



SOP 404: CONTINUING REVIEW

POLICY

The IRB must conduct continuing review of approved protocols for purposes of renewal of the IRB approval period. Continuing review is not required for studies determined to be exempt.

When considering whether or not to renew a study, the IRB revisits the same criteria used to grant initial approval. The IRB will not approve protocols submitted for continuing review, if, due to interim changes in IRB policies and procedures, the IRB would not approve that same protocol as a new proposal.

During continuing review, the IRB determines whether the study can be renewed at the same risk/benefit ratio, or if new information has changed that determination. As an outcome of continuing review, the IRB may require that the research be modified or halted altogether. Additionally, the IRB may need to impose new precautions or revise those it had previously imposed on the research protocol. The IRB will re-assess the approval period for each continuing review application. Determinations are made using the board member checklist.

Investigators are required to submit a continuing review application in the ERICA system prior to the expiration of the study. Please see SOP 307: Approval Period and Determination of Expiration for the policy regarding the expiration of a study.

Continuing review must occur at intervals appropriate to the degree of risk. Documentation of the determination of the length of the approval period is made in the board member checklist and, if applicable, the minutes of the convened board meeting. The determination of the length of the approval period is made by the IRB considering the degree of risk, and according to the following standards.

Continuing review for research subject to FDA regulation¹ or Grandfathered studies

For studies that are subject to FDA or pre-2018 Common Rule requirements, the following standards of continuing review apply:

- For studies reviewed at a convened meeting, continuing review must occur within one (1) year from the date of the convened meeting at which the IRB reviewed and approved the research study.
- For studies approved using expedited review procedures, continuing review must occur within one (1) year from the date the IRB Chair or designated expedited reviewer gives final approval to the protocol.

¹ 21 CFR 56.109(f)

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



Continuing review for research subject to the Final Rule

For studies conducted under the University of Utah's Federal-wide Assurance (FWA) with the U.S. Department of Health and Human Services (HHS) and subject to the Final Rule, the following standards of continuing review apply:

- For studies reviewed at a convened meeting, the continuing review must occur within one (1) year from the date of the convened meeting at which the IRB reviewed and approved the research study.
- Unless the IRB determines otherwise, continuing review of research is not required for research eligible for expedited review².
- Research reviewed by the IRB in accordance with the limited IRB review for exempt studies.
- Unless the IRB determines otherwise, continuing review of research is not required for research that has progressed to the point that it involves only one or both of the following³, which are part of the IRB-approved study:
 - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
 - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

Continuing review for studies conducted outside of the University of Utah's FWA

For studies conducted outside of the University of Utah's FWA, the following standards of continuing review apply:

- For studies that are determined to be **greater than minimal risk**, the continuing review must occur within one (1) year from the date of the convened meeting at which the IRB reviewed and approved the research study.
- For studies that are determined to be **no more than minimal risk**, continuing review must occur within two (2) years from the date of the convened meeting at which the IRB reviewed and approved the research study.
- Unless the IRB determines otherwise, continuing review of research is not required for research eligible for expedited review.
- Unless the IRB determines otherwise, continuing review of research is not required for research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
 - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
 - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

² 45 CFR 46.110

³ 45 CFR 46.109(f)(iii)

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