Continuing Review – Removing Requirement for Continuing Review

Summary

New studies approved on or after January 21, 2019 and ongoing studies that are minimal risk will be evaluated to assess criteria to remove the requirement for continuing review at the time of the study approval or continuing review occurring on or after January 21, 2019. The determination is based on investigator responses to questions related to sponsor or regulated status, status of participant interaction and research activities and the criteria outlined below. Removal of the continuing review requirement will be communicated to the study PI in the Review Outcome Letter and documented in the study's electronic IRB record – Continuing Review and Expiration dates will be removed from the Study Outcome tab and Outcome letter.

If the IRB determines continuing review for research that otherwise would not require continuing review as described below, the rationale for conducting continuing review of research will be documented in the IRB records and communicated to the investigator.

Removal of the requirement for continuing review does not impact other IRB submission requirements, e.g., any modifications to the IRB-approved protocol, documents, study personnel, etc. must be submitted for IRB approval prior to implementation of the change. In addition, this does not remove the requirement for reporting to the IRB any Unanticipated Problems (UPs) that increase risk to participants or non-compliance that meet criteria for Prompt Reporting.

Criteria

Ongoing continuing review of research is **NOT** required in the following circumstances:

- Research meets the definition of minimal risk, as defined in 45 CFR 46.102
- Research is eligible for expedite review in accordance with 45 CFR 46.110 with the following **exceptions** (per OHRP 2018 Requirements FAQs):
    - Where no subjects have been enrolled and no additional risks have been identified (expedited review category 8(b) – Rationale: Studies that qualify for expedited category 8(b) may involve interactions, interventions, or procedures that might present more than minimal risk to subjects. Continuing review provides the opportunity to monitor these studies once recruitment begins.

- Where (i) the research is not being conducted under an investigational new drug application or investigational device exemption, (ii) categories two (2) through eight (8) of the OHRP Expedited Review Categories (1998) do not apply, and (iii) the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified (expedited review category 9) – Rationale: Continuing review of studies that qualify for expedited category 9 provides the IRB with the opportunity to evaluate the progress of ongoing research activities otherwise not included in the list of permissible expedited review categories.

- Research was reviewed by the IRB in accordance with limited review required for certain exemption determinations

- Research has progressed to the point that it only involves one or both of the following:
  - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
  - Accessing follow-up care from procedures that participants would undergo as part of clinical care.
- Additional criteria:
  - **FDA regulations do not apply** to the study
  - Study sponsor does not require continuing review
  - No external institutions rely on GIRB for IRB review and ongoing oversight of their engagement in this study
  - The study does not involve additional regulatory oversight (e.g., conflict of interest (COI) management plan
  - There are no restrictions imposed by GIRB on the PI
  - The study or PI do not have a history of serious or continuing research non-compliance or pattern of non-serious non-compliance