Published on *UCSF Institutional Review Board* (https://irb.ucsf.edu)

Study Expiration Dates and Extended Approval Criteria

How Often Is Continuing Review Required?

Your approval letter will clarify how long the study is approved ? typically 1 year [see 45 CFR 46.109 (e) (only: except as described in 45 CFR 46.109 (f)) and 21 CFR 56..109 (d) (FDA)). You must submit a continuing review [1] before your study expires if you wish to continue the research.

Continuing Review is generally not required for:

- **Exempt Research**: There are no expiration dates for studies that the IRB certifies as exempt. (However, the IRB may require continuing review based on the research, if there is sufficient rationale to require additional monitoring.)
- **Expedited Review (Common Rule)**: There are no expiration dates for research eligible for expedited review in accordance with 45 CFR 46.110, unless the IRB determines otherwise and such determination will be described in the approval letter. 45 CFR 46.109(f)(1)(i) and 45 CFR 46.115(a)#3)(Common Rule). If the research is FDA-regulated, it is still required to undergo continuing review in accordance with 21 CFR 45.109(f).
- **Research in Data Analysis/Clinical Follow Up (Common Rule)**: There are no expiration dates for 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:

- Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
- Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care; unless the IRB determines otherwise and such determination will be described in the approval letter. 45 CFR 46.109(f)(1)(iii) and 45 CFFR 46.115(a)(3)(Common Rule). If the research is FDA-regulated, it still required to undergo continuing review in accordance with 21 CFR 45.109(f).

Determining Expiration Dates

For initial reviews and continuing reviews, the expiration date will be 1 year (minus 1 day) from the approval date for research subject to continuing review.

At UCSF the approval date is the day when study activities involving human subjects may start; the expiration date is the last day on which activities may continue, unless a new approval is given.

Federal regulations require that (1) except when an expedited review [2] procedure is used, each IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas; and (2) an IRB must conduct continuing review of research at intervals appropriate to the degree of risk, but not less frequently than once per year. The IRB should decide the frequency of continuing review for each study protocol necessary to ensure the continued protection of the rights and welfare of research subjects.

Page last updated:
Jan 20, 2019

Links
[1] https://irb.ucsf.edu/continuing-review
[2] https://irb.ucsf.edu/levels-review