How to Submit an Exempt Submission

Procedure Number: 1706.05.01P

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

Procedure Statement:

Federal regulations governing research involving human subjects identify specific categories of research activities that are exempt from Common Rule provisions ("Exempt Category"). Human subject research activities will be reviewed to determine whether they meet one or more exemption categories as defined by the Common Rule.

An exempt determination must be made by the IRB or IRB designee prior to the performance of research activities.

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.

Franciscan Research Administration is responsible for reviewing the submitted applications and documenting the review outcome.

Scope: This Procedure details how to submit an exempt application to the IRB in REDCap.

Definitions: See Research Services Program Acronyms and Definitions Reference

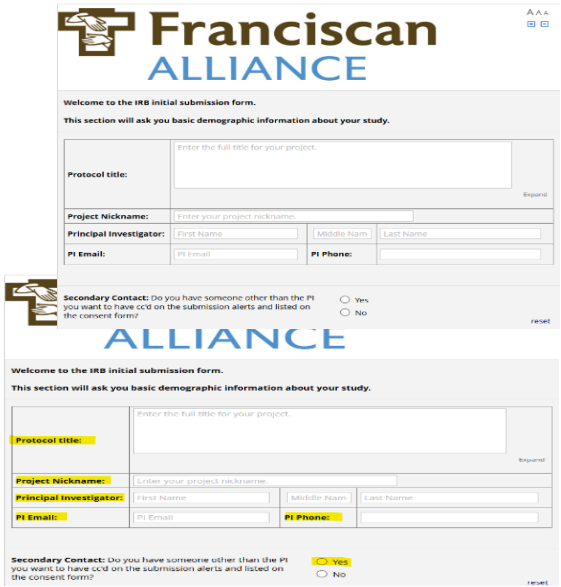
Exempt Category. The regulatory category the research project falls under to grant the exemption.

Exempt Determination. A decision that the research involving human subjects falls within the specific categories of activities provided in the regulations that are deemed exempt. An exemption removes the need to comply with some or all of the human participants reporting requirements provided in the Common Rule, even though the project is research involving human participants and otherwise would fit within the regulatory definition.

Abbreviations:

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

Procedure:



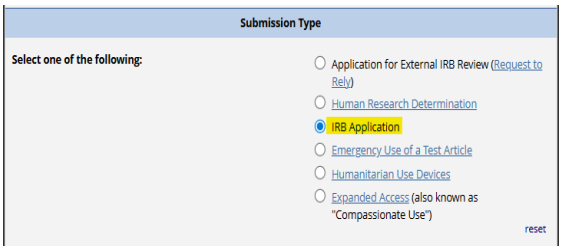
I. **Start New Submission**
   A. To start a new submission, click this link: New Submission. This action will open the initial submission form in REDCap.
   B. VPN: The user must be logged in to the Franciscan VPN to be able to access REDCap.

II. **Basic demographic information**: Enter basic

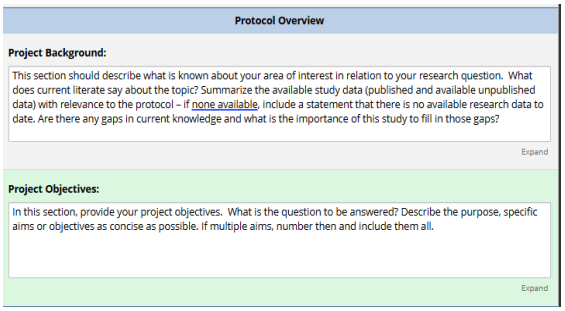
demographic information about your project, such as the project title, a short project nickname, Principal Investigator and their contact information.

The PI and secondary contact person's email will be used to send the IRB notifications, such as review progress updates and determination letters.

III. **Submission Type**: Exempt studies are considered research involving human subjects and would be a type of an IRB Application. Under submission type, select "IRB Application". Questions in the application form will be asked to verify if any possible exemptions would apply to your project.



