How to submit a Request to Rely

Procedure Number: 1706.04.01P

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

Procedure Statement:

Each institution is responsible for safeguarding the rights and welfare of human subjects in the conduct of cooperative or multi-site research projects. To avoid duplication of IRB review, federal regulations (45 CFR 46.114) allow for reliance agreements between institutions for cooperative research. In some cases, the use of a single IRB for cooperative or multi-site research is mandated by federal granting agencies.

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

All users are required to abide by all applicable regulations, policies and procedures governing research activities and proper use of computer systems to collect, store, protect and use data within REDCap.

Principal Investigators (PIs)/project owners are responsible for ensuring that their team members/project users comply with this procedure to submit IRB applications properly. Franciscan Research Administration is responsible for reviewing the submitted applications and documenting the review outcome.

Scope: This procedure outlines the process by which study staff can request that the Franciscan IRB rely on another IRB for the ethical review of their research study in REDCap.

Definitions:

See Research Services Program Acronyms and Definitions Reference

Assured Institution. The institution participating in human subjects research that has an active Federal-wide Assurance with OHRP.
Collaborating Independent Investigator. A collaborating independent investigator is:

A. not otherwise an employee or agent of the assured institution;
B. conducting collaborative research activities outside the facilities of the assured institution; and
C. not acting as an employee of any institution with respect to his or her involvement in the research being conducted by the assured institution.

Collaborating Institution Investigator. A collaborating institutional investigator is:

B. not otherwise an employee or agent of the assured institution;
C. conducting collaborative research activities outside the facilities of the assured institution;
D. acting as an employee or agent of a non-assured institution with respect to his or her involvement in the research being conducted by the assured institution; and
E. employed by, or acting as an agent of, a *non-assured institution* that does not routinely conduct human subjects research.

Cooperative Research. Projects that involve more than one institution. 45 CFR 46.114(a).
Funding Institute or Center (IC). Funding ICs are responsible for management and oversight of the award, including communicating with the awardee regarding the implementation of its proposed plan to comply with the sIRB Policy. If questions arise about the awardee's plan, including the IRB that has been selected to serve as the sIRB, the funding IC will work with the awardee to resolve them.
Individual Investigator Agreement (IAA). An agreement for a collaborating independent investigator engaged in research activities to collaborate with a FWA institution and who are not acting as employees of any institution with respect to the research activities.
IRB of Record (another name for the Single IRB or Reviewing IRB). The Institutional Review Board who will oversee the conduct of research.
Lead Principal Investigator (PI). The PI responsible for the conduct of the entire study, including all the research sites. The PI at the lead site is accountable for the overall conduct, while the PI at a relying institution is only accountable for the research conducted at his/her institution.
Local IRB (also known as Internal IRB or Relying IRB). The Institutional Review Board within the institution engaged in research.
Local Principal Investigator (PI). The PI responsible for the conduct of the research at a particular research site.

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Multi-site study. A study that uses the same protocol to conduct non-exempt human subjects research at more than one site.

Non-assured Institution. An institution that does not have an active FWA with OHRP.

Participating site. A domestic entity in a multi-site study that will rely on the Single IRB (sIRB) to carry out the site's IRB review of human subjects research.

Point of Contact (POC). An individual generally responsible for being the conduit of information, representing the local site, whether it is a lead or a relying institution. The Point of Contact could represent the lead study team coordinator or the IRB staff member identified as the point of contact. The Point of Contact is responsible for facilitation of communication between either the research study team(s) involved in the study or the communication between the IRB of Record and the Relying IRB.

Principal Investigator (PI). The individual in charge of the research project, responsible for preparing and carrying out the study protocol.

A. For a Non-employee Physician PI: The individual must be directly affiliated with Franciscan Alliance, Inc., have privileges at Franciscan, and have sufficient authority, appropriate background, knowledge, training, and accountability to carry out all aspects of the project.

Reliance Agreement (also known as Institutional Authorization Agreement). An agreement that documents the authorities, roles, responsibilities and communication expectations between the institution providing the ethical review and the institution relying on the single IRB.

Relying Institution. The institution relying on the sIRB to perform the ethical review.

Relying Study Team. The study team that is relying on review by an IRB outside of their institution. It is the responsibility of the Relying Study Team to designate a single Point of Contact who will serve as the communication portal with other Relying Site IRBs and the Lead Site IRB.

