How to submit a study closure to the IRB

Procedure Number: 1706.12.01P

Applies to: All Franciscan Alliance Hospitals and all Franciscan Alliance Entities (See Entity Listing)

Procedure Statement:

Once the research activities are ended and the protocol is eligible for closure, a completion report is required for all research involving human subjects, including exempt, limited IRB review studies, expedited, and full board.

All submissions to the Franciscan Institutional Review Board must be made through the Franciscan REDCap system.

The Principal Investigator is responsible for ensuring the study closure is submitted as soon as the study is eligible for closure. Franciscan Research Administration is responsible for reviewing the submitted applications and documenting the review outcome.

Scope:

These procedures detail how to submit a study closure request to the Institutional Review Board (IRB).

Definitions:

See Research Services Program Acronyms and Definitions Reference

Reactivate. Reactivate describes the situation where the protocol reopening does not require approval by an IRB member to move the status of the site from closed to active.

Reapproval. Reapproval describes the situation where the protocol reopening requires an IRB member to review to decide to reopen the site.

Study Closure Submission. An application to request the IRB closes the research protocol.

Abbreviations:

FRA: Franciscan Research Administration
IRB: Institutional Review Board
PI: Principal Investigator

Procedure:

I. When is a study closure submission required?
   A. Completion reports are required for all research involving human subjects, including exempt, limited IRB review studies, expedited and full board.
   B. When can a study be closed? Protocol closure can occur when all of the following activities have concluded:
      1. Subject recruitment has concluded (i.e., no participant recruitment is in progress or anticipated);
      2. All subject specimens, records, and data have been collected (i.e., no further collection of data/information from or about living individuals is needed);
      3. All interactions or interventions with participants are completed (i.e., no further contact with the subject is necessary or anticipated); and
      4. Analyses of identifiable subject data, records, and specimens are finished (i.e., use of or access to identifiable subject data is no longer necessary).

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II. Starting a Study Closure Submission in REDCap.

A. There are two options for initiating a study closure report, depending on the study's expiration date and when the study is eligible for closure.

B. Option 1: Closure with Continuing Review Invitation Link

1. When 90 days prior to the expiration date is reached, a continuing review invitation will be sent to the PI and the secondary contract set in the initial application.
2. The survey invitation will include a link to your continuing review form. Click the link to open the application for your protocol.

C. Option 2: Request an Invitation Link. If your protocol is not due for a continuing review and you wish to close it, please email irb@franciscanalliance.org to request a study closure invitation. Click the link to open the application for your protocol.

D. For either option, click the invitation link to open the application.
*** To make the link work, be sure you are logged in through the VPN.***

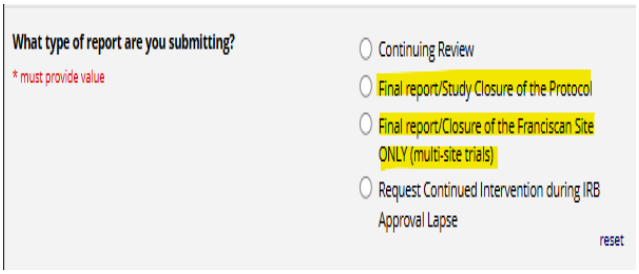
III. Complete the Submission Form.

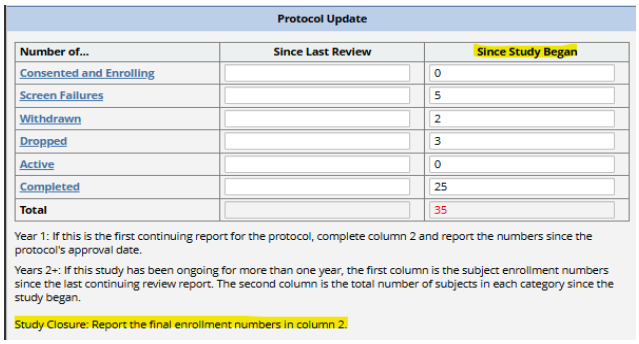
A. Answer the questions. These answers will open relevant sections of your application based on your answers.

