IRB Continuing Review of Approved Research Guidelines

I. Overview

This guidance explains when and how to conduct continuing review of IRB-approved research, in accordance with federal regulations and institutional policy. It ensures ongoing compliance, protects human participants, and supports ethical study conduct throughout the research lifecycle.

II. Requirement for Continuing Review

1. Continuing review of previously approved non-exempt human subjects research is required no less than once a year.[1,2] The IRB may require more frequent review based on risk level.
2. Human subjects research found exempt under 45 CFR 46.104(d) is exempt from all federal human research protection requirements, including further IRB review. If the investigator modifies an exempt human subjects research study so it no longer qualifies for exemption, they must submit the modified protocol to the IRB for review before implementation.
3. Unless the IRB decides otherwise, continuing review is not required under the following circumstances:
    a) Research initially approved under expedited review continues to be eligible for expedited review and poses no more than minimal risk.[3] If the study proposes changes that pose more than minimal risk to subjects or involves procedures that do not qualify for expedited review, the investigator should submit a request for continuing review.
    b) Research that initially received a limited review conducted as part of an exemption determination.
    c) Research that has progressed to the point where the only activity is data analysis or accessing clinical follow-up data.
4. Continuing review is required even if a) no changes have been made to the study, or b) data collection or analysis has not started.
5. If the researcher wishes to discontinue the study, she/he should submit a closure report.

III. Level of Review:

[1] 45 CFR 46.109(e)
[2] 22VAC40-890-70F
[3] 45 CFR 46.109(f)(1)(i)

If the research was initially approved under a Full Board review, it will continue to require annual review by the full board at a convened meeting, unless it meets the following conditions for an expedited review by the IRB Chairperson (or designee):

1. where (a) the research is permanently closed to the enrollment of new subjects; (b) all subjects have completed all research-related interventions; and (c) the research remains active only for long-term follow-up of subjects; or
2. where no subjects have been enrolled and no additional risks have been identified; or
3. where the remaining research activities are limited to data analysis.

IV. Investigator Responsibilities

Sufficient Time: For multi-year research, the PI must submit a continuing review to VDSS IRB before approval expires, allowing at least 30 days for full review and 10 days for expedited review. Submit via irb@dss.virginia.gov.

Materials for Review: Complete and submit the *Continuing Review Form*. The *Continuing Review Form* asks for an update on the study over the past year, including the number of subjects enrolled and withdrawn, reasons for withdrawal, unanticipated problems including complaints about the study, approved amendments to the study since the last review, proposed changes to the study protocol and materials (e.g., consent forms), and any new information related to risks to subjects.

Amendments to the Protocol: Changes to study protocol or documents may be submitted with the *Continuing Review Form*. **Investigators may not implement changes until approved by the VDSS IRB.**

For an outline of the materials required for all continuing review submissions see *Checklist of Materials Required for IRB Review* (under "Resources for Investigators").

V. Avoiding Lapses in Approval

If IRB approval expires, all human research activities must stop! Activities include subject contact, data collection, and analysis. Exceptions are activities needed for participant safety. Contact the IRB if this occurs. No new subjects may be enrolled.

The IRB will decide case-by-case if treatment can continue for enrolled subjects and notify investigators if permitted under federal guidelines.

If activities continue after expiration, the investigator is out of compliance with federal and state regulations. The IRB cannot grant retroactive approval for work after expiration. Activities must stop until approval is granted, even if the review was submitted.

VI. IRB Review Responsibilities

1. Review Criteria: Continuing review must be substantive and meaningful, with criteria identical to initial review. The IRB (or Chair/designee for Expedited reviews) must determine all the following requirements are satisfied:

    a. Risks to subjects remain minimized and reasonable relative to benefits.

    b. Subject selection remains equitable.

    c. Informed consent is sought or waived per 45 CFR 46.116 (21 CFR 50.25 for FDA-approved research).

    d. Consent will be documented or waived per 45 CFR 46.117 (21 CFR 50.27 for FDA-approved research).

    e. The research plan provides adequate monitoring of data collected to ensure safety of subjects; when appropriate, (i) it includes sufficient privacy and confidentiality protections when appropriate; (ii) appropriate safeguards for vulnerable subjects are provided; and (iii) for multi-site research, management of information relevant to subject protection is adequate.

2. Review of Recruitment, Screening and Consent Documents: When reviewing the recruitment, screening, and consent documents, the IRB will ensure:

    a. They are complete, accurate, reflect the study application, and meet regulatory criteria.

    b. Any new findings affecting subjects' willingness to continue are provided via updated consent or addendum.

3. Determining Frequency of Continuing Review: The IRB will determine which projects need review more often than annually to protect subjects. The IRB considers factors like study nature, risk level, and vulnerability of subjects. The IRB will notify investigators in writing of any requirement for review more often than annually and record this in meeting minutes.

4. Verification from Other Sources: On a case-by-case basis, the IRB will determine which projects require verification from sources other than investigators that no material changes occurred since prior IRB review.

VII. Continuing Review Reminders

The investigator is responsible for submitting a review application and allowing sufficient time for the review and re-approval before current approval expires. The expiration date on the approval letter is the last date research activities may occur.