PROTOCOL CLOSURES	**SOP 7.1.01**

1. Purpose & Policy

This SOP provides guidance on the IRB process for closing protocols and the PI process for requesting to close protocols. See *IRB Policy Section 7.1*.

2. General Information

The responsibility for compliance with the IRB Policy and associated SOPs rests, first and foremost, with the Principal Investigator (PI). The PI is responsible for submissions of protocols and responding to IRB requests. Failure to submit protocols or respond to IRB requests in a timely manner may result in delays in research or withholding of research funds.

PIs have the responsibility of informing the IRB when a study has been completed. This requirement is for any study that initially underwent full committee review, expedited review, or exempt review. If not closed by the IRB for one of the reasons outlined in Section 4a, a protocol is considered to be open and active until the PI has notified the IRB via the IRB Protocol Application System (PAS) that the study has been completed.

PIs should not request to close a protocol if any of the below conditions apply. Such studies should remain active and continue to receive ongoing IRB review and approval:

- Enrollment and/or data collection at the Caltech-approved site is ongoing.
- Research-related interventions and/or follow-up at the Caltech-approved site is ongoing.
- Participant follow-up at the Caltech-approved site is ongoing.
- Data analysis that involves the use or access to personally identifiable information is ongoing.
- If there is an external study sponsor and the sponsor has not provided permission to close the study with the IRB.

If a PI is leaving Caltech, the PI is obligated to either transfer their protocols to another Caltech investigator via amendment, who then must be approved by the Caltech IRB, or close the protocol via the IRB PAS. The PI is responsible for ensuring the data and records for any studies are stored properly and used going forward according to the approved protocol.

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3. Training Requirements

Other than the normally required and study specific training for all human subjects research, there are no additional specific training requirements associated with the closure of protocols; however, investigators should carefully read and follow this guidance.

4. Procedure

A. Closures by the IRB

Failure to respond to any IRB action, memorandum, or request for information or modification within the below timeframes may result in closure of a pending application or active protocol.

1. Active Protocols (Renewals)

   Protocols will be closed 30 days after the expiration date if no communication is received from the PI or lab regarding renewal status.

2. Pending Applications (New)

   If an application is submitted but there is no response from the PI or lab within 2 weeks of the IRB's review and request for modifications, the protocol will be closed 30 days after the initial 2-week period.

3. Pending Applications (Amendments)

   If an amendment application is submitted but there is no response from the PI or lab within 2 weeks of the IRB's review and request for modifications, the amendment will be determined as Not Approved 30 days after the initial 2-week period. The protocol will revert back to its previous version.

4. Official Correspondence from the IRB

   Protocols may be suspended or closed within 30 days if no communication is received from the PI or lab in response to the correspondence.

In any of the situations described above, the IRB will notify the PI of the administrative closure via the IRB PAS or via email.

B. Closure Request by the PI

In order to close a Caltech IRB approved study, the PI needs to submit a Request to Close Protocol in PAS within 30 days of completion or termination of all research activities. The PI need not wait for the end of the study approval period to submit the study closure request to the IRB.

From the PAS Dashboard, click on *Request Close Protocol*, found in the Quick Links box.
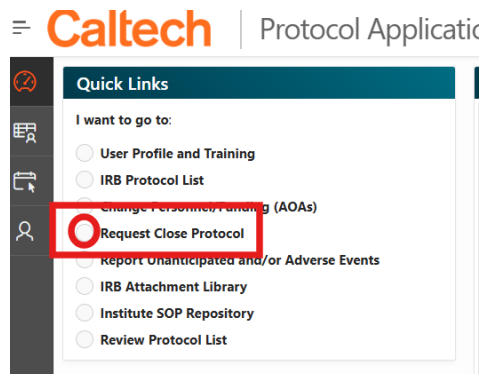
From the next page, click the pencil on the protocol to close.
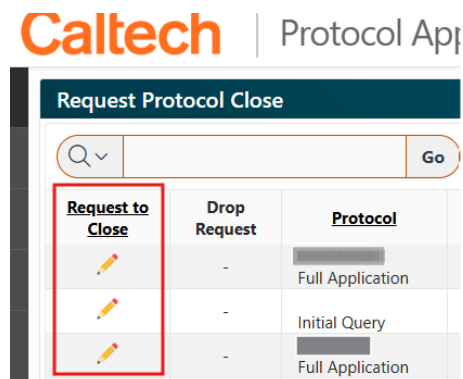
A pop-up window will appear. Enter the date of protocol closure and click *Save.*

The IRB will close the protocol per the requested closure date.