How to submit a Case Report to IRB

Procedure Number: 1706.03.01P

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 case report to the IRB in REDCap for a not human subjects determination.

Definitions:

See Research Services Program Acronyms and Definitions Reference

Case Report. A single case report or case series (three or fewer cases) does not constitute human subjects research requiring review and approval by the Franciscan IRB.

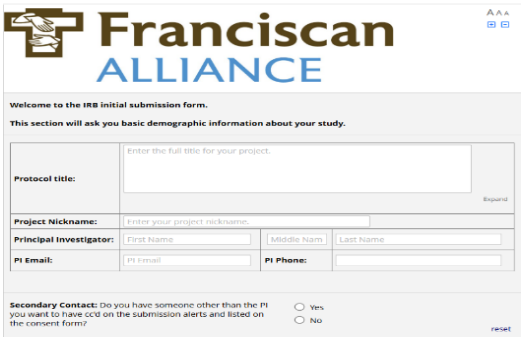
Non-Human Subjects (NHS) Determination. A decision that the project does not fall within the regulatory definition of research or involving human subjects. A non-human subjects determination indicates that the Common Rule does not apply and the IRB has no oversight of the activities.

Abbreviations:

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

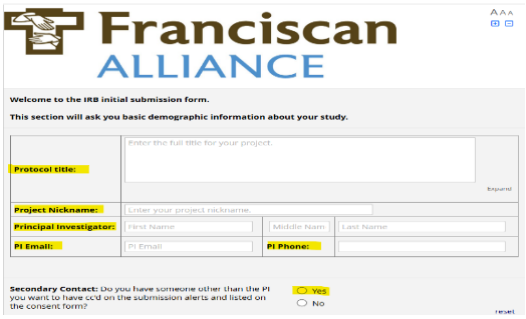
Procedure:

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.

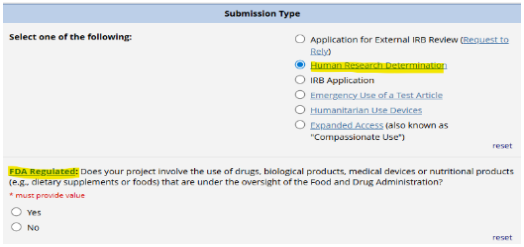


B. VPN: The user must be logged in to the Franciscan VPN to be able to access REDCap.

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.

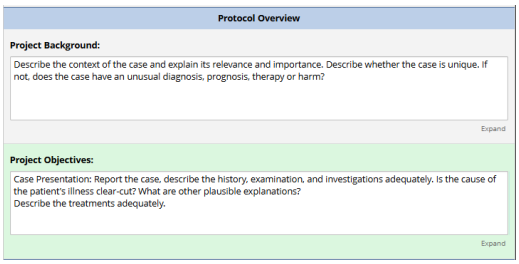


III. **Submission Type:** Case reports are typically not considered research. To verify this for your project, you will submit Human Research Determination as the submission type.



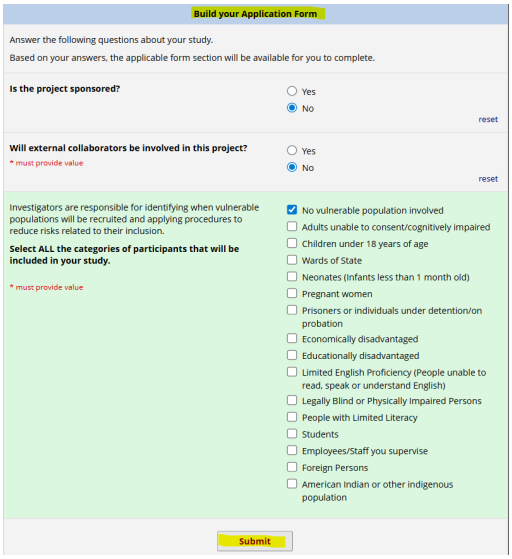
This will open the question to verify the project is not FDA-Regulated. For case reports, you will answer "no".

