How to Submit a QI Submission

Procedure Number: 1706.03.03P

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

Procedure Statement:

Research involving human participants must be reviewed and approved by an IRB before any activity may begin. If there is any question as to whether an activity constitutes "human subjects research," it is advisable to seek a determination by the IRB rather than the individual project personnel.

The Not Human Subjects (NHS) determination must be made by the IRB or IRB designee prior to the performance of research activities and/or enrollment of human participants or procurement of identifiable information of living participants.

Federal regulations do not allow for retroactive IRB approval. Failure to secure IRB approval of the project that would constitute research involving human subjects will be considered as research conducted without IRB approval.

All submissions to the Franciscan Institutional Review Board must occur 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 (PI)/project owners are responsible for ensuring that their team members/project users comply with this procedure to properly submit IRB applications. Franciscan Research Administration is responsible for reviewing the submitted applications and documenting the review outcome.

Scope: This Procedure reviews how to submit a quality improvement project to the IRB in REDCap for a not human subjects determination.

Definitions:

See Research Services Program Acronyms and Definitions Reference

Non-Human Subjects (NHS) Determination. A decision that the project does not fall within the regulatory definition of research or involving human subjects. A non-human subjects determination indicates that the Common Rule does not apply and the IRB has no oversight of the activities.

Quality Improvement Project. Quality improvement (QI) is a systematic, formal approach to the analysis of practice performance and efforts to improve performance.

Research. A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research, whether or not they are conducted or supported under a program that is considered research for other purposes. 45 CFR 46.102(l).

Abbreviations:

FRA: Franciscan Research Administration
IRB: Institutional Review Board
NHS: Not Human Subjects Research
PI: Principal Investigator
QI: Quality Improvement

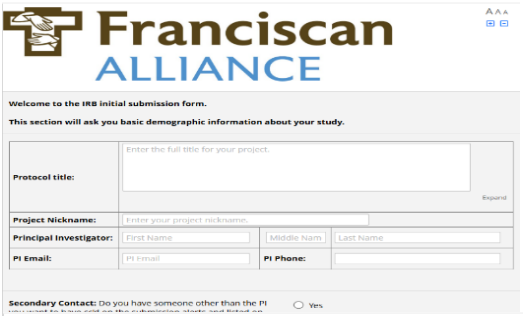
How to Submit a QI Submission

Procedure:

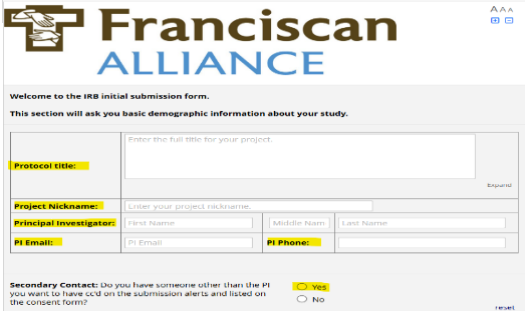
I. Start New Submission

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.

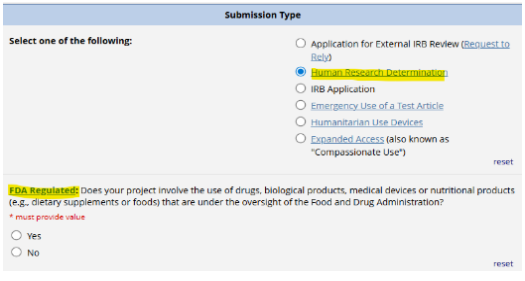


II. **Basic demographic information**: Enter basic demographic information about your project, such as the project title, a short project nickname, Principal Investigator and their contact information. The PI and secondary contact person's email will be used to send the IRB submission notifications,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

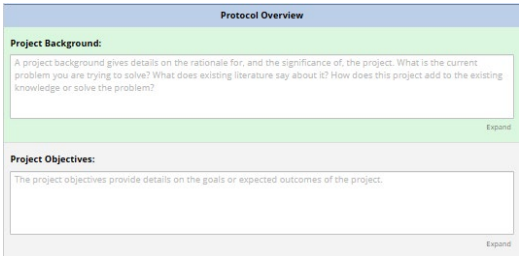


III. **Submission Type:** Quality Improvement Projects are typically not considered research. To verify this for your project, you will submit Human Research Determination as the submission type.

