FRANCISCAN
MISSIONARIES OF OUR LADY
UNIVERSITY

IRBManager
Application for Project Review
User's Guide

Summer 2020

Email IRB@franu.edu for questions or assistance.

Table of Contents

1.0 Before you begin

For details on using IRBManager see tutorial *"IRBManager User's Guide"* located on the FranU IRB web page under Institutional Review Board (IRB) Documents.

Link: https://franu.edu/offices-services/office-of-academic-research/institutional-review-board

1.1 Who submits projects for IRB review?

Complete an IRB application if:

- You are conducting a project directly involving human subjects, or on retrospective data collected from human subjects, **and**,
- You, or one or more members of your project team, are affiliated with Franciscan Missionaries of Our Lady University (FranU), Our Lady of the Lake Regional Medical Center (OLOLRMC), or other Franciscan Missionaries of Our Lady Health System (FMOLHS) facility.

1.2 What projects require IRB review?

All projects involving human subjects should be submitted to the IRB for review. Not all projects involving human subjects are classified as Human Subjects Research, but the IRB makes that determination through this review process.

Based on your answers to questions in this application your project is categorized as Human Subjects Research (**HSR**) or Not Human Subjects Research (**NHSR**). Projects categorized as **NHSR** have fewer requirements and sections that only apply to **HSR** will automatically be removed.

Some projects involving human subjects may not need to go through the formal IRB review process. They include Scholarship of Teaching and Learning (SoTL), Quality Improvement (QI), and Evidence Based Practice (EBP). However, if submitted for IRB review, the IRB can affirm that the project is **NHSR** and does not require IRB oversight.

1.3 Getting permission where your research is conducted

The IRB only ensures that your project adequately minimizes risks to human subjects. It DOES NOT grant permission to conduct your research at a facility. That must come first through feasibility review.

1.4 Feasibility Review Requirements

Feasibility review for **HSR** projects is necessary to ensure project feasibility and that it does not violate the core values of FMOLHS.

- **Franciscan Missionaries of Our Lady University (FranU) Employees & Students**
  DO NOT request feasibility review before submitting your application to the IRB. This application is sent for feasibility review and a Letter of Endorsement is automatically attached upon approval.
- **OLOLRMC and FMOLHS Affiliates**
  DO submit OLOLRMC Feasibility Review Submission through IRBManager to OLOLRMC Office of Research. You are prompted to attach their Letter of Endorsement to this application.
- **Sites off-campus** (not affiliated with FranU, OLOLRMC or FMOLHS)
  Provide site-use approval and/or feasibility approval from facility. You are prompted to attach their site-use approval to this application.

1.5 Get trained

If your project is **HSR**, you need to take the training modules developed by the Collaborative Institutional Training Initiative (CITI). To access CITI modules used by FMOLHS:

- Click the link: https://www.citiprogram.org/Default.asp
- Click "Register" and select "Franciscan Missionaries of Our Lady Health System" as your organization affiliation, and complete the registration process
- Take one or both of the following courses, depending on the type of research:
  - Social & Behavioral Research - Basic/Refresher, Basic Course
  - Biomedical Data or Specimens-Only Research - Basic/Refresher Course
  - *NOTE - Students investigators should complete "Student" course*
- Save your CITI completion certificate to upload when prompted in IRBManager

1.6 Set up your IRBManager account

Don't have an IRBManager account? For details see tutorial *"IRBManager User's Guide"* located on the FranU IRB web page under Institutional Review Board (IRB) Documents.

Link: https://franu.edu/offices-services/office-of-academic-research/institutional-review-board

1.7 Prepare documents to upload to IRBManager

Before you submit your IRB application, you need to prepare documents in advance. **HSR** projects require more documents than **NHSR** projects. For a list of documents see sections **1.7a** and **1.7b**.