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



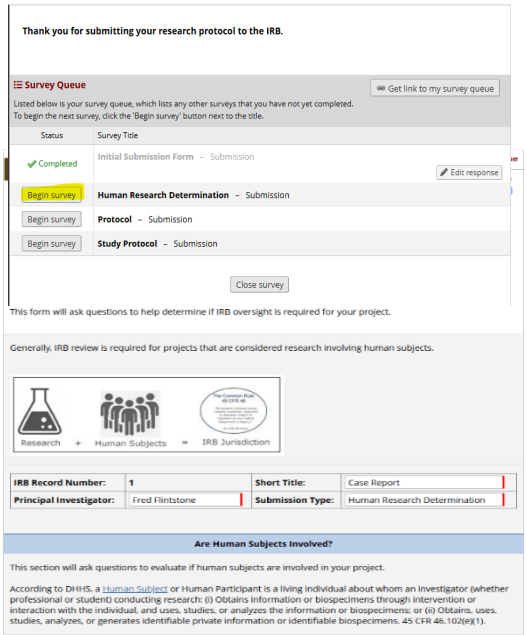
V. **Build your Application Form:** Answer the questions. These answers will open relevant sections of your application based on your answers.

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



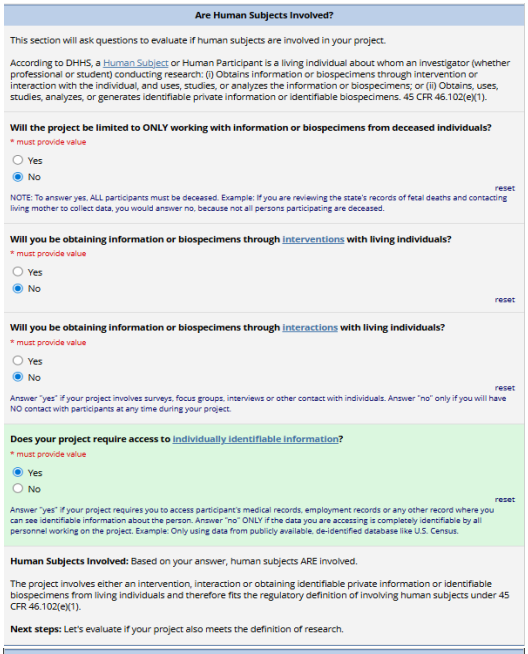
VI. **Survey Queue:** You will then be taken to the survey queue. Think of the survey queue as your to-do list for submitting a complete application.
Click Begin survey button to be taken to that page.
ORDER: Your answers provided may determine what questions you see or pre-populate other fields. So,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

VII. **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.

VIII. **Are Human Subjects Involved?** The first section will determine if human subjects are involved in your project. Answer these questions. Displayed to the right are responses typical of a case report study.



Are Human Subjects Involved?

This section will ask questions to evaluate if human subjects are involved in your project.

According to DHHS, a Human Subject or Human Participant is a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. 45 CFR 46.102(e)(1).

Will the project be limited to ONLY working with information or biospecimens from deceased individuals?
* must provide value
- Yes
- (•) No

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NOTE: To answer yes, ALL participants must be deceased. Example: If you are reviewing the state's records of fetal deaths and contacting living mother to collect data, you would answer no, because not all persons participating are deceased.

Will you be obtaining information or biospecimens through interventions with living individuals?
* must provide value
- Yes
- (•) No

reset

Will you be obtaining information or biospecimens through interactions with living individuals?
* must provide value
- Yes
- (•) No

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Answer "yes" if your project involves surveys, focus groups, interviews or other contact with individuals. Answer "no" only if you will have NO contact with participants at any time during your project.