This will open the question to verify the project is not FDA-Regulated. For case reports, you will answer "no".

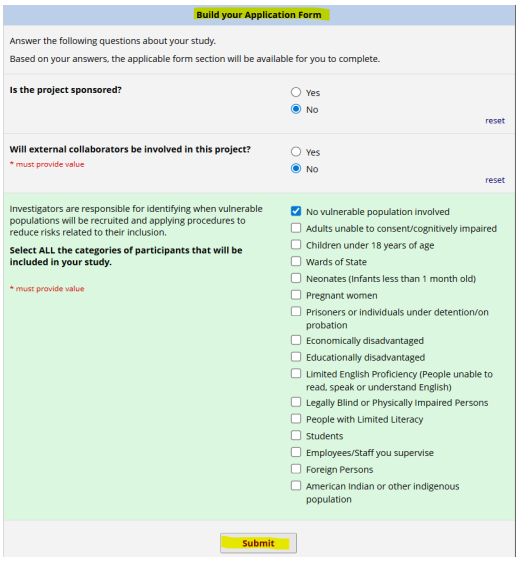


IV. **Project Overview:** Answer the questions. These answers will open relevant sections of your application based on your answers.

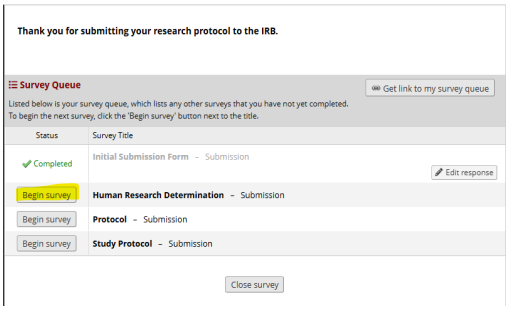


V. **Build your Application Form:** Answer the questions. These answers will open relevant sections of your application based on your answers.

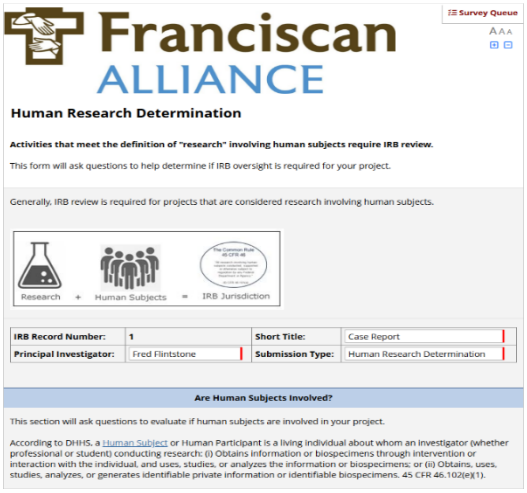
Hit Submit at the bottom of the form when this page is completed.



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.

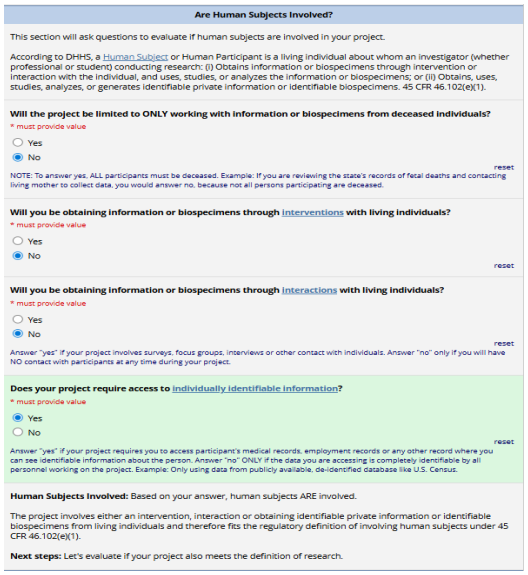


VI. **Human Research Determination Survey**. Click the Begin survey next to the Human Research Determination form (shown above). This will open the Human Subject Determination form.
Some background on the regulations related to this request is displayed.