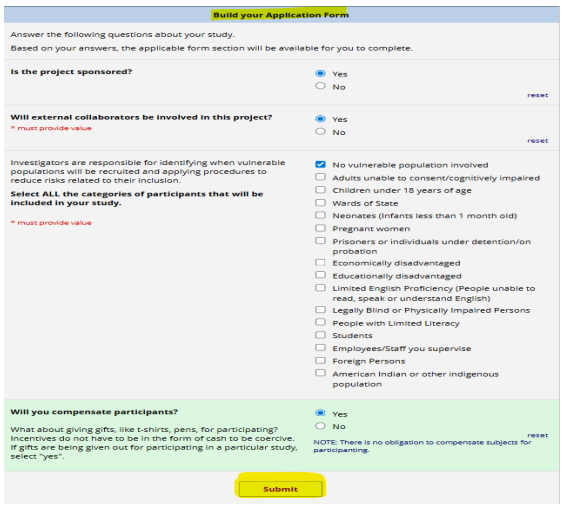
IV. **Project Overview**: Answer the questions. These answers will open relevant sections of your application based on your answers.



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

NOTE: Some exempt categories have limitations to the ability to enroll vulnerable populations such as prisoners and children.

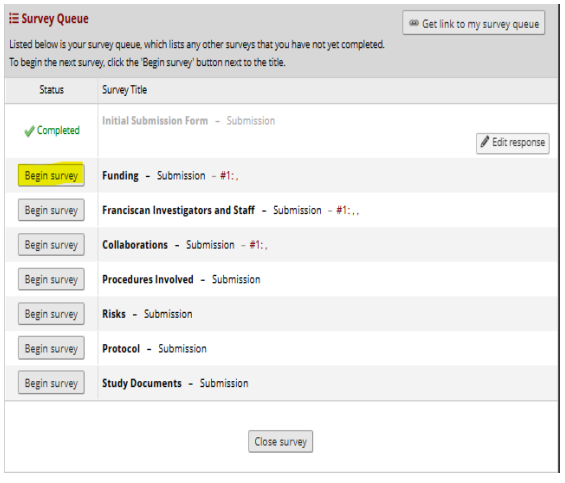
Hit Submit at the bottom of the form when this page is completed.



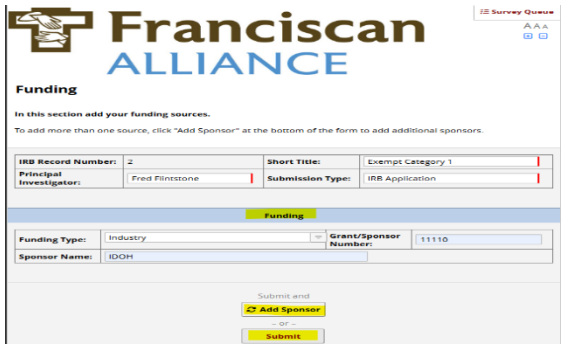
VI. **Survey Queue**: You will be taken to the survey queue. Think of the survey queue as your to-do list for submitting a complete application. The sections presented are based on your previous answers. You may not see all the options shown to the right.

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.

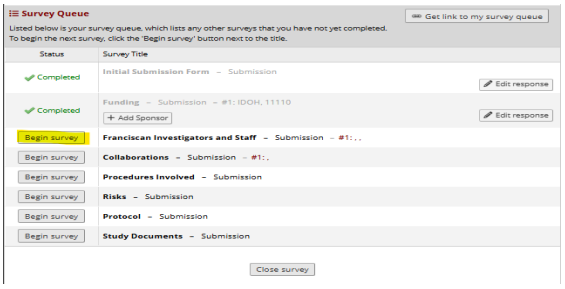


VII. **Funding**. If you selected that your study was funding, you will go to the funding form to enter the details on the study sponsor.



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.

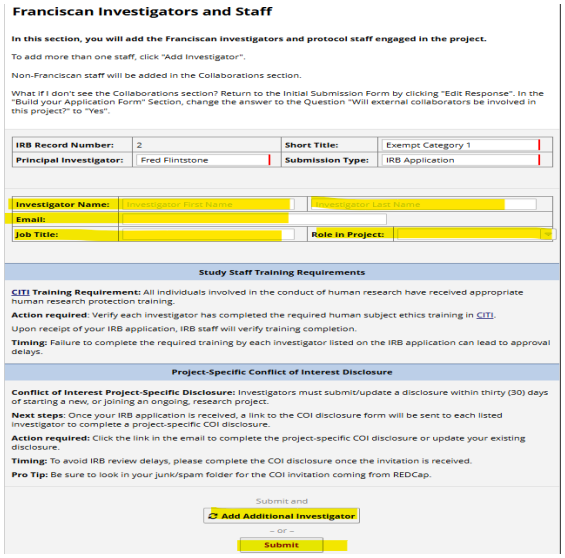


VIII. **Franciscan Investigators and Staff:** In this section, you will provide details on the members of the Franciscan research staff. Non-Franciscan researchers will be in the subsequent collaborations section.