Relying IRB (also known as local IRB). The IRB not designated as the IRB of record and accepts the review of the IRB of record. The Institutional Review Board at the relying institution that relies on the sIRB.

Single IRB (sIRB) (also known as Central IRB or Reviewing IRB). The Institutional Review Board that provides the ethical review for all institutions participating in the cooperative or multi-site research.

Abbreviations:

DHHS: Department of Health and Human Services
FRA: Franciscan Research Administration
FWA: Federal Wide Assurance
HSR: Human Subjects Research
IAA: Institutional Authorization Agreement
IC: Funding Institute or Center
IO: Institutional Official
IRB: Institutional Review Board
OHRP: Office for Human Research Protections
PI: Principal Investigator
POC: Point of Contact
sIRB: Single IRB

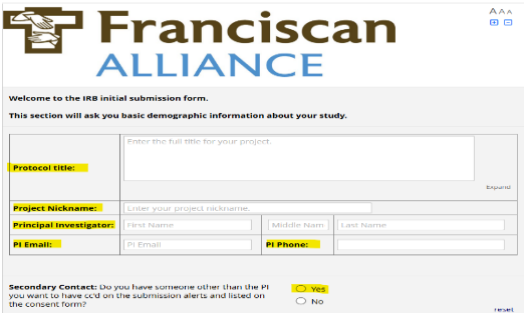
Procedure:

I. Start New Submission

A. To start a new submission, click this link: New Submission. This action will open the initial submission form in REDCap.

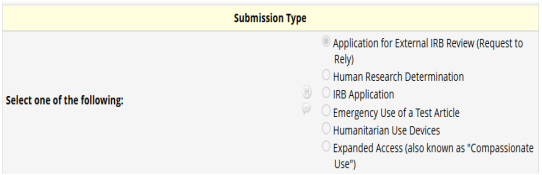
B. VPN: The user must be logged in to the Franciscan VPN to be able to access REDCap.

II. **Basic demographic information**: Enter basic demographic information about your project, such as the project title, a short project nickname, Principal Investigator and their contact information. The PI and secondary contact person's email will be used to send the IRB submission notifications, such as review progress updates and determination letters.

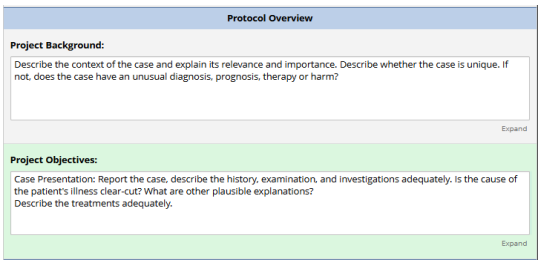


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III. **Submission Type:** To request the Franciscan IRB rely on another IRB, select "Application for External IRB Review (Request to Rely)".

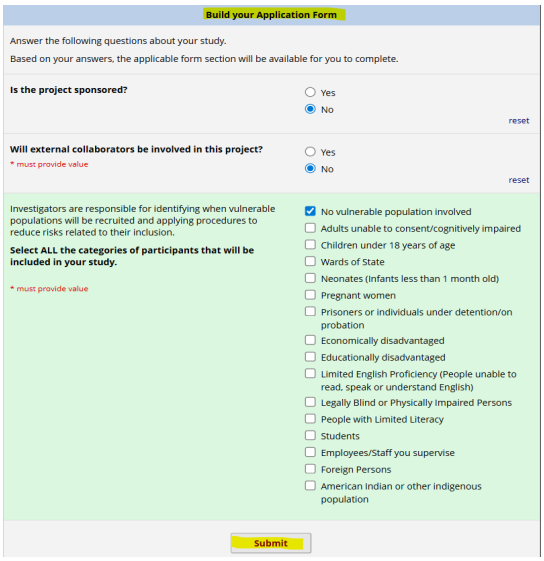


IV. **Project Overview:** Answer the questions. These answers will open relevant sections of your application based on your answers.

