Approval Period

Q. What is the approval period for my protocol that was reviewed/approved prior to January 21, 2019 (pre-2018 Common Rule)?

A. Exemptions are assigned three-year approval periods.

Expedited protocols are assigned either annual or three-year approval periods. Contact the Office of Research to learn more about what qualifies for a three-year approval period.

Full board protocols are assigned annual approval periods.

Q. What is the approval period for my protocol that was reviewed/approved after to January 21, 2019 (post-2018 Common Rule)?

A. Exemptions and most Expedited protocols no longer require continuing review. Continuing review for Expedited protocols that might require continuing review if:

- The project is regulated by a sponsor that requires continuing review (FDA)
- The project involves additional regulatory oversight, such as COI
- The research will be conducted internationally and/or research with a reliance agreement
- The investigator has had previous serious non-compliance or a pattern of non-compliance

Full Board protocols require continuing review.

Studies (regardless of review type) that have completed subject intervention/interaction and in which activity is limited to either final analysis of identifiable data/biospecimens or involve accessing follow-up clinical data from procedures that subjects undergo as part of clinical care.

Q. What is the 5-year update submission?

A. For studies that do not require continuing review, researchers must complete a submission at the 5-year mark to either close-out the protocol or confirm it is ongoing and active. This allows the IRB office to close protocols that are no longer active.