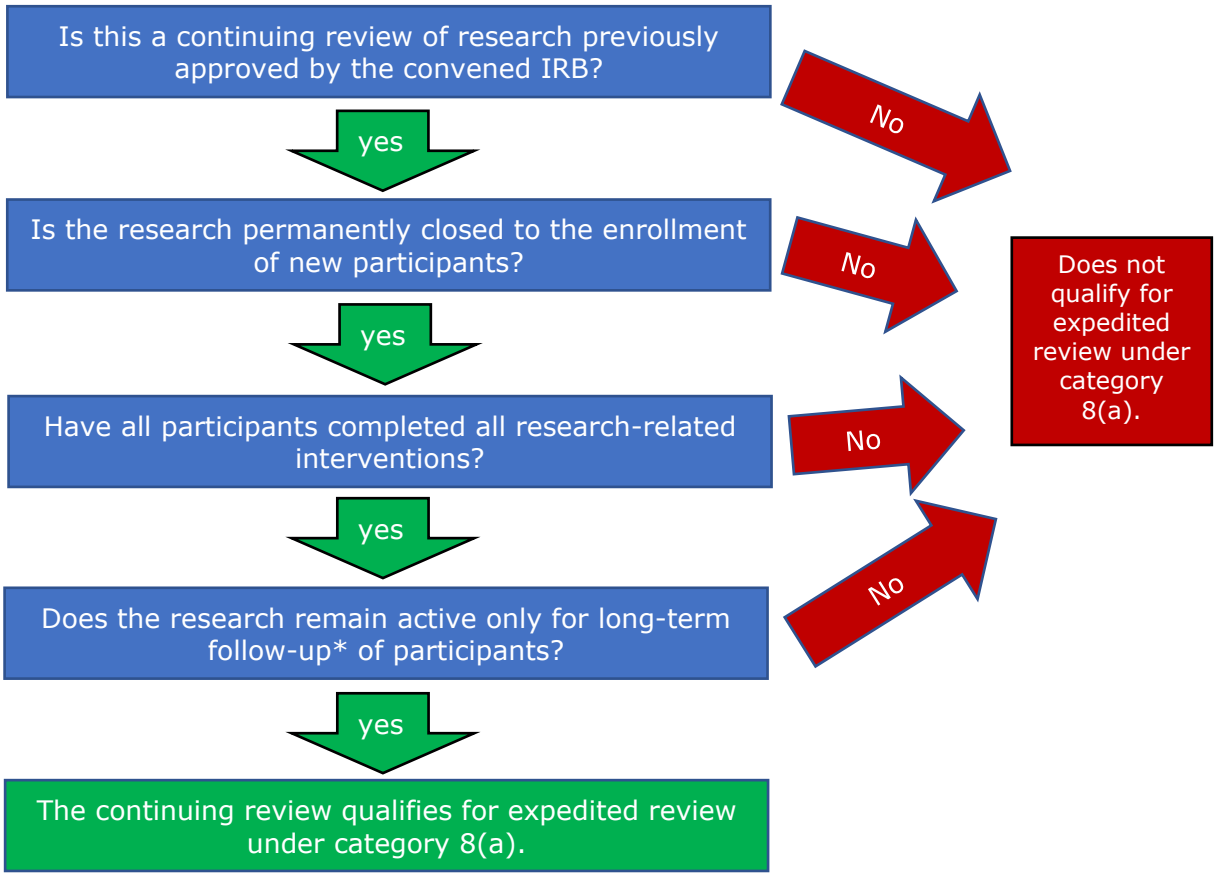
EXPEDITED CATEGORY 8(A) DECISION CHART

Description

Allowing the research to be reviewed using expedited review procedures under category 8(a)[1] requires a clear understanding of the status of the study. If in doubt, ask for more details about the status of the participants and what remaining research procedures are part of "long-term follow-up".

Decision Chart



*What is Long-Term Follow-Up?

Under expedited review category (8)(a), OHRP/FDA interprets "long-term follow-up" to **include**:

- Research ***interactions***[2] that involve no more than minimal risk to subjects (e.g., quality of life surveys); and

[1] The continuing review of research previously approved by the convened IRB may be reviewed by expedited procedures 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.

[2] **Interaction** includes communication or interpersonal contact between investigator and subject.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

- Collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol.

In contrast, OHRP/FDA interprets "long-term follow-up" to **exclude**:

- Research ***interventions***[3] that would not have been performed for clinical purposes, even if the research interventions involve no more than minimal risk.

What research procedures are remaining?

The continuing review application will show the study's status. The protocol may also outline clearly what follow-up includes. It is up to the study team to describe the "progress of the study" and if there is not enough information, ask your IRB coordinator to send a revision request to the study team.

- **Status page:** The questions on the status page of the continuing review application will provide information about what research procedures remain.
- **Progress and Enrollment page:** The study team are asked to provide a description of what remaining research interventions or interactions are planned.

If the study team has indicated that the study is in "follow-up", it needs to be clear that they will NOT be conducting **research-specific** procedures like physical exams, CT scans, MRIs, etc. to qualify for expedited category 8(a). Collection of follow-up data from procedures or interventions that would have been done as part of routine clinical care are acceptable under expedited category 8(a).

Continuing Review

No further continuing review is required if:

1. The study is not subject to FDA-regulation
2. The study is subject to the Final Common Rule (or approved on or after 1/21/19).
3. The research 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.

Remember, FDA-regulated studies still require annual continuing review!

- If you have questions about whether a study needs a continuing review, ask an IRB administrator or manager.
- If you feel like the study SHOULD still have a continuing review, please provide an explanation in your board member checklist as documentation that "the IRB determined otherwise".
- See IRB SOP 404: Continuing Review for the complete policy.

[3] ***Intervention*** includes both physical procedures by which information or biospecimens are gathered (*e.g.,* venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

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References & Links

OHRP Guidance on Continuing Review (2010) – Expedited Review Category 8	*https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html*
FDA Guidance IRB Continuing Review After Clinical Investigation Approval (2012)	*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/irb-continuing-review-after-clinical-investigation-approval*
OHRP 2018 Requirements FAQs	*https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/2018-requirements-faqs/index.html*
IRB SOP 404: Continuing Review	*https://irb.utah.edu/guidelines/irb-standard-operating-procedures/*