# IRB Tip Sheet: Continuing Reviews

**An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in § 46.109(f).**

**From the OHRP Continuing Review Guidance:**

- When conducting continuing review, the IRB should start with the working presumption that the research, as previously approved, does satisfy all criteria for approval.
- The IRB should focus on whether there is any new information provided by the investigator, or otherwise available to the IRB, that would alter the IRB's prior determinations, particularly with respect to the IRB's prior evaluation of the potential benefits or risks to the subjects.
- The IRB should assess whether there is any new information that would necessitate revision of the protocol and/or the informed consent document.
- If the IRB determines that the protocol no longer meets criteria for approval, the IRB must require changes that would result in research satisfying these criteria, defer taking action, or disapprove the research.

When conducting continuing review and evaluating whether research continues to satisfy the criteria for IRB approval of research, the IRB should pay particular attention to the following four aspects of the research:

- Risk assessment and monitoring
- Adequacy of the process for obtaining informed consent
- Investigator and institutional issues
- Research progress

**Continuing Reviews in PROTECT**

***Before the IRB Meeting***

- *Review the Continuing Review (CR) Submission*
  - You can navigate to this review via either the meeting agenda or from a reviewer task assigned to you
  - Open the Modification/CR Smart Form to review the information submitted by the research team
    - In PROTECT, the CR may be paired with a Modification (MOD)
  - Study documents can also be viewed outside the Smart Form under the "Documents" tab
  - The Analysts pre-review note is found under the "Reviews" tab along with any other pre-review activities
- *Request additional information from the research team*
  - Use the "Add Private Comment" to communicate to members of the IRB and IRBO
  - Use the "Add Comment" function to communicate directly to the research team (Not anonymous)
  - You may use the "Request Clarification by Committee Member" option to ask the PI for additional information. The study team will not be able to edit any documents/their submission with their response, they will just be able to answer your question(s).
- *Enter any Reviewer Notes*
  - Select "Add Review Comments" to enter any reviewer notes, checklists, or other supporting documents
  - Your comments will appear under the "Reviews" tab and can be updated any time before the meeting
  - Note: Your comment(s) will disappear from the system after the review of the submission is completed

***During the IRB Meeting***

- *Presentation of the Continuing Review by the Primary Reviewer*
  - Presentation and discussion of a CR can be brief if there are no concerns to address
  - Focus on items that are relevant to the approvability of the protocol
- *IRB Determination and voting*
  - Focus on if the protocol continues to the meet the criteria for approval when discussing the determination
  - If the IRB is requiring additional action before approval, pay attention to the protocol expiration date
  - Consider if a shortened approval period is needed to address any concerns
  - If the PROTECT submission is a CR only, changes to the consent or protocol cannot be made by the IRB during the meeting
  - If the PROTECT submission is both a CR and a MOD, you cannot give separate determinations for each item