

Policy Number:	203	Version Number:	5.0
Approval Date:	February 14, 2020		
Title:	Continuing Review		

Purpose

To provide a policy and procedure for the research community and the Princeton University Institutional Review Board (IRB) for continuing review and approval of previously approved research.

Scope

This policy and procedure applies to all Investigators, including students, conducting human research under the jurisdiction of the Princeton IRB.

Regulatory Background

Continuing review is a monitoring tool to ensure that ongoing safeguards are in place to protect the rights and welfare of human subjects enrolled in research studies.

An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in the following circumstances:

- (i) Research eligible for expedited review;
- (ii) Research reviewed by the IRB in accordance with the limited IRB review described in the federal regulations;
- (iii) 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:
 - (A) 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.

During continuing review, the IRB will consider any new information, re-assess the informed consent process and any newly submitted changes to the research to assure that, among other things, risks to subjects are being minimized and are still reasonable in relation to anticipated benefits to the subjects and research objectives. Investigators must **not** continue any research activity beyond the expiration date without IRB approval.

A study can be closed when all of the following criteria are met:

The protocol is permanently closed to enrollment; and all subjects have completed all protocol-related interventions and interactions; and no additional identifiable private information about the subjects is being obtained; and analysis of private identifiable information is completed.

Responsibilities

Principal Investigator: Investigators are responsible for submitting continuing review requests to ensure the IRB has sufficient time to approve the continuation request before the study's approval end date. Investigators are responsible for providing all continuing review materials as well as a separate Modification Request Form for any proposed changes.

IRB Staff: Staff will make a preliminary determination about whether a continuing review request should undergo expedited or full Committee review. IRB staff will perform preliminary reviews of continuing review documents to ensure completeness of the submission and request additional information as appropriate. Staff will also aid the IRB Committee in identifying important issues and concerns that should be considered during review.

IRB Member(s): IRB members are responsible for assessing the continuing review and related information to ensure that the research continues to meet the criteria for approval, that new information or study materials, if any, do not change the risk/benefit ratio and that the informed consent process continues to be adequate. The IRB member(s) make the final risk assessment and determine whether the continuing review should be reviewed through expedited or full Committee review procedures.

Policy Determining the Frequency of Continuing Review

The Princeton IRB will determine the frequency of continuing review for each research project to ensure continued protection of human subjects in research.

At the time of initial review of a research project, the IRB will determine and specify the duration of the approval period along with the interval by which continuing review must occur (e.g., 4 months, 6 months, or 1 year) in order for the research to continue. During the time of continuing review, the IRB will consider whether the current frequency of review for the research study is adequate or should be adjusted.

Lapses in Continuing Review: As noted above, the regulations permit no grace period or extension of approval after approval has expired. Research that is conducted after the approval period has expired is conducted without IRB approval.

If a continuing review for a study is not approved by the expiration date IRB approval expires automatically and:

- All research activities must stop, including recruitment, enrollment, consent, research interventions, data collection.
- The IRB administrative staff will notify the Investigator of the approval expiration and that all research activities must stop.

It is the Investigator's responsibility to ensure that continuing review requests are approved in advance of the expiration date. As a courtesy, the IRB Office will send reminder notices to Investigators 60 and 30 days before the expiration date.

Investigators must submit the continuing review form via eRIA.

For full and expedited review, the IRB members will each receive the above documentation. IRB members will be given access to all IRB records related to the research, including those associated with the initial review and approval, and any other pertinent information associated with previous reviews.

Key Considerations when Evaluating Research Undergoing Continuing Review

- Criteria for IRB Approval - In order to re-approve research at the time of continuing review, the IRB must determine that all criteria for approval have been met (45 CFR46.111).
- Risk Assessment and Monitoring - the IRB will consider whether there is any new information provided by the Investigator or available to the IRB, that would alter the IRB's previous conclusion that the criteria for approval have been met.
- When appropriate, the IRB must confirm that provisions established for monitoring the research data to ensure safety of subjects have been implemented and are working as intended.

References

OHRP - Guidance on IRB Continuing Review of Research
<http://www.hhs.gov/ohrp/policy/continuingreview2010.html>

OHRP -Guidance on IRB Approval of Research with Conditions
<http://www.hhs.gov/ohrp/policy/conditionalapproval2010.html>

Version History

Version Number	Revision Date	Revision Description
1.0	6/17/2013	Initiation
2.0	10/1/2015	Edited to describe the closed/expired process and edited for clarity.
3.0	10/16/2017	Edited to reflect the use of eRIA
4.0	01/19/2018	Edited to reflect the Final Rule
5.0	2/14/2020	Revised to reflect RIA policy template