# Lapsed Study Policy

## What if my continuation was not submitted on time and approval has lapsed?

If the IRB has not reviewed and approved a research study by the end of the approval period specified by the IRB, all research activities must cease, including recruitment and enrollment of subjects, consent, interventions, interactions and data collection, unless the IRB concludes it is in the best interests of individual subjects to continue participation in the research interventions or interactions. This will occur even if the investigator has provided the continuing information before the expiration date because, the IRB was unable to review due to the time of receipt, non-inclusion of required information or other delays ensue.

Failure to submit continuing review information on time is considered non-compliance.

If the study is FDA regulated, the IRB Director and IRB Chair must follow FDA requirements set forth in 21 CFR 56.108(b)(3)in reaching their decision.

The sponsoring agency, private sponsor or other federal agencies must be informed of any lapse in research via the Office of Clinical Trials or Sponsored Programs Administration as appropriate.

The procedure for obtaining approval to continue subject participation after expiration of IRB approval is as follows:

1. The PI will submit to the IRB Chair a written list of research subjects for whom stopping of the research would cause harm;
2. The IRB Chair will review written requests from investigators who wish to continue with the study.
3. The IRB Chair will further determine the specific procedures that may continue to be performed when ceasing such procedures will harm the subject.
4. The IRB Chair will either orally communicate the decision to the investigator(s) or communicate such decisions via electronic mail. The IRB Chair will also provide a written response.

## Can a continuing review be expedited?

Yes. A project may be expedited review in the following circumstances: (1) the protocol falls under the limited circumstances described by the expedited review categories [8] and [9] at 63 FR 60364-60367 (see: Categories Research Eligible for Expedited Review; (2) The protocol was originally approved by the expedited reviewer in the initial review process.

A project that cannot be reviewed in an expedited manner are those projects that fall under the following: (1) the research did not qualify for expedited review at the time of initial review of the application or (2) the research activities that previously qualified for review in accordance with 45 CFR 46.110 changed or will change, such that expedited review would no longer be permitted for continuing.

## When should I submit my continuation request?

Approximately 120 days before the approval period expires, the principal investigator will receive an e-mail reminder notice of the expiration of the approved project. A reminder will be provided monthly until the project is submitted or expires.

Renewals should be submitted as early as possible to ensure the continuation review does not occur after the expiration date. Continuations to be reviewed at a convened IRB meeting may be submitted any time prior to the posted deadline dates on the NYU SoM IRB website. Ensure the meeting date you are submitting on the appropriate deadline for is before the project’s expiration date. It is important to provide enough time in case your renewal is deferred or provided a conditional approval.

Continuations that qualify for expedited review are accepted one week prior to posted submission deadlines or one week after the deadline. Full board review continuations take preference on the deadline dates. Expedited projects submitted on the deadline date will be delayed.

Submissions are accepted during the IRB Office’s hours: 8 am to 5 pm. It is preferred at this time documents be hand delivered. The office is located at the VAMC, 423 East 23rd Street, 10th Floor, West Side, NY, NY. The main number is (212) 263-4110.

If the project is not reviewed and approved by the expiration date, new enrollment to the project must cease. Current study subjects who remain in follow-up or active therapy may continue to do so only, if they are placed at an increased risk.