VII. **Are Human Subjects Involved?** The first section will determine if human subjects are involved in your project. Answer these questions.

QI projects involve either interactions with individuals or their individually identifiable data. It is not unusual to get a determination that humans are involved in the project.



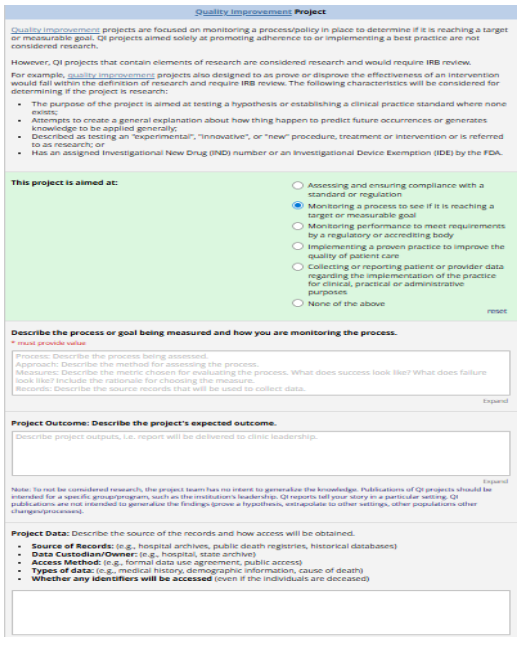
VIII. **Is it research?** The second section of this form will determine if the project is considered research under the regulatory definition.

QI projects are typically considered as not "research" under the Common Rule. Select Quality Improvement Project Report. This will then open the next section to provide additional information relevant to a QI project.



IX. **Quality Improvement Project**. QI projects typically do not fall under the definition of research under the Common Rule. The project cannot be a systematic investigation intended to contribute to generalizable knowledge.

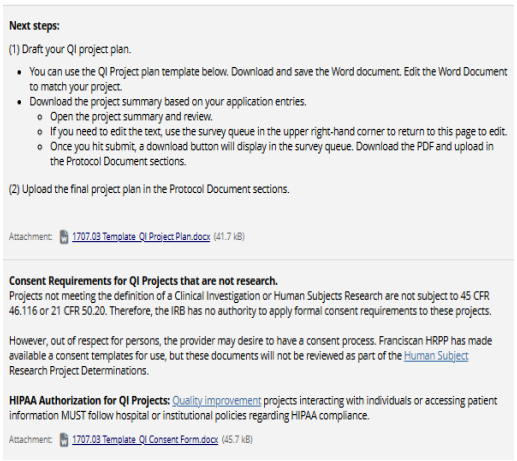
Enter details about your project.



X. **Consent requirements for QI Projects**
The Common Rule does not apply and, therefore, cannot require consent.

However, for projects with interactions, you may want to secure consent out of basic respect for persons. A consent template will be available.

Use of PHI. Even if the human subjects regulations do not apply, HIPAA still applies. And patient authorization may be required. A template consent/HIPAA Authorization is provided.



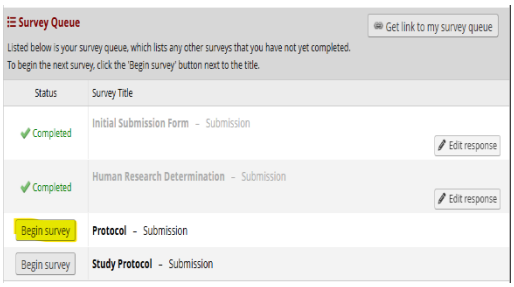
XI. **Protocol**. This form takes the information you have entered into the form this far and drafts your protocol.