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. **Collaborations:** In this section, you will enter information about any external collaborator. Click Begin survey to begin.

Enter the Collaborator's information.

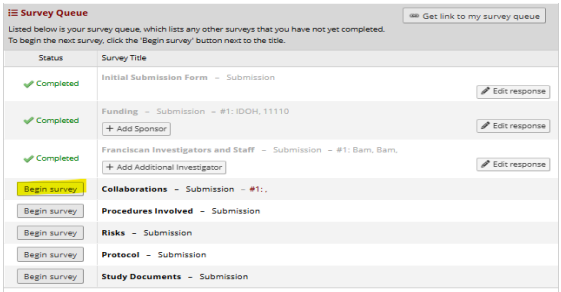
IRB coverage for collaborator: Indicate if the collaborator

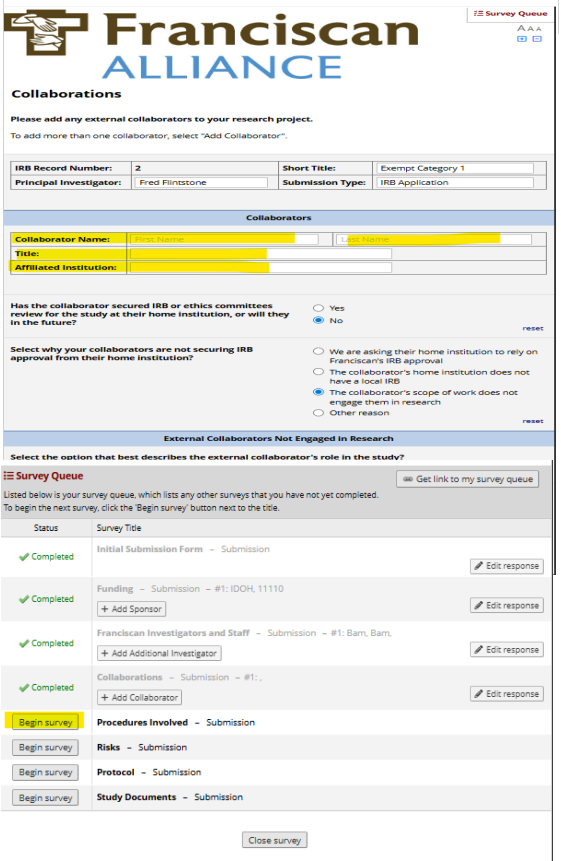
has secured IRB approval at their home institution.

Answer follow-up questions. This helps the IRB determine if a reliance agreement is required.

This is a repeating form – meaning you can add more than one collaborator. Click Add Collaborator to be presented with a second form to add an additional staff member.

Click Submit when done entering the collaborator's information.





X. **Procedures Involved**. In this section, you will detail the study procedures used in your project.

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Click Begin survey to open this section.

Procedures Involved: Based on what you select, additional questions will be displayed.

Eligibility for various exempt categories are dependent on involving certain procedures.

Category 1: Examination of educational practices, instructional techniques, curricula or classroom management.

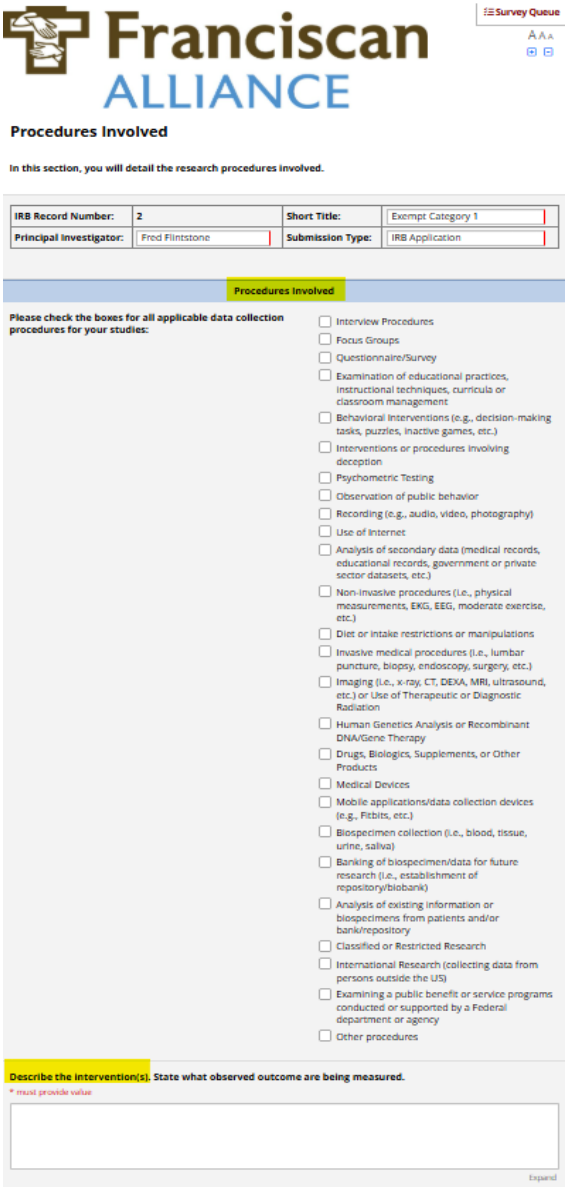
Category 2: Educational test, survey procedures, interview procedures, or observations of public behavior