Does your project require access to individually identifiable information?
* must provide value
- (•) Yes
- No

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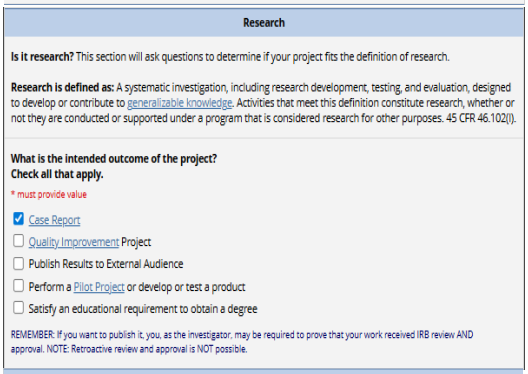
Answer "yes" if your project requires you to access participant's medical records, employment records or any other record where you can see identifiable information about the person. Answer "no" ONLY if the data you are accessing is completely identifiable by all personnel working on the project. Example: Only using data from publicly available, de-identified database like U.S. Census.

Human Subjects Involved: Based on your answer, human subjects ARE involved.

The project involves either an intervention, interaction or obtaining identifiable private information or identifiable biospecimens from living individuals and therefore fits the regulatory definition of involving human subjects under 45 CFR 46.102(e)(1).

Next steps: Let's evaluate if your project also meets the definition of research.

IX. **Is it research?** The second section of this form will determine if the project is considered research under the regulatory definition. Case reports are typically considered as not "research" under the Common Rule. Select Case Report. This will then open the next section to provide additional information relevant to a case report.



Research

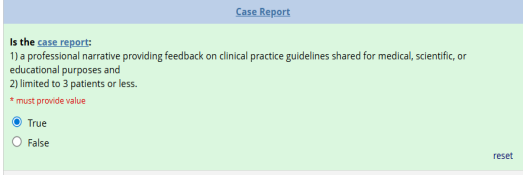
Is it research? This section will ask questions to determine if your project fits the definition of research.

Research is defined as: 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).

What is the intended outcome of the project?
Check all that apply.
* must provide value
- [x] Case Report
- [ ] Quality Improvement Project
- [ ] Publish Results to External Audience
- [ ] Perform a Pilot Project or develop or test a product
- [ ] Satisfy an educational requirement to obtain a degree

REMEMBER: If you want to publish it, you, as the investigator, may be required to prove that your work received IRB review AND approval. NOTE: Retroactive review and approval is NOT possible.

X. **Case Report**. To not fall under the definition of research under the Common Rule the project cannot be a systematic investigation.



Case Report

Is the case report:
1) a professional narrative providing feedback on clinical practice guidelines shared for medical, scientific, or educational purposes and
2) limited to 3 patients or less.
* must provide value
- (•) True
- False

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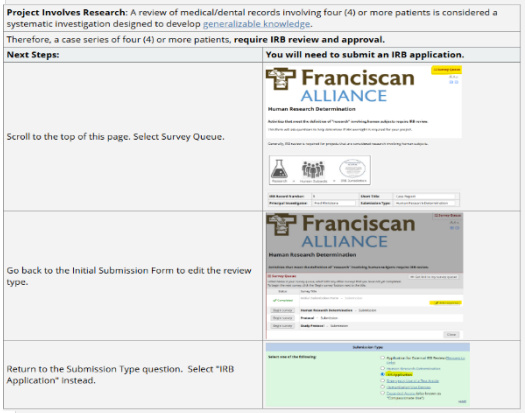
Not Research: Case reports are not considered research under 45 CFR 46.102 because it does not involve a systematic investigation when it involves less than 3 patients.

Next steps: The next page will build a protocol template based on the information you have provided. You can download this template and upload in the Study Protocol Form or upload your own case report protocol. Submit your application.

Three patients or less: Case reports must be limited to 3 patients or less. Answer the first question to verify your project fits this definition. If true, you will then be prompted to complete the case report protocol template.

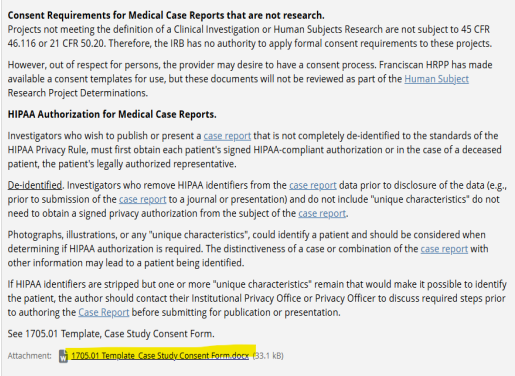
More than 3 patients: Answer False as shown to the right.