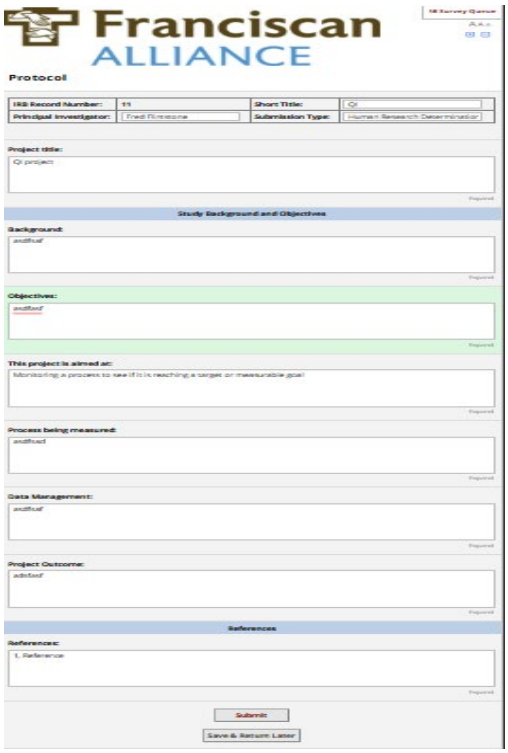
Click Begin Survey to open the protocol builder.

This will present a form where your previous answers are displayed in each section. You can then edit that information within this form. This will create for you a protocol document.

Edit the protocol.

Click Submit when done at the bottom of the form.

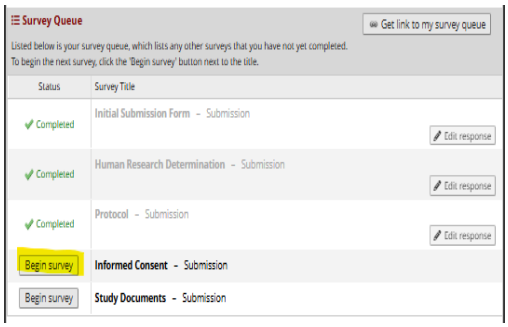




XII. **Informed Consent**: This form takes the information you have entered into the form this far and drafts the consent form.

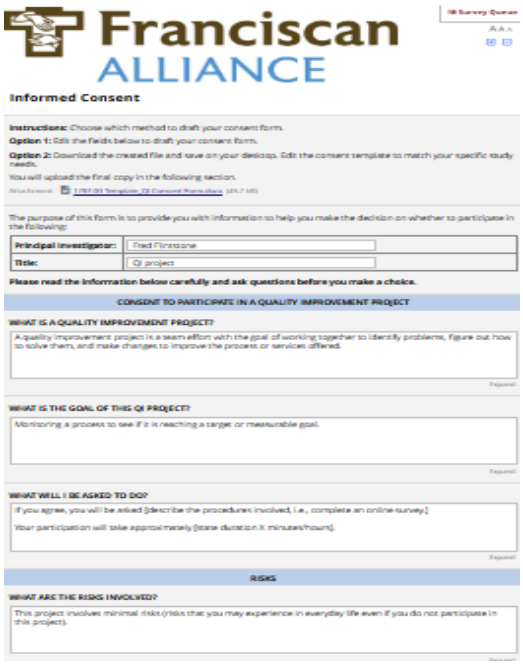
Click Begin Survey to open the consent builder.

This will present a form where your previous answers are displayed in each section. You can then edit that information within this form. This will create for you a consent document.



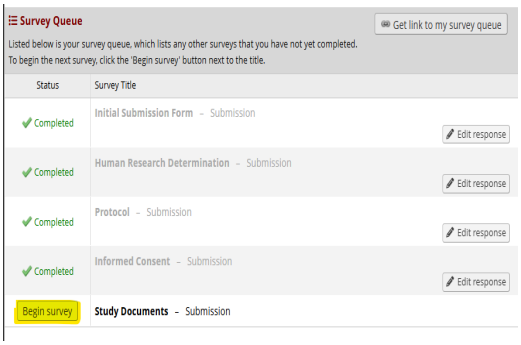
Edit the consent
Click Submit when done at the bottom of the form.

This will present a form where your previous answers are displayed in each section. You can then edit that information within this form. This will create for you a consent document in the next section.



