DUKE UNIVERSITY HEALTH SYSTEM
Human Research Protection Program

CONTINUING REVIEW

7/7/2021

The DUHS IRB conducts continuing review of approved human subjects research where required by applicable federal regulations. The DUHS IRB is authorized to conduct the process in accord with federal regulations using either (1) an expedited review process (see Policy titled Expedited Review) or (2) a convened review process (see Policy titled Conduct of Convened Board Meeting). The IRB uses the Expedited Review procedure for the continuing review of research that involves solely one or more of the activities published at 63 FR 60364-60367 (expedited review categories 1-9).

Principal Investigators (PIs) are responsible for submitting sufficiently detailed continuing review applications regarding the research to allow the IRB to determine: 1) whether the research continues to meet the requirements outlined in 45 CFR 46.111 and 21 CFR 56.111, and 2) that any significant new findings that arise from the research and the review process will be provided to participants, if they might relate to participants' willingness to continue participation.

If the IRB determines that significant new findings regarding the research might affect participants' willingness to continue taking part in the research, the IRB has the authority to require provision of such information to participants. This may include requiring re-consent of the participants.

The IRB must ensure that the criteria outlined in 45 CFR 46.111 and 21 CFR 56.111 are satisfied at the time of both initial and continuing review. In particular, when conducting continuing review, the IRB will carefully consider the Continuing Review Progress Report form completed by the study team. The IRB determines whether any new information has emerged, since the last IRB review, – either from the research itself or from other sources – that could alter the IRB's previous determinations, particularly with respect to risk to subjects. This would include, but not limited to, amendments to the research, modifications, and any interim findings. Information regarding any unanticipated problems involving risks to subjects or others, or complaints about the research that have occurred since the previous IRB review will be pertinent to the IRB's determinations at the time of continuing review. In addition, the IRB must ensure that the current consent document(s) are still accurate and complete.

In determining how often continuing review should occur, the DUHS IRB will consider the risks posed by the study intervention, what type of data and safety monitoring is provided for, and any other factors which affect the health and welfare of the study participants. The IRB may approve research for a defined time period of not more than one year if the research involves greater than minimal risk to participants.

Calculating Expiration Dates

The expiration date for an IRB protocol is the first date that the protocol is no longer approved.

Examples illustrate how the expiration date is determined for studies approved for one year by the IRB at a convened meeting:

1. The IRB reviews and approves a study without any conditions (modifications) at a convened meeting on October 1, 2021. Continuing review must be completed within 1 year of the date of the meeting, that is, before October 1, 2022. The study will expire at 12:00 AM in the early morning on October 1, 2022 (midnight September 30, 2022). October 1, 2022 is the first date that the protocol is no longer approved.

2. The IRB reviews a study at a convened meeting on October 1, 2021, and approves the study contingent on specific minor modifications to which the investigator can respond by simple concurrence and the IRB chair or his/her designee can verify. On October 31, 2021, the IRB chair or designee confirms that the required minor changes were made. Continuing review must be completed within 1 year of the date of the convened IRB meeting at which the IRB reviewed and approved the study, that is, before October 1, 2022. The study will expire at 12:00 AM in the early morning on October 1, 2022 (midnight September 30, 2022). October 1, 2022 is the first date that the protocol is no longer approved.

3. The IRB reviews a study at a convened meeting on October 1, 2021, and has serious concerns or lacks significant information that requires IRB review of the study at subsequent convened meetings on October 15 and October 29, 2021. At their October 29, 2021 meeting, the IRB completes its review and approves the study. Continuing review must be completed within 1 year of the date of the convened meeting at which the IRB reviewed and approved the study, that is, before October 29, 2022. The study will expire at 12:00 AM in the early morning on October 29, 2022. October 29, 2022 is the first date that the protocol is no longer approved.

For a new study approved using the expedited review procedure, the expiration date is based on the date the IRB Chair or IRB member designated by the Chair gives final approval to the study. Once the period of approval is established, it will be communicated to the investigator in writing in the approval notice.

Review of only an amendment or change in a study does not alter the date before which continuing review must occur.