Category 3: Benign behavioral interventions

Category 4: Analysis of secondary data

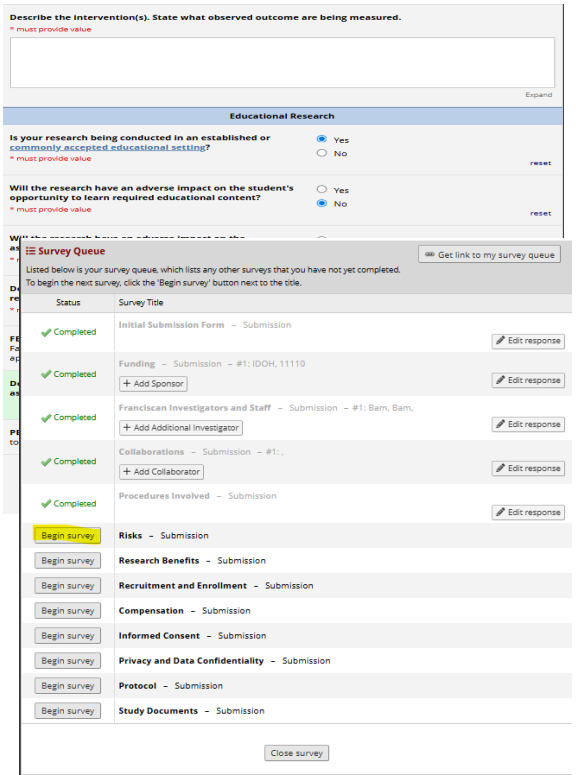
Category 5: Examining a public benefit or service programs conducted or supported by a Federal department or agency

Category 6: Taste and food quality evaluation or consumer acceptance study



XI. **Exempt Category Follow-Up Questions**

Example: Exempt Category 1 - If you select Examination of educational practices as a procedure, questions will be displayed to evaluate if the exempt category 1 is eligible.



XII. Risks - This section will review the risks related to the procedures involved in your project.

Click Begin Survey to open the risk section.

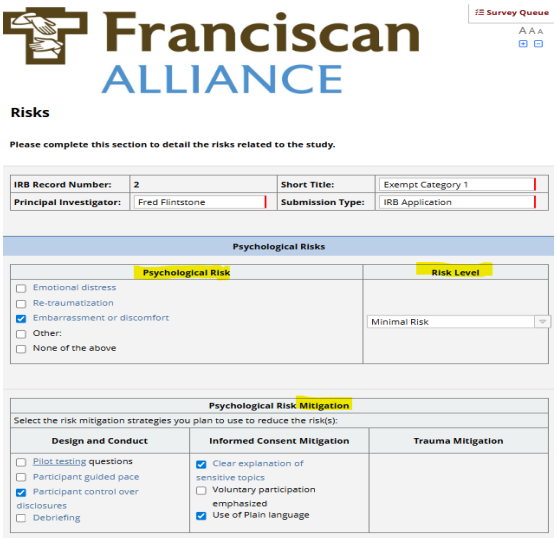
How to Submit an Exempt Submission

Go through the various types of risk. Select if the risk applies to your project or select “None of the above”.

Select the risk level.

If the risks are present, select mitigation strategies you will deploy to reduce the risk.

Click Submit at the bottom of the form when done.

