

Request Form - Continue Essential Study Activities on an Expired Study for Subject Safety

When a study expires, all ongoing research activities involving human subjects must cease, including recruitment/enrollment, study procedures, and collection and analysis of study data. Any ongoing research activities involving human subjects are in violation of both federal regulations and University policy.

However, if there are currently enrolled subjects that require study treatment or monitoring for patient health or safety concerns, as determined by the PI, **complete this form and receive IRB acknowledgment prior to conducting these activities.**

You must submit a Continuing Review Form in iRIS if you haven't done so already.

In addition, lapse in study approval is a reportable event that must be submitted via a Protocol Violation/Incident Report Form in iRIS.

Principal Investigator (PI)

Study Title

IRB Study Number

Date of Expiration

Instructions: For each subject, include the following:

- Subject number (Must be enrolled prior to study expiration; do not include PHI)
- Activities/procedures the PI has deemed necessary to continue for subject health/safety
- Rationale for why the activities are necessary
- Dates of the activities/procedures

Email this completed form to the UCSF IRB. The email must be sent by the PI or Co-PI.

- To: IRB@ucsf.edu
- Subject: Request to Continue Essential Study Activities on an Expired Study
- Attachment: Request Form

Version 12/16/2021