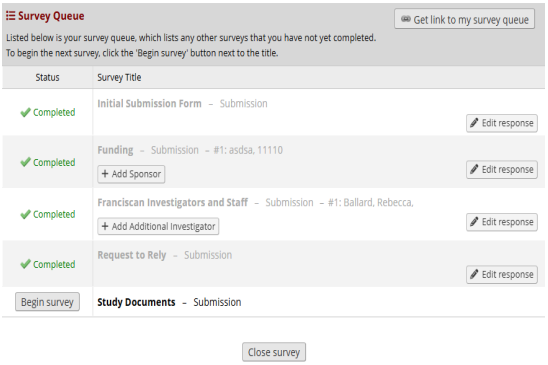


V. **Build your Application Form:** Answer the questions. These answers will open relevant sections of your application based on your answers.

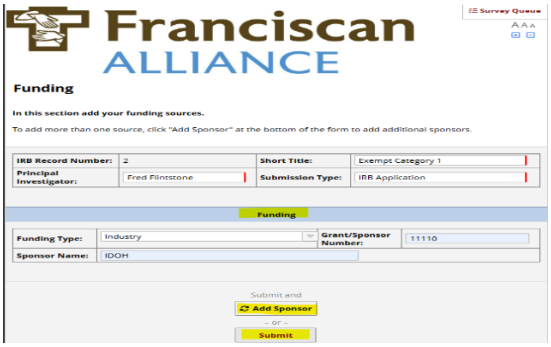
Hit Submit at the bottom of the form when this page is completed.



VI. **Survey Queue:** You will then be taken to the survey queue. Think of the survey queue as your to-do list for submitting a complete application.
Click Begin survey button to be taken to that page.
ORDER: Your answers provided may determine what questions you see or pre-populate other fields. So, start from the top to the bottom of the survey queue.



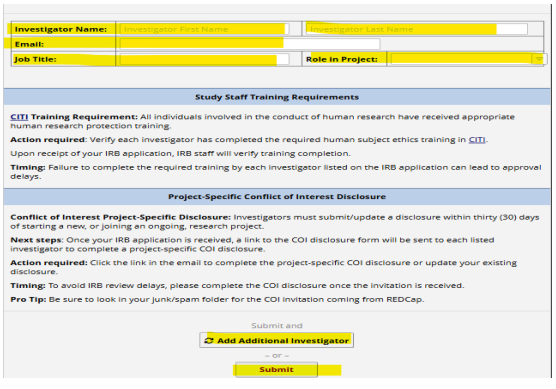
VII. **Funding.**
If you selected that your study was funding, you will go to the funding form to enter the details on the study sponsor. This is a repeating form – meaning you can add more than one sponsor. Click Add Sponsor to be presented with a second form to add an additional funding source.
Click Submit when done with entering funding information.



VIII. **Franciscan Investigators and Staff.** In this section, you will provide details on the members of the Franciscan research staff. Non-Franciscan researchers will be in the subsequent collaborations section.

Answer the question for each individual study staff.

This is a repeating form – meaning you can add more

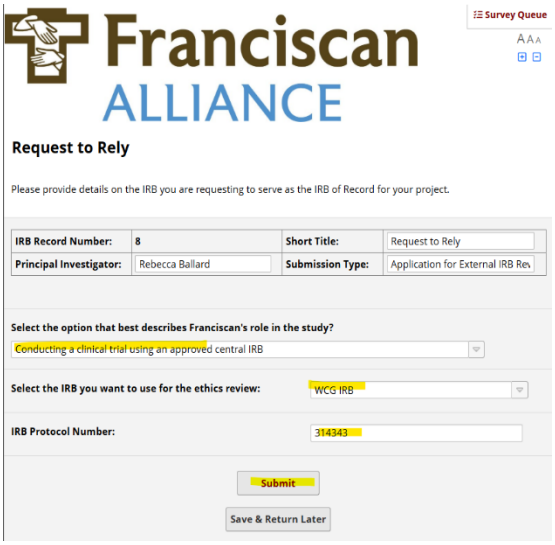


than one study staff. Click Add Additional Investigator to be presented with a second form to add an additional staff member.

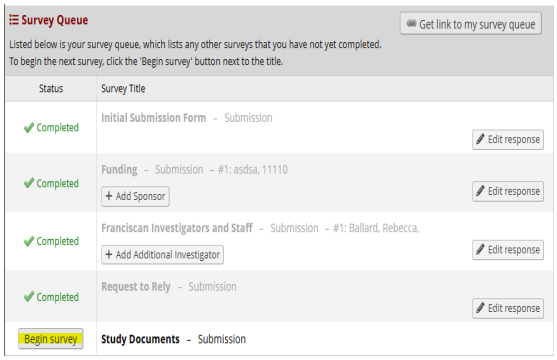
Click Submit when done entering the staff member's information.