You will be prompted to follow the next steps to reroute your application to an IRB submission:



Project Involves Research: A review of medical/dental records involving four (4) or more patients is considered a systematic investigation designed to develop generalizable knowledge. Therefore, a case series of four (4) or more patients, **require IRB review and approval.**	
Next Steps:	**You will need to submit an IRB application.**
Scroll to the top of this page. Select Survey Queue.	Franciscan ALLIANCE Human Research Determination
Go back to the Initial Submission Form to edit the review type.	Franciscan ALLIANCE Human Research Determination
Return to the Submission Type question. Select "IRB Application" instead.	

XI. **Consent requirements for medical case reports that are not research**



Consent Requirements for Medical Case Reports that are not research.
Projects not meeting the definition of a Clinical Investigation or Human Subjects Research are not subject to 45 CFR 46.116 or 21 CFR 50.20. Therefore, the IRB has no authority to apply formal consent requirements to these projects.

However, out of respect for persons, the provider may desire to have a consent process. Franciscan HRPP has made available a consent templates for use, but these documents will not be reviewed as part of the Human Subject Research Project Determinations.

HIPAA Authorization for Medical Case Reports.

Investigators who wish to publish or present a case report that is not completely de-identified to the standards of the HIPAA Privacy Rule, must first obtain each patient's signed HIPAA-compliant authorization or in the case of a deceased patient, the patient's legally authorized representative.

De-identified. Investigators who remove HIPAA identifiers from the case report data prior to disclosure of the data (e.g., prior to submission of the case report to a journal or presentation) and do not include "unique characteristics" do not need to obtain a signed privacy authorization from the subject of the case report.

Photographs, illustrations, or any "unique characteristics", could identify a patient and should be considered when determining if HIPAA authorization is required. The distinctiveness of a case or combination of the case report with other information may lead to a patient being identified.

If HIPAA identifiers are stripped but one or more "unique characteristics" remain that would make it possible to identify the patient, the author should contact their Institutional Privacy Office or Privacy Officer to discuss required steps prior to authoring the Case Report before submitting for publication or presentation.

See 1705.01 Template, Case Study Consent Form.

Attachment: 1705.01 Template_Case Study Consent Form.docx (33.1 kB)

The Common Rule does not apply and, therefore, cannot require consent.

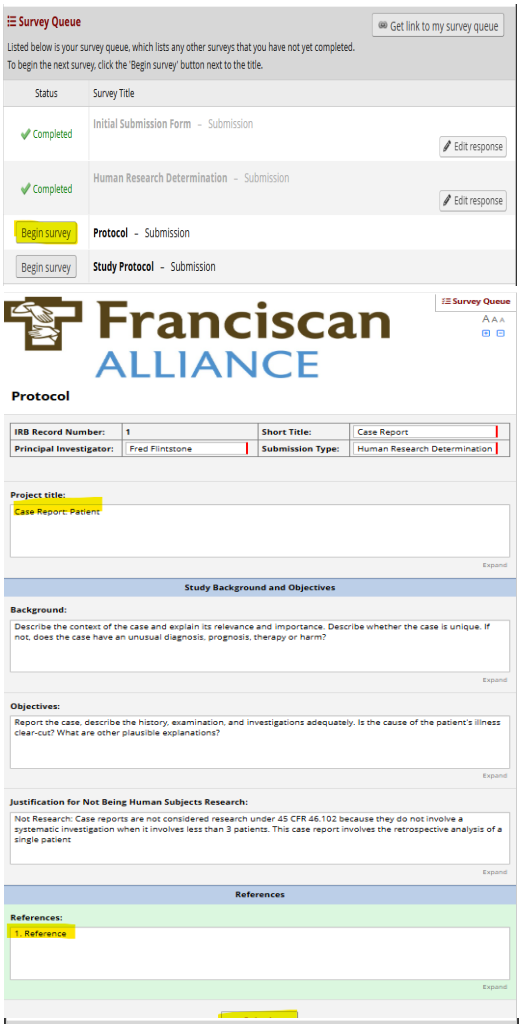
However, HIPAA still applies. And patient authorization may be required. A template consent/HIPAA Authorization is provided.