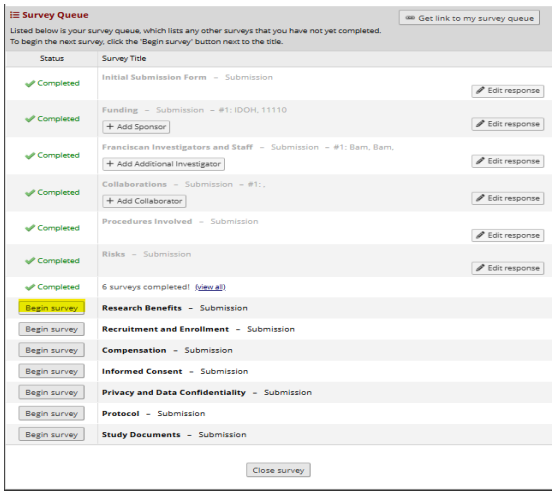


XIII. **Research Benefits:** This section will review the benefits related to the procedures involved in your project.

Click Begin Survey to open the benefit section.

Most exempt protocols would not likely result in a direct benefit to the subject. “No benefits expected” is a default answer.

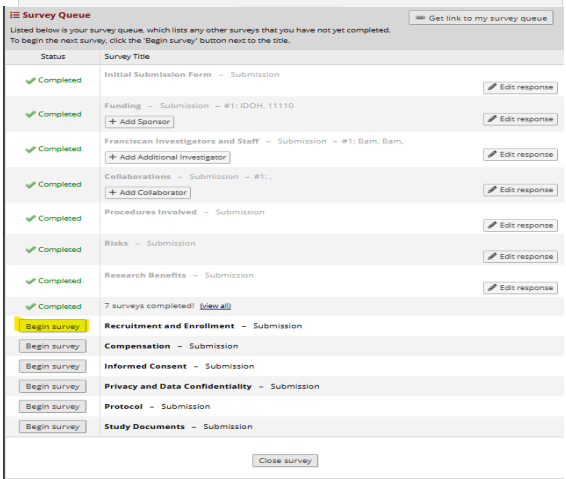
But you can change this default and describe the benefits to be expected.





IX. **Recruitment and Enrollment**: This section will review your recruitment and enrollment plans.

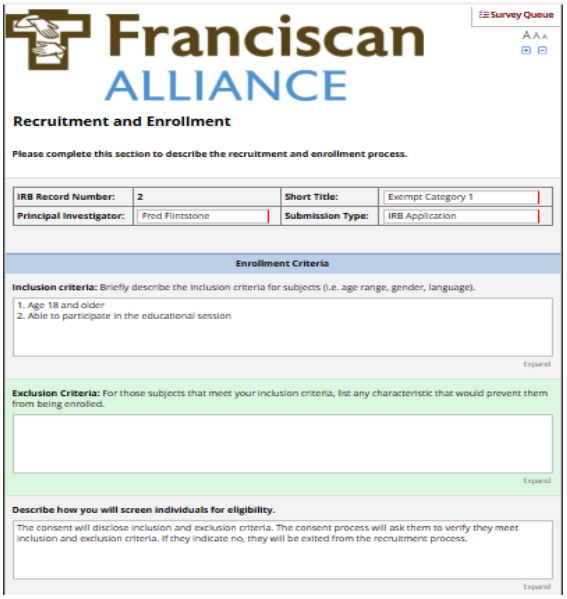
Click Begin survey to open the section.



How to Submit an Exempt Submission

Detail your recruitment and enrollment plan.

Click submit when the section is complete.

