Continuing Review

Purpose

The purpose is to outline the policy and procedures for continuing review of human research.

Definition

Continuing review of research refers to an official review which is conducted at a designated interval after a project has received initial review and approval by the Institutional Review Board (IRB) or Exempt Review Committee (ERC)**.**

Policy

According to Federal regulations at 45 CFR 46, the IRB shall conduct continuing review of research requiring review by the convened IRB (full review) at intervals appropriate to the degree of risk, but not less than once per year. This means that at least an annual re-review must occur for full research, unless the IRB determines that more frequent review is necessary. The IRB shall also determine which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

If research requiring full review is expected to last longer than the year's approval period, an investigator must apply for continuing review (annual renewal), allowing adequate time for the IRB to carry out its review prior to the current approval's expiration date.

Lapses in approval are not allowed. If a project's approval expires without submission to the IRB/ERC, all research activities, including recruitment, obtaining

informed consent, enrollment, data collection, long-term follow-up, and data analysis (of private, identifiable information), must cease (see Closure policy). The only exception is where the investigator requests to continue the activities in the best interest of participants (e.g., taking a study drug), and the IRB finds that it is in their best interest to continue with such interventions or interactions.

NOTICE - Continuing Review in the Revised Common Rule

For studies approved on or after January 21, 2019, the Revised Common Rule (45 CFR 46) has eliminated the need for certain types of official continuing review. Unless a study was approved prior to this date, or unless the IRB determines otherwise, continuing review of research may no longer be required if:

- research is eligible for exempt review
- research is eligible for expedited review
- research is eligible for full review, but has progressed to 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
    - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care

Annual check-in reports are required for all open studies for which official continuing review is not required, including those reviewed as exempt. Annual check-in reports are due upon the current approval's anniversary date for the study. See our Mandatory Reporting policy.

Procedures

1. The Principal Investigator (PI) monitors the study's expiration or report due date, which is clearly communicated in the study's approval letter, the instructional email sent by staff upon approval, the IRBNet system at www.irbnet.org (Project Overview tab on left menu), and on documents stamped with an expiration date. In addition:

1. IRBNet sends an automated e-mail reminder to the PI and those with full IRBNet access at -90/-60/-30/-10 days prior to and one day after the expiration date, or at an interval within a few weeks of the check-in due date.
2. When possible and based on current workload, an IRB/ERC staff member attempts to send a courtesy reminder. **However, it is ultimately the PI's responsibility to monitor due dates and submit required materials in a timely fashion if a study is to persist.**

2. The PI uses the below chart to determine the original regulatory timing and review type to determine what action must be taken. Regardless of review category, study changes require continuing review instead of check-in.

If Approved	Full (IRB)	Expedited (IRB)	Exempt (ERC)
Prior to January 21, 2019	Continuing Review	Continuing Review	Continuing Review (1st Year; Annual Check-In thereafter)

On or After **January 21, 2019**	Continuing Review (ongoing recruitment, enrollment or data collection) <u>or</u> Annual Check-In (ongoing data analysis or follow-up with clinical care data, unless IRB requires CR)	Annual Check-In (unless IRB requires CR)	Annual Check-In

3. The PI submits a completed form to the IRB or ERC via IRBNet.
4. If recruitment or enrollment will continue, The PI also submits clean copies of documents which are part of the consent process, such as informed consent/assent, parental/guardian permission, and any advertisements (email, flyer, etc.) for the board to stamp with the new approval date.
5. If making changes, the PI describes them and attaches any additional documentation related to such changes (continuing review only).
6. The IRB/ERC staff assigns the submission package to the IRB/ERC for official review or acknowledges the check-in report.

Related Policies

Approval of Research

Closure or Withdrawal

Mandatory Reporting

Suspension or Termination

History

07/19/2013 - Updated
10/24/2014 - Updated identifiable data
05/22/2019 - Updated policy as a result of the Revised Common Rule
05/23/2019 - Updated procedures as a result of the Revised Common Rule