IX. **Request to Rely.** Enter information related to the IRB you would like to use as the IRB of Record.

Click Submit when done.



X. **Study Documents**. This final form will allow you to attach any supporting documents to your application for review.
Click Begin Survey to open this section.

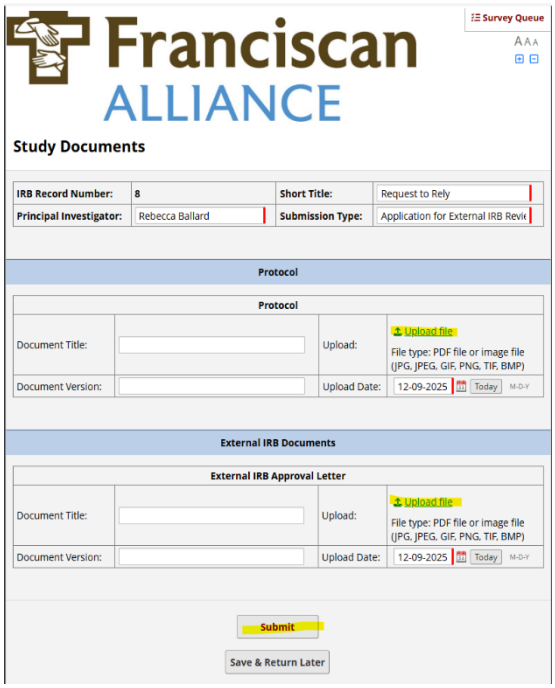


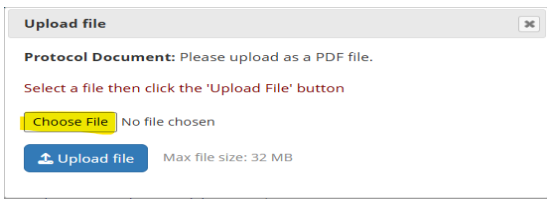
XI. **Upload the protocol:**

Click Upload File to add the supporting documents.

Once uploaded, it will present the file and default to today as the upload date. Enter in the document title and document version to help tracking document version.

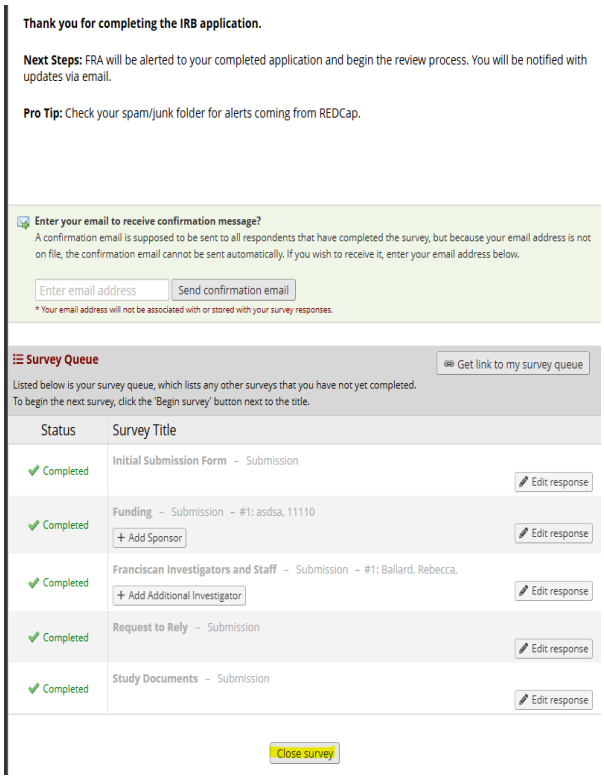
Repeat this upload process for the remaining study documents. Click submit when all documents are uploaded.





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

Edit response: This button allows you to return to any component and edit.
Once done, click Close survey button to submit the application.



See Policy:

1703.04 Multi-Site Trials and IRB of Record

See Related Documents:

None

See Attachments:

None

Notes: New Procedure.