Procedure title: How to submit a continuing review submission to the IRB

Procedure Number: 1706.10.01P

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

Procedure Statement:

The IRB will conduct a continuing review of research, as required, at intervals appropriate to the degree of risk, but not less than once per year, for projects that require continuing review. 45 CFR 46.109(e); 21 CFR 56.109(f).

Investigators are responsible for: (1) Verifying all study personnel remain compliant with human research educational requirements; (2) Submitting the continuing review application in time for the IRB review prior to the study's expiration date; and (3) Providing sufficient and accurate information to the IRB for the determination of whether the criteria for approval of research continue to be met. IRB staff and members carry out these procedures.

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

The Principal Investigator is responsible for ensuring the continuing review application is submitted with enough time to complete the review prior to the study's expiration date. Franciscan Research Administration is responsible for reviewing the submitted applications and documenting the review outcome.

Scope: This Procedure provides instructions on how to submit a continuing review submission to the IRB.

Definitions:

See Research Services Program Acronyms and Definitions Reference

Not less than once per year. The research must be reviewed before the one-year anniversary of the previous IRB approval date, even though the research activity may not have begun until after the IRB gave its approval.

Abbreviations:

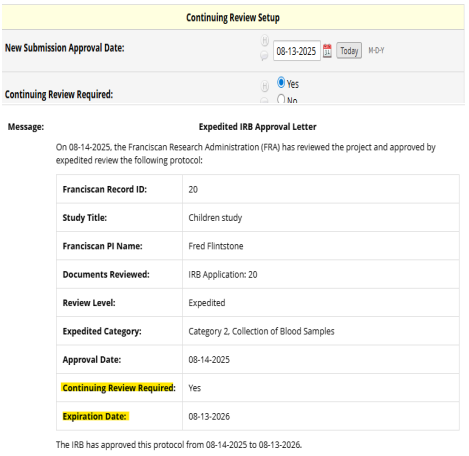
CR: Continuing Review
FRA: Franciscan Research Administration
IRB: Institutional Review Board
PI: Principal Investigator

Procedure:

I. **Continuing Review Required:**

Federal regulations require the IRB to conduct a meaningful continuing review not less than once per year when required.

When is a Continuing Review required? Expedited, Full Board research projects, and projects where the IRB has determined



Continuing Review Setup

New Submission Approval Date: 08-13-2025 Today M-D-Y

Continuing Review Required: Yes No

Message: **Expedited IRB Approval Letter**

On 08-14-2025, the Franciscan Research Administration (FRA) has reviewed the project and approved by expedited review the following protocol:

Franciscan Record ID:	20
Study Title:	Children study
Franciscan PI Name:	Fred Flintstone
Documents Reviewed:	IRB Application: 20
Review Level:	Expedited
Expedited Category:	Category 2, Collection of Blood Samples
Approval Date:	08-14-2025
Continuing Review Required:	Yes
Expiration Date:	08-13-2026

The IRB has approved this protocol from 08-14-2025 to 08-13-2026.

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continuing review is necessary.

When finalizing your protocol approval, IRB staff will mark if the protocol requires a continuing review. The approval letter will indicate if continuing review is required.

II. **Protocol Expiration Date**

Expiration period: The IRB approval period may not extend past 365 days after the research was last approved. The expiration date is set at 364 days after the date of initial approval, unless the IRB determines a shorter period is required.

The letter of approval will show the protocol's expiration date.

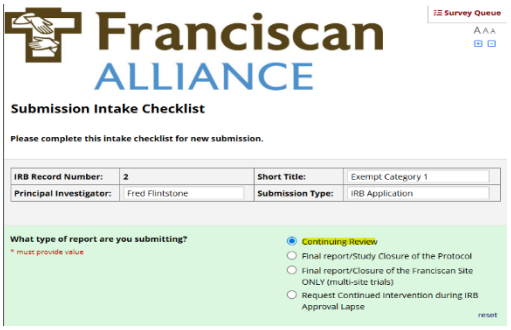
No grace period. Federal regulations permit no grace period and no exceptions to the one-year requirement. Extensions beyond the expiration date cannot be granted.

III. **Continuing Review Reminder**: From the expiration date, a 90-day reminder date is calculated. When the 90-day reminder is reached, a continuing review invitation will be sent to the PI and the secondary contract set in the initial application.

The survey invitation will include a link to your continuing review form. Click the link to open the continuing review application for your protocol. *** To make the link work, be sure you are logged in through the VPN.***

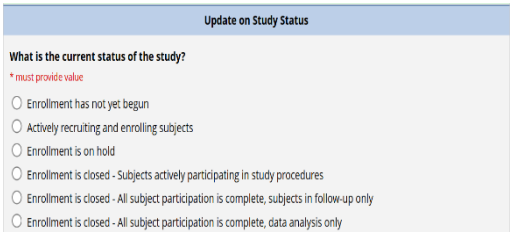
IV. **Application**

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



Submission Type: If you need to continue the active protocol, select "Continuing Review". If you do NOT need to continue the active protocol, select a final report option to close the protocol. See How to submit a study closure to the IRB instructions.

