DFCI Institutional Review Board:
Expiration of IRB Approval and Administrative Closures

Expiration of IRB Approval

If a continuing review of an active study is not approved prior to the end of the previously approved duration of the study, the IRB approval shall automatically expire and the study shall be suspended in accordance with federal regulations.

The OHRS may provide warning notices of study expiration to Principal Investigators prior to the study expiration date, but investigators should understand that these are a courtesy and are not required. It is the responsibility of the Principal Investigator to monitor approval periods and to ensure that continuing reports are filed in ample time to allow for IRB review. The Office of Data Quality monitors expirations dates and notifies the Principal Investigator of a suspension for lapse in IRB approval.

Expiration of IRB approval is not considered suspension or termination of research and will not be reported to OHRP or FDA. This is in contrast to the reporting that must occur pursuant to HHS and FDA regulations if a study is suspended or terminated for cause by the IRB.

Cessation of Research Activities

Principal Investigators are responsible for suspending study-related activity, including subject accrual, recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information and identifiable biospecimens, pursuant to regulations whenever IRB approval has lapsed.

Research activities that must stop upon a lapse of IRB approval include, but are not limited to, recruitment and enrollment of subjects, collection of specimens, research on previously collected specimens, review of medical records or other health information, data analysis, performance of research tests/procedures, and treatment or follow-up on previously enrolled subjects. Advertisements running in the media must also be pulled.

Requests to Continue Research Interventions

If treatment or follow-up of subjects is necessary for subject safety and welfare, the Principal Investigator must request permission of the IRB via a Request to Continue Research Interventions form in iRIS to continue treating previously enrolled subjects on study. The reviewing IRB Chairperson or medical reviewer designee is responsible for considering these requests on a case-by-case basis and providing the investigator with written documentation of permission, when granted.

Restoring IRB Approval of Expired Research

If a study has lapsed in IRB approval and the Principal Investigator wishes to continue the research, a continuing review must be submitted immediately but in no case should a continuing review be submitted to the OHRS later than 45 days after the lapse in IRB approval.

During the suspension for lapse in IRB approval, initial (i.e. new) studies from the Principal Investigator may be submitted and the IRB may review and approve such studies, but the IRB has the authority to make activation of the new study contingent upon approval of either a continuing report or a final report (or administrative closure) for the study which has lapsed in IRB approval.

Administrative Closures

If a study suspension for lapse in IRB approval extends beyond 90 days, the study shall be administratively closed unless this closure is waived by the Institutional Official. Administrative closures shall be reported to the IRB by the OHRS.