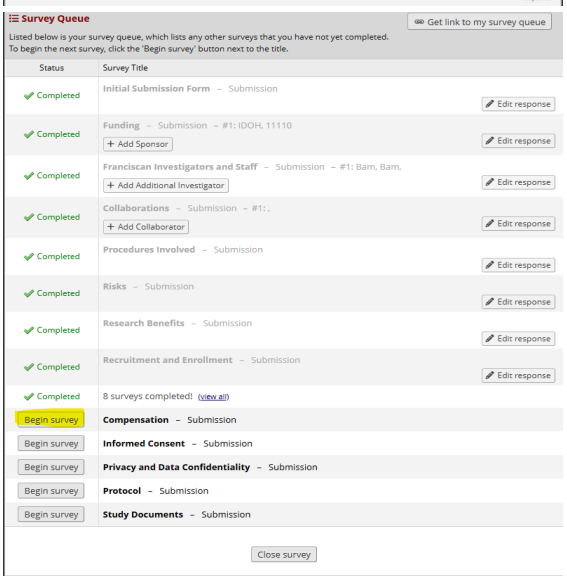


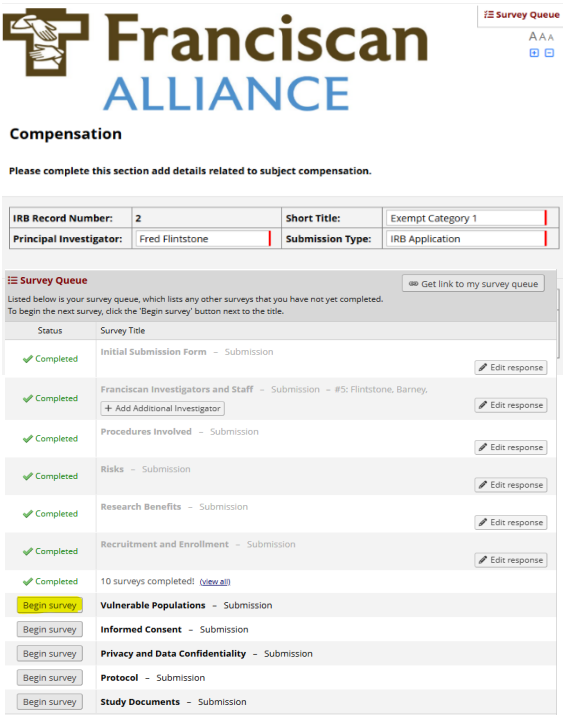
X. **Compensation**: If you indicated in the initial submission page you will offer compensation, you will see this section to detail the compensation plan.

Click Begin survey to open the section.

Detail your compensation plan.

Click submit when the section is complete.

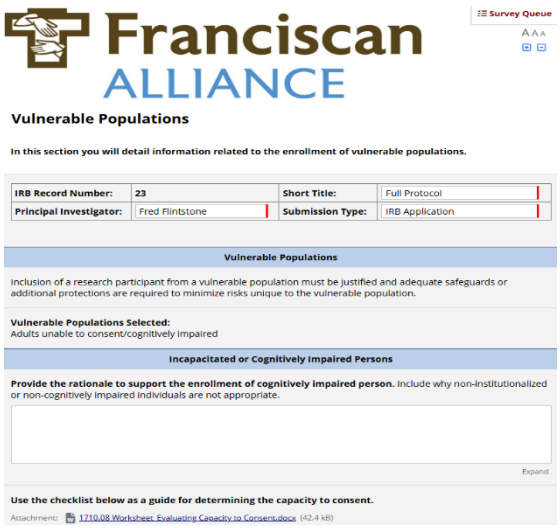




XI. Vulnerable Population

If you select a vulnerable population, this section will display.

Enter information about the vulnerable population you plan to enroll.