V. **Reporting Updates**: Provide an update on the protocol.



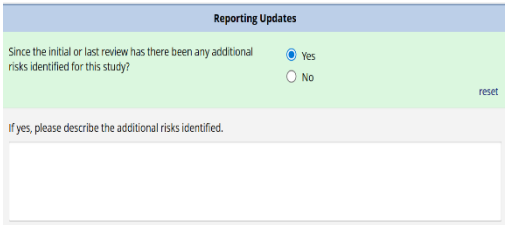
Update on Study Status: Select the current enrollment status for the protocol. If actively recruiting, enter the subject numbers for each group.



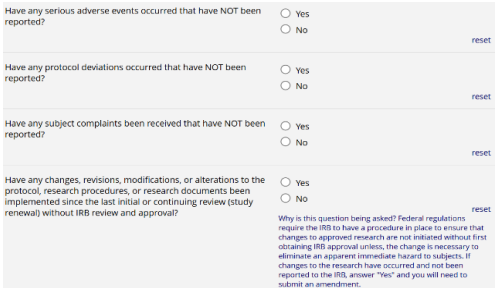
Number of...	Since Last Review	Since Study Began
Consented/Enrolled		
Screen Failures		
Withdrawn		
Dropped		
Active		
Completed		
Total		

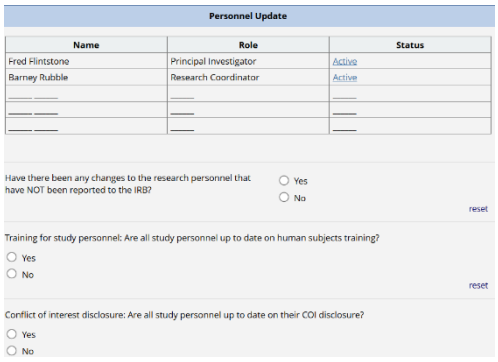
If this study has been ongoing for more than one year, the first column is the subject enrollment numbers since the last continuing review report. The second column is the total number of subjects in each category since the study began.

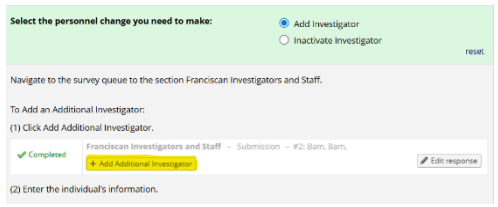
If this is the protocol's first continuing review report, complete column 2 and report the numbers since its approval.

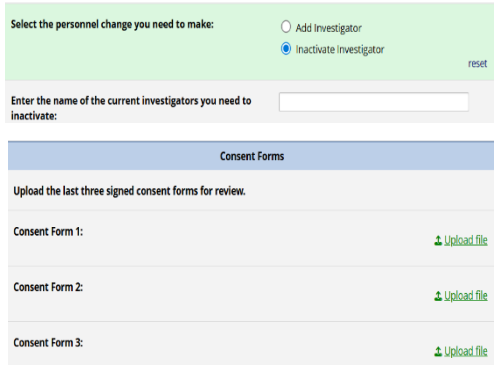


New Risks: Review the current list of risks and evaluate if any new risks have been identified since the protocol's approval or last continuing review report. If yes, describe the new risks identified.









Reporting: Review the protocol files to ensure all events have been reported to the IRB as required. If all events have been reported, answer "No." If any event has not been reported, answer "Yes" and follow-up with a report of the unreported event.

Personnel Update: The application will display the personnel as entered from the initial application or as updated through amendment (personnel changes). Review this information and verify that the study personnel are up-to-date. If not, then you will be prompted to update the study personnel.

Check records to verify that training and conflict of interest disclosures for study staff are up-to-date.

Adding new study personnel through CR form: Select "Add investigator." Instructions will be displayed on how to use the survey queue to navigate to the Franciscan Investigators and Staff section of the protocol. Click Add Additional Investigator to enter the information for the new investigator.

Inactivating study personnel through CR form: Enter the name of the study staff you want to inactivate. Once your CR is received, IRB staff will update the investigator's status in your protocol.

VI. **Consent Review.** To meet regulatory requirements that the continuing review be substantial and meaningful, the study team will submit to the IRB for review the last three (3) signed consent forms used to enroll subjects.

When is the consent review required? For protocols where:

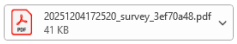
- Consent not waived: Consent process or consent documentation is not waived by the IRB.
- No active external monitoring: Studies where no active monitoring of sponsors is performed.
- Current IRB status: Studies where the status is actively enrolling subjects.
- Enrolled/reconsented subjects: Studies where consent forms were signed within the last continuing review period.

If your study meets the criteria for consent review, you will be prompted to upload your last three (3) signed consent forms.

Upload the last 3 signed consent forms. File type accepted: PDF file or image file (JPG, JPEG, GIF, PNG, TIF, BMP)

VII. **Completed and Submit the Application**

Once done, click Close survey button at the bottom of the page to submit the application.
Submission verification: You will receive an automated email confirming your application submission.



Dear Research Staff,

This is an automatic email confirming the following application has been submitted to the IRB for review:

Franciscan Record ID:	4
Study Title:	Expedited Protocol
Franciscan PI Name:	Rebecca Ballard
Submission Type:	Continuing Review

Action required: None.

IRB staff will contact you to provide updates to the submission process.

Best regards,

Franciscan Research Administration

See Policy:

1706.10 Continuing Review

See Related Documents:

None

See Attachments:

None

Notes: New Procedures