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

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.

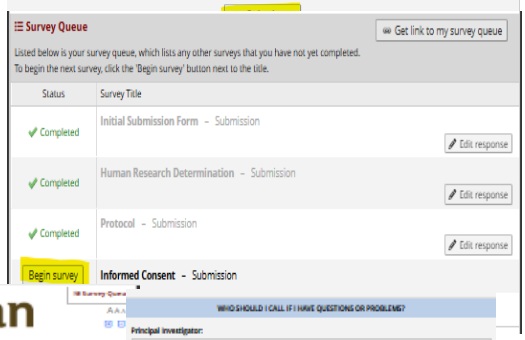
Edit the protocol.

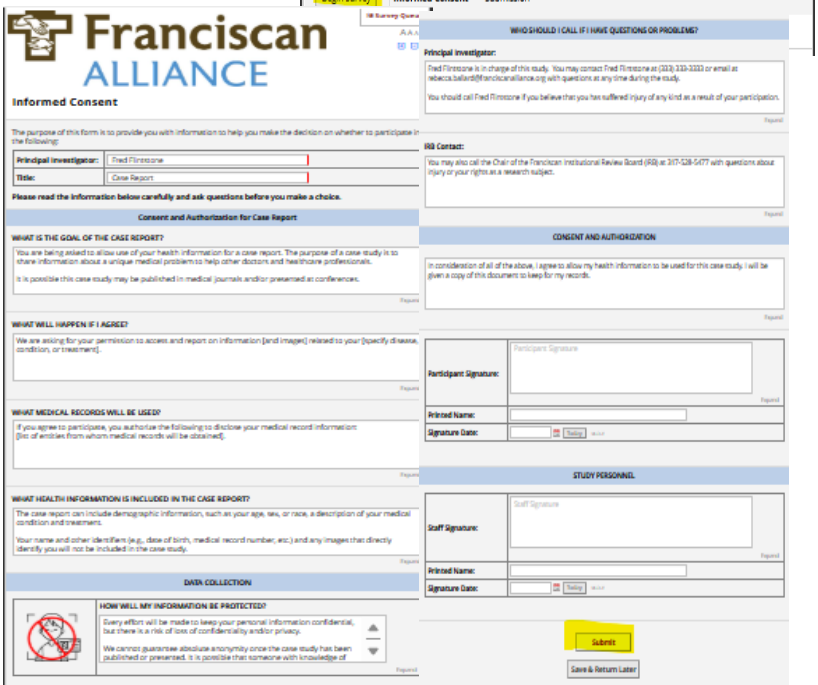
Click Submit when done at the bottom of the form.



XIII. **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.

XIV. **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.

XV. **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.

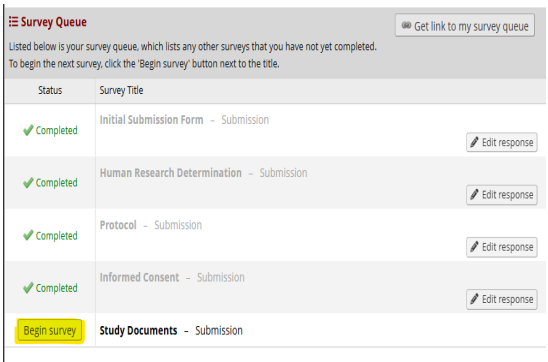
To download: Click the link on the protocol document title. The PDF will then save in your computer's download folder.