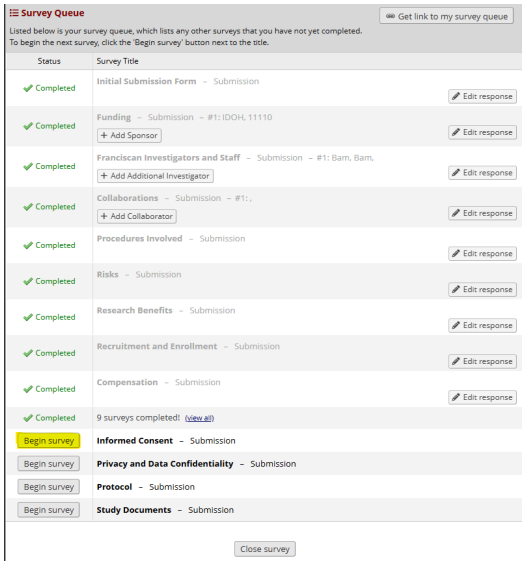
XII. Informed Consent

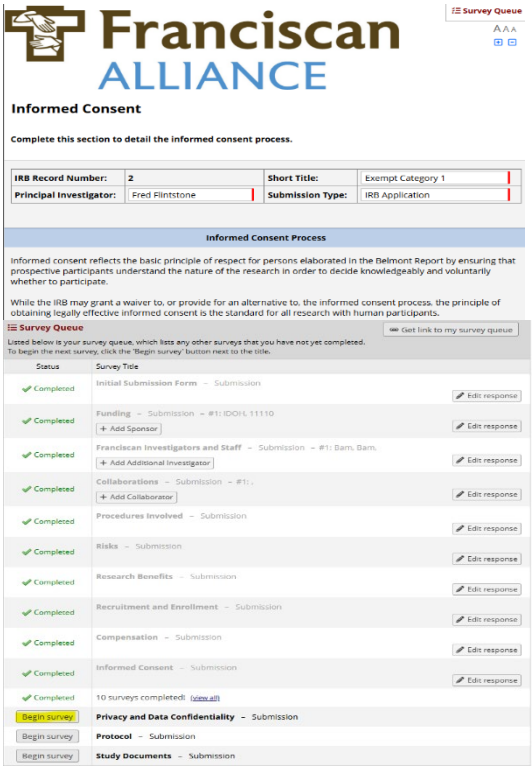
Click Begin survey to open the section.

Detail your informed consent plan.

Often exempt protocols may ask for a waiver of consent process or waiver of consent documentation. You can indicate these options and will be guided through eligibility for these two consent waivers.

Click submit when the section is complete.

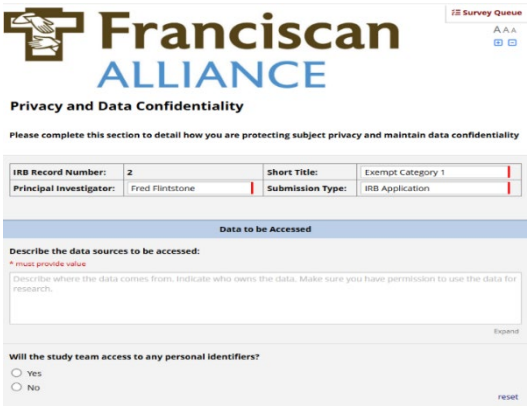




XIII. Privacy and Data Confidentiality: Click Begin survey to open the section.

Detail your data collection plan and how you will protect privacy and confidentiality.

Click submit when the section is complete.



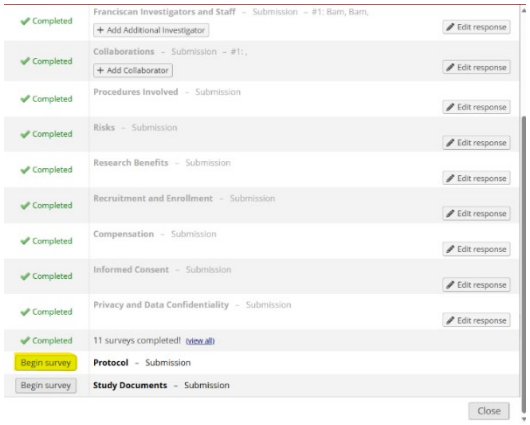
XIV. Protocol. This form takes the information you have entered into the form this far and drafts your protocol.

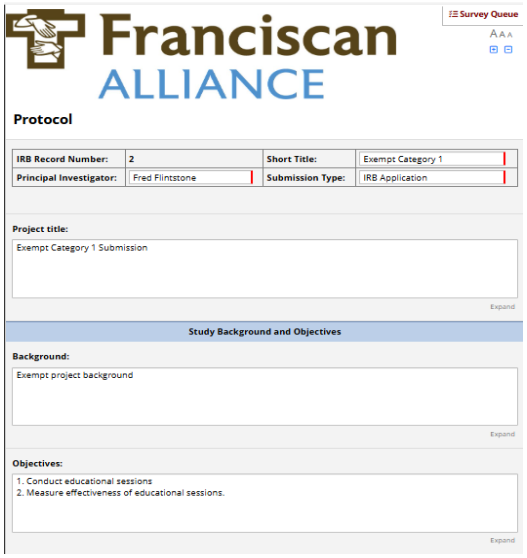
Click Begin Survey to open the protocol builder.

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.

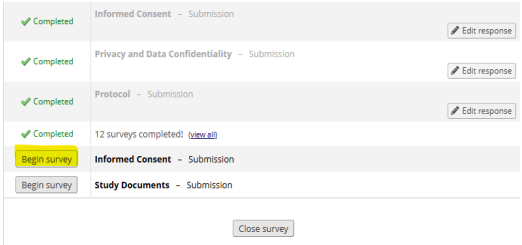
Click Submit when done at the bottom of the form.





