* Continuing review (CR) must take place at a convened meeting at which a majority of the IRB members are present **unless** the research qualifies for review under an expedited review procedure (**45 CFR 46.108(b)**).
* IRBs may use an expedited review procedure to conduct continuing review of research that:
  + Involves only procedures described in one or more of the nine categories of expeditable research activities (see [OHRP Continuing Review Guidance 2010](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html)); and
  + Currently involves no more than **minimal risk[[1]](#footnote-1)** to the subjects (**45 CFR 46.110(b)**)

## Decision Process

1. Was the study originally approved under an expedited review procedure?
   1. Yes
      1. Have any additional risks been identified and/or has the research changed such that it no longer falls under expedite categories 1-7?
         1. No. CR can be expedited.
         2. Yes. CR cannot be expedited under categories 1-7.
   2. No
      1. CR cannot be expedited unless the study falls into one of the categories below:
         1. **Category 8(a)**: Enrollment permanently closed, all subjects have completed all research related interventions and the study remains open only for **long-term follow-up[[2]](#footnote-2)**. If ANY research procedures are still ongoing, the study does not qualify for expedited review under this category.
         2. **Category 8(b)**: No subjects have been enrolled and no additional risks have been identified. E.g., a study awaiting site initiation visit & sponsor sign off to begin.
         3. **Category 8(c)**: Enrollment permanently closed, all subjects have completed all research related interventions and the study remains open only for data analysis.
            * As long as a study continues to involve use, study, or analysis of identifiable private information by the investigators, the research continues to involve human subjects and must undergo continuing review by an IRB, but the review may be expedited (**45 CFR 46.109(e)**).
            * If study is only temporarily paused, for example, for interim analysis, this category does not apply.
         4. **Category 9**: Research is not conducted under IND / IDE, categories 2-8 do not apply, and the convened Committee has previously determined that the study involves no greater than minimal risk and no additional risks have been identified. E.g., study previously went full board for risk determination and was found to be minimal risk.

1. **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 CFR 46.102(j)) [↑](#footnote-ref-1)
2. **Long-term follow-up** is the 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. Long-term follow-up excludes: research interventions that would not have been performed if the subject was not in the study, even if the research interventions involve no more than minimal risk, such as a survey or blood draw. [↑](#footnote-ref-2)