1.7a HSR Project Documents

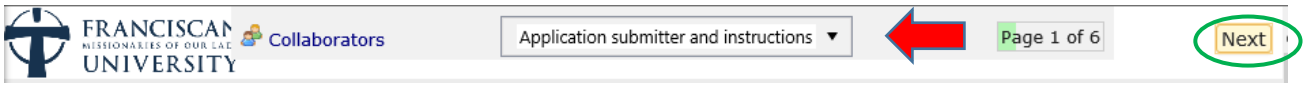
- Feasibility Letter of Endorsement from OLOLRMC (except FranU Students & Employees)
  - Or, Site-use approval if off-campus and not affiliated with OLOLRMC or FMOLHS
- Project member(s): CITI training certificate, CV, and clinical license (if applicable)
- Signed Financial Conflict of Interest (FCIO) form for **EACH** project member
  - Link to template: https://s3.franu.edu/uploads/documents/IRB-Conflict-of-Interest-Form-FranU-2017.pdf?mtime=20190724105247&focal=none
- Project protocol document - *12 page limit including title page and references*
  - If you do not have a project protocol document, prepare a more detailed description of the project, including sufficient details about the methods.
- Document(s) that detail your data collection (survey questions, interview guide, etc.)
- Materials indicating how your sample is collected (such as recruitment materials)
- Informed consent documents unless you are requesting to waive the requirement for documentation of informed consent (if there is minimal risk).
  - For details see FranU IRB web page: https://franu.edu/offices-services/office-of-academic-research/institutional-review-board

1.7b NHSR Project Documents

- Project member(s): CV and clinical license (if applicable)
- Project document or furnish detailed description of your project.
- Document(s) that detail your data collection (survey questions, interview guide, etc.)
- Materials indicating how your sample is collected, such as recruitment materials (if applicable).

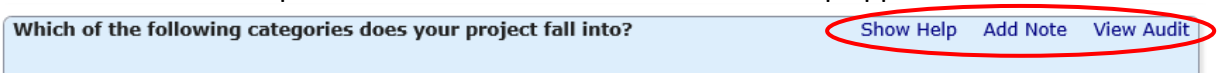
1.8 IRBManager Navigation Tips

- **Across the top of each screen:**
  "Navigation Drop-Down" allows you to jump to other screens (**red arrow**)
  "Next" advance one screen (**green circle**)



- **Buttons across bottom of each screen** (**purple arrow**):
  "Previous" return to prior screen
  "Next" advance one screen
  "Save for Later" save progress and return later from your **Dashboard**
  "More" view questions, notes, changed responses and view application as PDF
  "Submit" (last screen) application is complete, send for review

- **Links within sections** (**red circle**)
  "Show help" additional guidance related to a specific section.
  "Add Note" opens window to enter note applicable to the section
  "View Audit" opens window to view audit and time stamp applicable to the section



1.9 Required Information

The designation ***(Required)*** at any section does not allow you to advance using **"Next"** until the requirement is satisfied. If this message appears, click on **red link(s)** to jump to the specific area and resolve the issue.

The following issues exist. Click on an issue to jump there.

- Title of Project - Required.
- Attach PI CV - Required.

> *NOTE: Using **"Navigation Drop-Down"** (top of each screen) allows you to jump to other screens to continue filling out your form. Any missing **(Required)** items are identified when you click **"Submit"** on the final screen.*

2.0 Log-in to IRBManager

- Log-in to IRBManager with your User Name and Password
  https://franu.my.irbmanager.com

Don't have an IRBManager account?
For details see tutorial *"IRBManager User's Guide"* located on the FranU IRB web page under Institutional Review Board (IRB) Documents.
Link: https://franu.edu/offices-services/office-of-academic-research/institutional-review-board

