Rush University Medical Center
Policies and Procedures

Policy Number:	RA-IRB-111
Category Name:	Research
Title:	Continuing Review of Approved, Ongoing Studies
Type:	Policy and Procedure
Revised:	2/2014 (replaces 11/2011)

Applies To: Rush Investigators, Study Staff, Department/Division Approvers, Rush IRB Members, and IRB Administrative Staff.

Policy: **The Rush Institutional Review Board (IRB) shall conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year, in accordance with federal regulations. At the discretion of the IRB, more frequent reviews may be required (see IRB Policy and Procedure RA-IRB-109 "Institutional Review Board (IRB) Authority to Impose Study Restrictions").**

Continuing review must occur as long as one of the following is true:

- **The research is open to the enrollment of new subjects;**
- **Enrolled subjects have not completed all research interventions, including follow-up activities;**
- **Data collection and/or analysis is ongoing.**
- **A manuscript is in preparation.**

Definitions: The **date of expiration** is considered the last day the study is approved.

Procedure: As a courtesy, Investigators will be reminded when projects are due for continuing review upon initial approval and then at 60, 30, 45, and 15 days prior to the date of expiration. Investigators will also be notified on the date of expiration. The day after the date of expiration, Investigators, study staff, and Department/Division approvers are informed that the study has expired and that study activities must cease

immediately (please see IRB Policy and Procedure RA-IRB-112 “Lapse of IRB Approval for Ongoing Studies” for the procedure regarding studies with lapsed IRB approval.) However, **the Investigator is responsible for tracking IRB approval lapse dates. The Department/Division Approver or Section Head is responsible for ensuring that research activity ceases when approval of a study in his/her department or section lapses. It is the responsibility of the PI to track and fulfill renewal obligations for ancillary committees (Institutional Biosafety Committee, Radiation Safety Committee, Conflict of Individual Interest in Research).**

Allowing adequate time for re-approval, the Investigator will submit the “Continuing Review Application” form to the IRB for review via the Rush Research Portal (RRP). This application also requires that a clean copy of the most recently approved informed consent(s) and/or assent(s) be uploaded in the electronic continuing review application.

An IRB Administrative staff member takes ownership of the electronic continuing review applications and assigns them to the Continuing Review Subcommittee, which is comprised of a small number of IRB members and IRB Administrative staff. The subcommittee examines the continuing review application, submitted consent forms, and re-examines the complete IRB file, including the current protocol, previously approved changes to the study, safety reports, and any additional pertinent information to ensure that the proper documentation has been submitted.

After review by the Continuing Review Subcommittee, the Continuing Review Application for those projects requiring review by the fully convened IRB are scheduled for the next available full board meeting. The complete review includes subject accrual, the research risks, benefits, study design, process, safety issues, issues of confidentiality, safeguards in place for vulnerable subjects, correspondence with sponsors, and adverse event reporting. The review will also comment on whether or not the consent documents still adequately reflect the study.

If it is determined that significant new findings were disclosed that may relate to subjects’ willingness to continue participation, a request to provide that information to subjects will be made by the IRB.

To assist in conducting their review of the Continuing Review Application, IRB Members have access to the

entire study history, including the currently approved protocol, safety reports, and history of changes to the study (amendments).

Expedited Continuing Review
Continuing review applications are sometimes eligible for expedited review if initially approved under 45CFR46.110(1) through (7) or if it meets the following additionally criteria under 45CFR46.110:

- **45CFR46.110(8)** Continuing review of research previously approved by the convened IRB as follows:

  a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

  b. where no subjects have been enrolled and no additional risks have been identified; or

  c. where the remaining research activities are limited to data analysis.

- **45CFR46.110(9):** Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Continuing review applications for those projects that qualify for expedited review are approved by Continuing Review Subcommittee members who are also experienced IRB members. Experience is determined by years serving on the IRB and quality of full IRB presentations. Subcommittee members who are conducting expedited review of continuing review applications are provided the same information in the RRP as the full committee receives during fully convened IRB reviews. They conduct reviews in the same depth and use the same criteria for approval as the convened IRB. The individual reviewer has all of the authority of the IRB, including requests for consultant input, except that he or she may not disapprove the renewal of the research.

	Any requests for revisions and/or clarifications (including those from the subcommittee reviewer), information regarding approval, and time for continuing review will be sent to the investigator by IRB Administrative staff through the Rush Research Portal. Research reviewed and approved within 30 days prior to the expiration date may have the new expiration date set at 1 year from the original expiration date. Studies that lapse in approval and are submitted within 60 days of expiration (as outlined in IRB Policy and Procedure RA-IRB-112 “Lapse of IRB Approval for Ongoing Studies”) will be reviewed by the fully convened IRB, regardless of whether the study was reviewed by the expedited procedure in the past. A list of all continuing reviews approved by expedited reviewers will be sent monthly via email to members of all IRB committees, IRB Administrative staff, the Director of Human Subjects Protection, the Assistant Vice President for Research, and Vice President for Research.
Reference	45 CFR 46.109(e); 21 CFR 56.109(f)
Related Policies	RA-IRB-112 “Lapse of IRB Approval for Ongoing Studies” RA-IRB-109 “Institutional Review Board (IRB) Authority to Impose Study Restrictions”

Last Reviewed: 4/8/2014