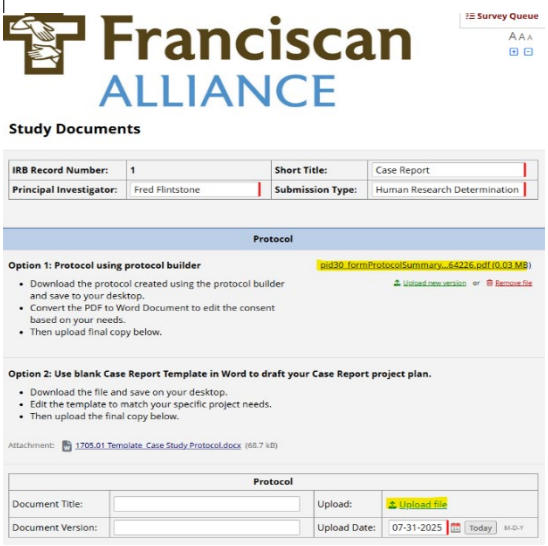
To upload: Click Upload File in REDCap. This will open a window allowing you to choose the file downloaded on your computer.

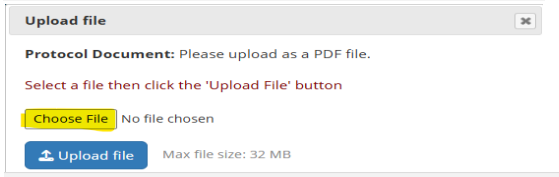
Find the file. Click Upload file.

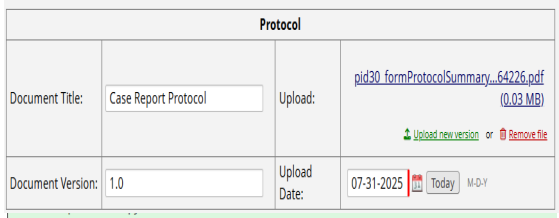
Once uploaded, it will present the file and default to today as the upload date. Enter in the document title and document version to help tracking document version.

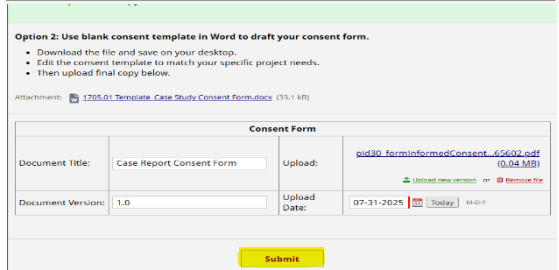
Repeat this upload process for the remaining study documents. Click submit when all documents are uploaded.





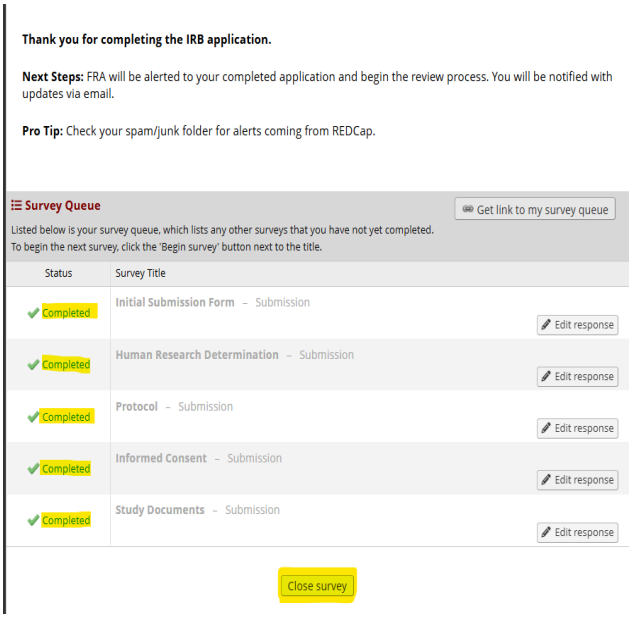






XVI. **Completed and Submit the Application.** The survey queue will show completed as you work through the application form.

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, Case Study Protocol
1706.03 Template, Case Study Consent Form
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.