2.1 Dashboards

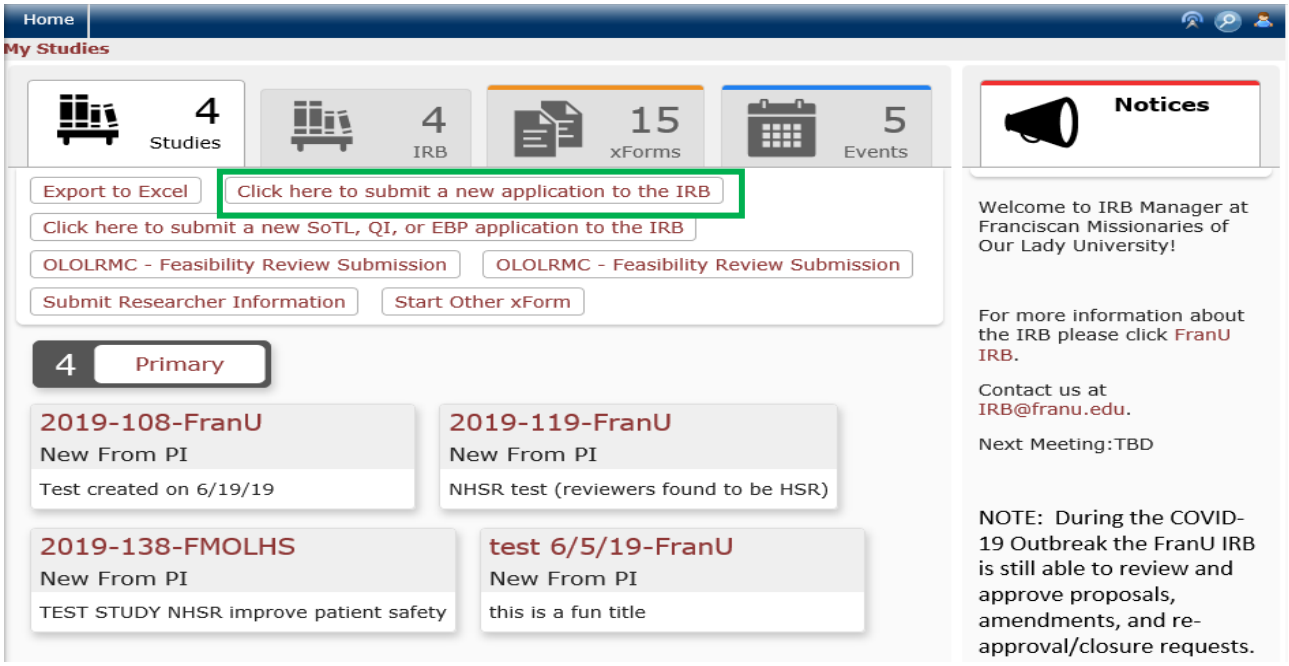
- Your **Dashboard** is the first screen you see when you log-in to IRBManager.
- **Power Dashboard** or **Bubble Dashboard** (see examples below)**.** The appearance is different, but the functionality is the same. The NEW **Bubble Dashboard** is considered more visually friendly using tabs to navigate. See tutorial - *"IRBManager User's Guide"* on FranU IRB web page for details on selecting dashboards.
  - Link: https://franu.edu/offices-services/office-of-academic-research/institutional-review-board