XV. 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.

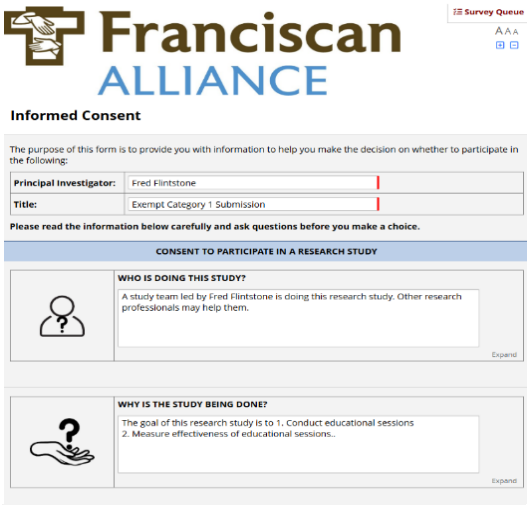


How to Submit an Exempt Submission

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 a consent document.

Edit the consent.

Click Submit when done at the bottom of the form.

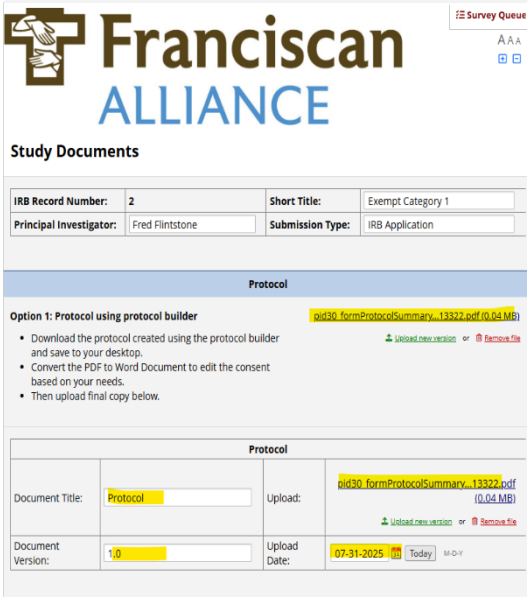


XVI. Study Documents. This final form will allow you to attach any supporting documents to your application for review. Click Begin Survey to open this section.
Upload the protocol:

Two options are detailed.

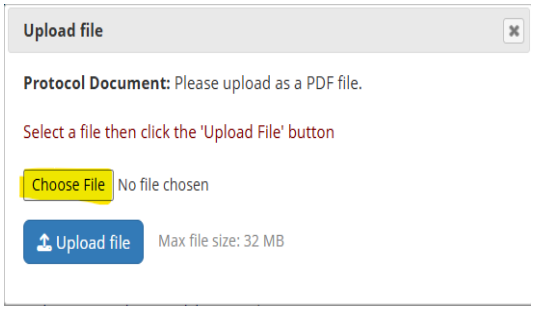
Option 1: Use Protocol Builder
You can download the PDF you just built using the REDCap protocol builder and upload it as your final protocol to submit.

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.



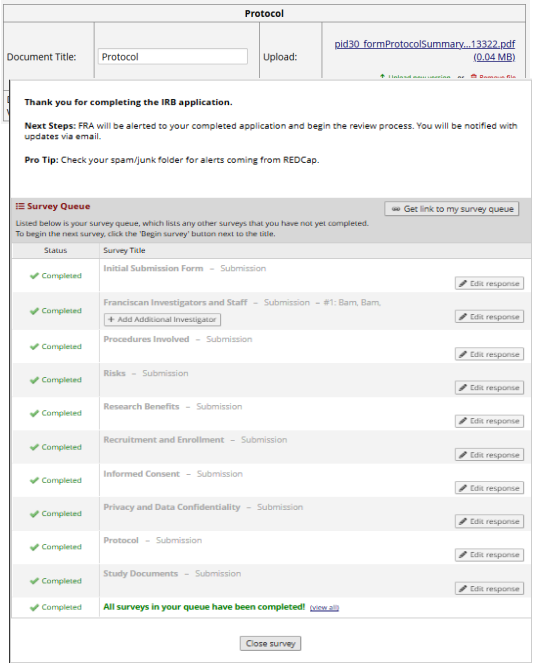
This will open a window allowing you to choose the file downloaded on your computer.

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.



XVII. Completed and Submit the Application

The survey queue will show completed as you work through the application form.

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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:

1706.05 Exempt Determinations

See Related Documents: None

See Attachments: None

Notes: New Procedure.