Since the regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval, continuing review and re-approval of research must occur before the date when IRB approval expires. In keeping with OHRP guidance (Guidance on Continuing Review, November 10, 2010), when continuing review occurs annually and the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the same “anniversary date” from year to year. This would be, for example, October 1, 2022, in the above examples 1 and 2, and October 29, 2022, in example 3, even if the continuing reviews took place within 30 days prior to these dates. This principle applies to either continuing review conducted by a convened IRB or continuing review using the expedited review procedure.

Verification from Other Sources

As part of the continuing review process, information submitted by the investigator may involve discrepancies or may not be able to be verified by the IRB. In such cases, the IRB may request

verification of information from sources other than the investigators. Verification may be required if the IRB finds inconsistency with data submitted from previous years, determines there is a history of non-compliance with continuing review requirements, or believes unapproved changes have occurred since the last IRB approval of a protocol. The IRB may also request verification for any other cause. Please see the policy titled Determining Which Studies Need Verification from Sources Other than the Investigator.

Determining the Frequency of Continuing Review
Please refer to the DUHS IRB Policy on Determining Frequency of Continuing Review.

Lapses in IRB Approval
Where continuing review is required, approval to conduct the research automatically expires if a continuing review application is not submitted for IRB review, and approved, prior to the expiration date. For more information on lapses of IRB approval, see the policy titled Expiration of IRB Approval and Subsequent Notice to Cease Study Activity.

Revised Common Rule Changes Regarding Continuing Review

The revised Common Rule (2018 Common Rule) brought new requirements surrounding Continuing Review.

Unless the IRB determines otherwise, continuing review of research is not required in the following circumstances, for new studies submitted in iRIS on or after January 21, 2019:

- Research eligible for Expedited Review in accordance with 45 CFR 46.110 (minimal risk studies)
- 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
    - (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

For studies meeting the criteria above, a brief IRB “check-in” will be required at the first two-year mark of the study. This “check in” will consist of a brief summary of events over the last 2 years. Study teams complete the two year check-in form in iRIS.

At the two-year check-in, CITI training status will be verified for all key personnel listed on the study.

Also at the first two-year check-in, the IRB will assess the study to determine if the study can be released from ongoing oversight. If the IRB does not have any outstanding concerns, (including for example, compliance concerns), the study will be released from having to complete all future continuing reviews or two-year check-in forms. This will be communicated to the Investigator in the approval notice.

If, at the discretion of the IRB reviewer, the IRB decides to retain ongoing oversight of the study, the review period will be set back to annual review going forward. This will be communicated to the Investigator in the approval notice.

The IRB will document (in iRIS) its reason for retaining ongoing oversight of the study.

PLEASE NOTE: For studies that are released from ongoing oversight, meaning no continuing reviews are required in the future: All changes to research and personnel must continue to be reported to the IRB via Amendment, and Closure (Final Progress) Reports continue to be required as usual when studies close. All Safety Events must continue to be reported to the IRB as they occur, for the life of the study, according to the reporting criteria and timelines specified in the policy titled Problems or Events that Require Prompt Reporting to the IRB.

PLEASE NOTE: All FDA regulated studies will still require annual Continuing Review (or more often than annual, if specified by the IRB).

For studies where continuing review is not required by regulation the IRB may determine continuing review is required, provided the rationale for this determination is documented in iRIS as part of the IRB review process.

Transition Provisions for Ongoing Research

The IRB decides on a study-by-study basis whether a currently approved minimal risk study that received an Expedited Review upon initial review (initially approved under the old Common Rule), may transition to the revised (2018) Common Rule. The Investigator will be notified of the decision in the IRB's approval notice.

Exempt Research

Research studies that qualify for exemption under 45 CFR 46.104(d) are exempt from all requirements of 45 CFR 46, including the requirements related to continuing review. However, if an Investigator decides to modify an exempt human subjects research project, the Investigator must submit the modified research protocol to the IRB for review before the changes are implemented.

Previous Version Date(s): 05/27/2008; 06/02/2011, 03/07/2016