2.2 Begin an application

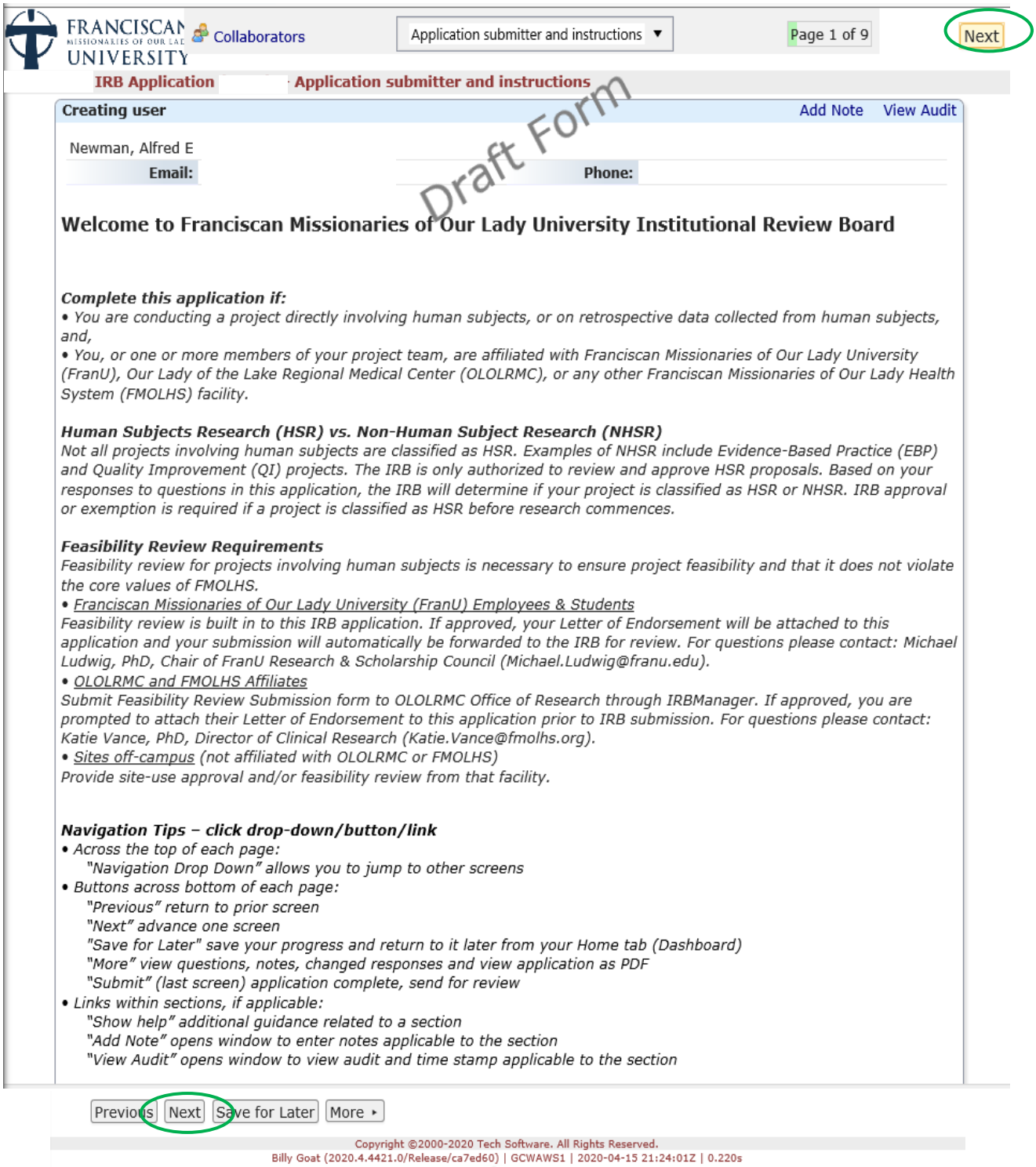
- To start select – **"Click here to submit a new application to the IRB"** (**green box**).

2.3 Example of Power Dashboard

2.4 Example of Bubble Dashboard



3.0 Welcome to FranU IRB and Instructions



- Click **"Next"** at the top or bottom of the screen to proceed to the next screen.