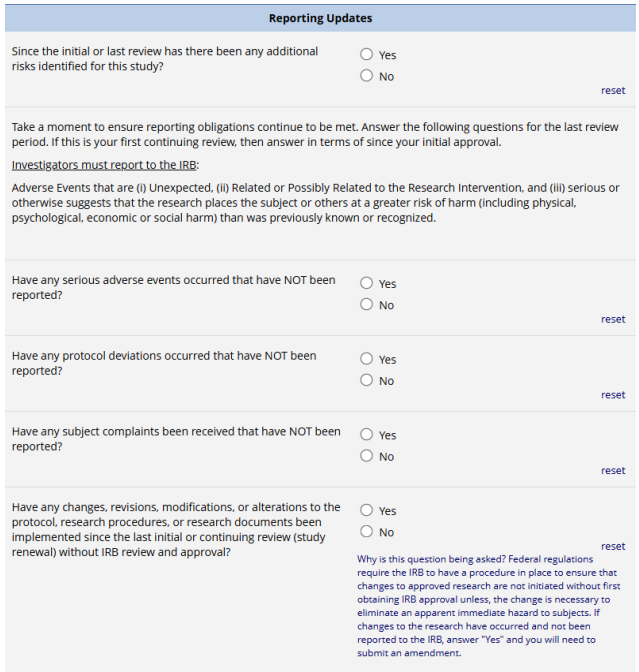
B. Submission Type: For a single-site protocol, select "Final report/Study Closure of the Protocol." For a multi-site protocol where the protocol remains active at other sites but is closing at Franciscan, select "Final report/Closure of the Franciscan Site."

C. Final Enrollment Numbers: Provide the final enrollment numbers for the protocol.

D. **Reporting Updates**: Provide a final report for the protocol.

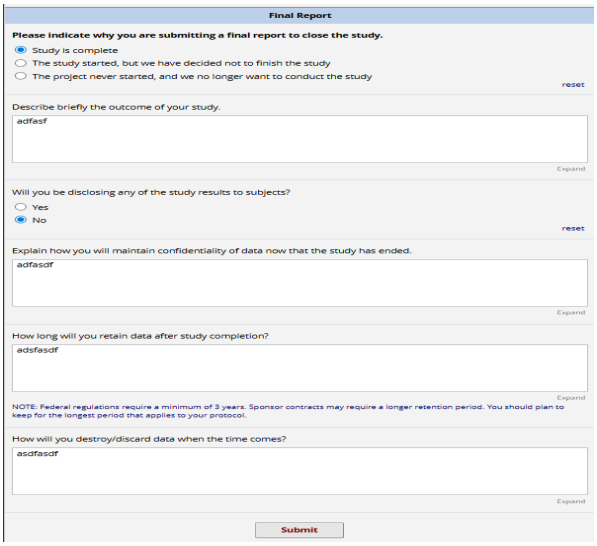






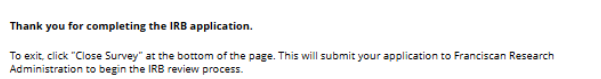
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E. **Final Report**: Answer the questions. Click Submit at the bottom of the page when done.



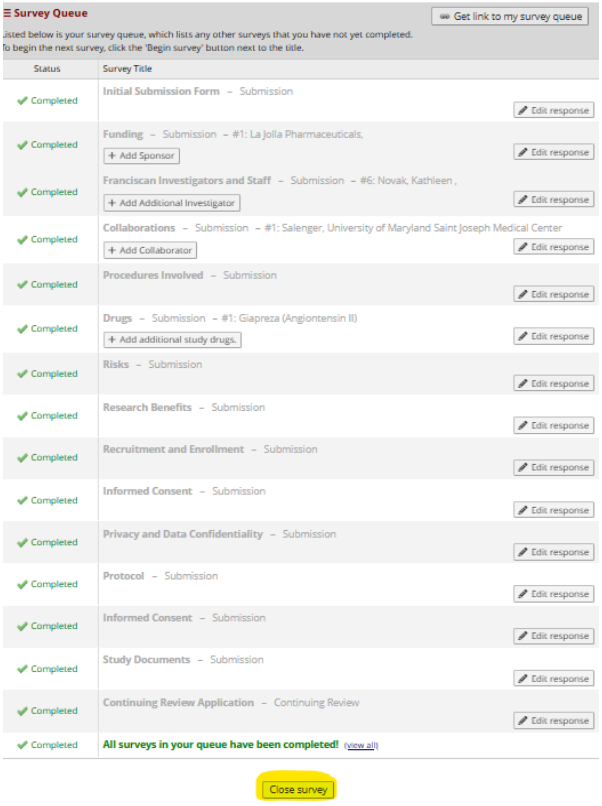
F. **Survey Queue**: You will then be taken to the survey queue.

G. **Completed and Submit the Application.** The survey queue will show completed as you work through the application form.



Edit response: This button allow you to return to any component and edit.

Once done, click Close survey button to submit the application.



See Policy:

1706.12 IRB Study Closure

See Related Documents:

None

See Attachments:

None

Notes: New Procedure