XIII. **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.



XIV. **Upload the protocol:** Two options are detailed.

Option 1: Use Protocol Builder.
You can download the PDF you just built using the REDCap protocol builder and upload it as your final protocol to submit.

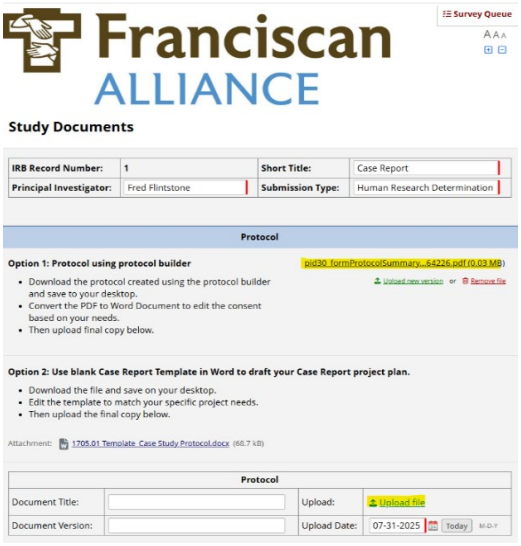
To download: Click the link on the protocol document title. The PDF will then save in your computer's download folder.

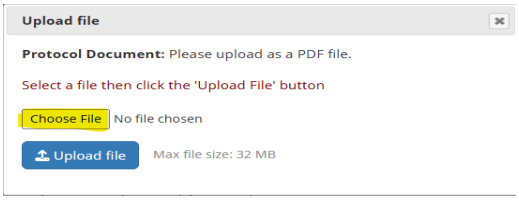
To upload: Click Upload File in REDCap. This will open a window allowing you to choose the file downloaded on your computer.

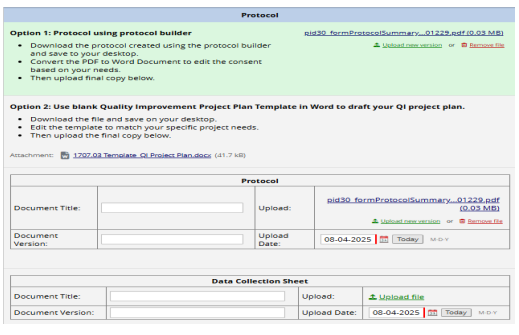
Find the file. Click Upload file.

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.



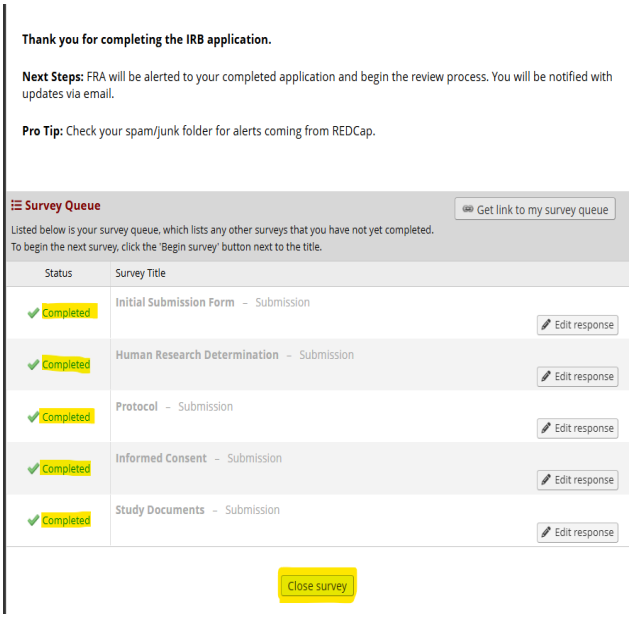




XV. **Completed and Submit the Application.** The survey queue will show completed as you work through the application form.

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:

1706.03 Human Subjects Research Determinations

See Related Documents:

1706.03 Template, QI Project Plan
1706.03 Template, QI Consent Form
1706.03 Template, QI consent with broad consent

See Attachments:

None

Notes: New Procedure.