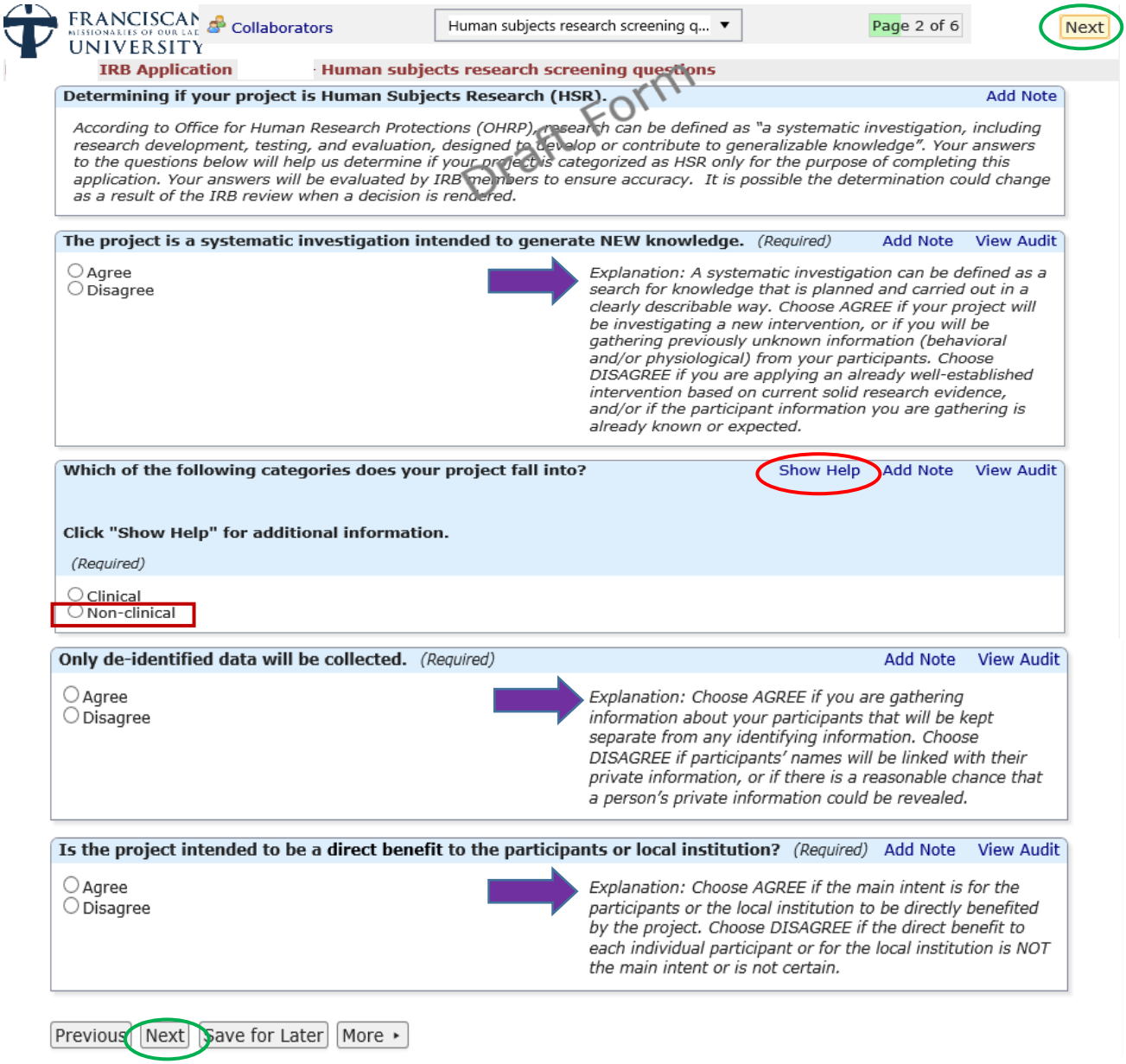
4.0 Human Subjects Research Screening Questions

4.1 Determining if your project is Human Subjects Research

Not all projects involving human subjects are classified as Human Subjects Research. Based on your answers to questions in this section, and only for the purpose of completing your application your project is categorized as Human Subjects Research (**HSR**) or Not Human Subjects Research (**NHSR**). It is possible this determination could change as a result of the IRB review.

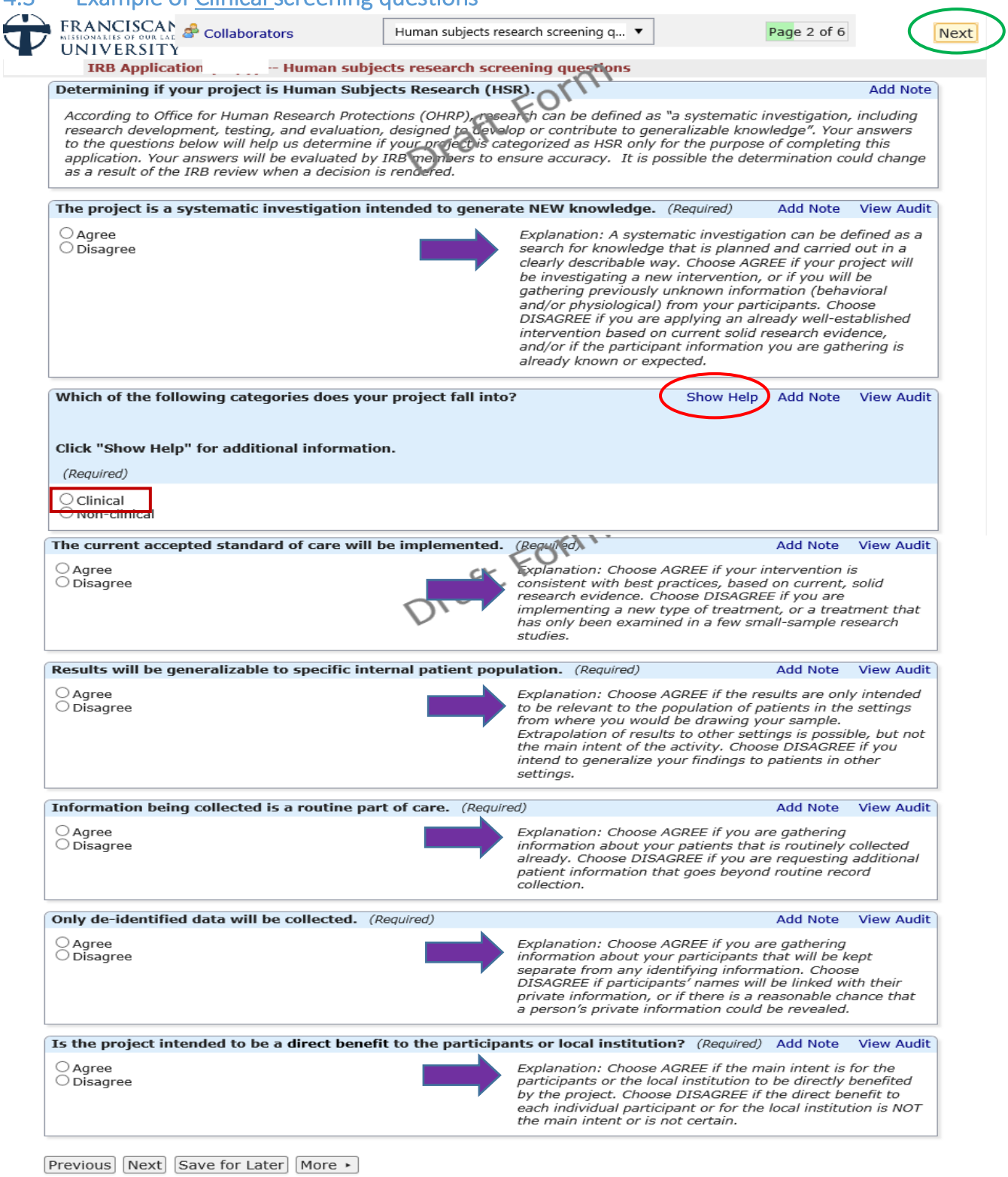
- For more information see ***"Explanation"*** (**purple arrows**) & click **"Show Help"** (**red circle**)
- Additional questions generate depending on your answers.

4.2 Example of Non-Clinical screening questions



- Click "**Next**" at top or bottom of the screen to proceed to the next screen.

4.3 Example of Clinical screening questions



- Click "**Next**" at top or bottom of the screen to proceed to the next screen.

5.0 Adding New Contact to IRBManager

- Anyone affiliated with your proposed project will need to have his or her contact information added to IRBManager.

Please read these instructions before using the following sections:

6.3 Principal Investigator/Project Lead (PI)

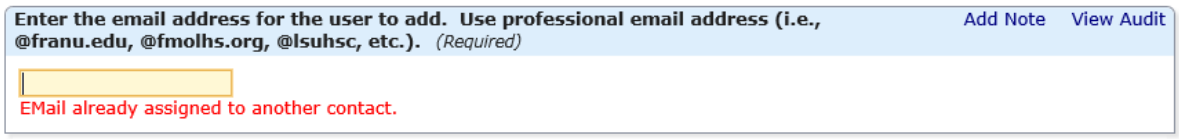
6.4 Faculty Advisor Section

6.5 Study Staff Members

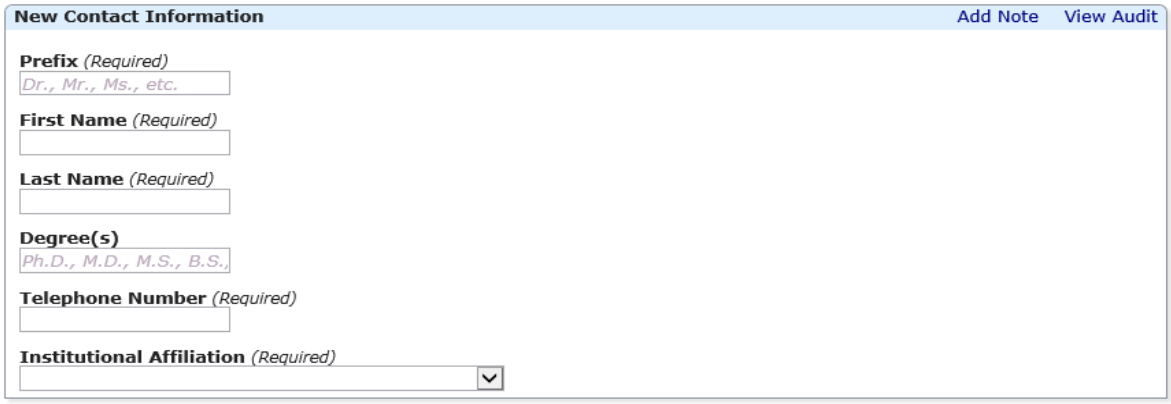
To populate names for selection in the drop-down list in **PI, Faculty Advisor and Study Staff Member** section(s) the name must first be entered in the IRBManager contact list.

If the person you are adding is not found in the drop-down list, you are instructed to click the **"Click here to add a new contact"** link (**red circle**).

- After clicking **"Click here to add a new contact"** a new window opens.
- Enter the email address for the user you are adding to IRBManager. Use professional email addresses (i.e., @franu.edu, @fmolhs.org, @lsuhsc.edu).
- **Warning** message appears if the email is already assigned to another contact.

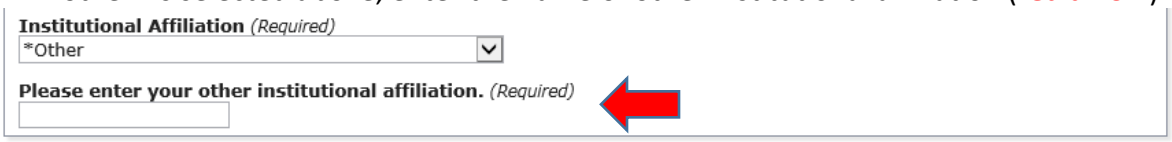


- Complete required fields.

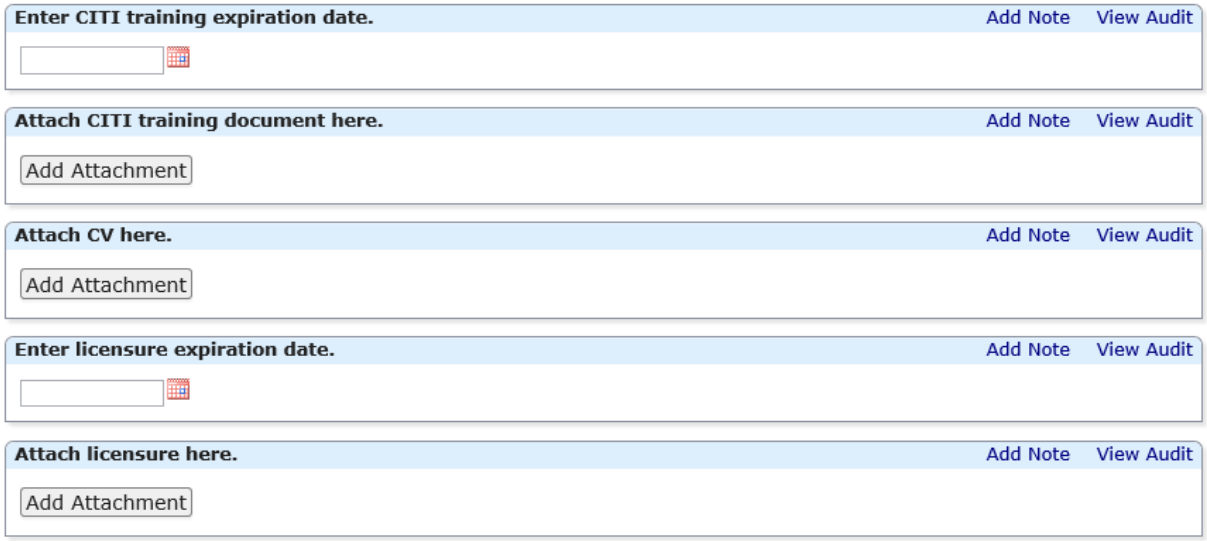


5.0 Adding New Contact to IRBManager (continued)

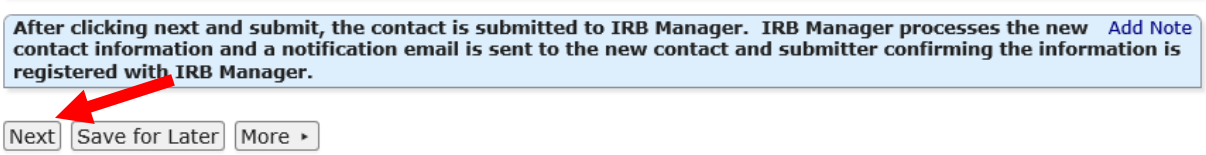
- If “other” is selected above, enter the name of other institutional affiliation (**red arrow**).



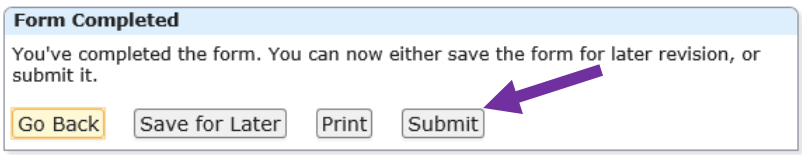
- Enter expiration dates and attach backup documents.



- Click “Next” if you are ready to submit this form (**red arrow**).
- Or click "Save for Later" to save progress and return later from your **Dashboard**



- Click “Submit” (**purple arrow**) and close window.



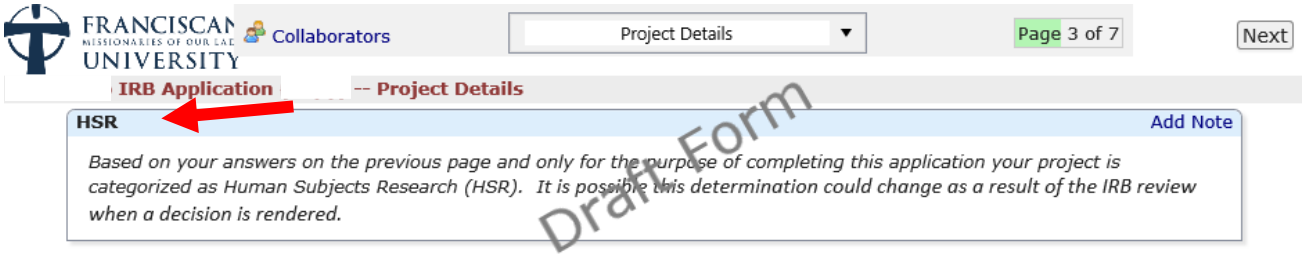
NOTE: After you click “Submit” IRBManager processes the new contact information and a notification email is sent to you (the submitter) and the new contact just entered confirming the information is registered with IRBManager.

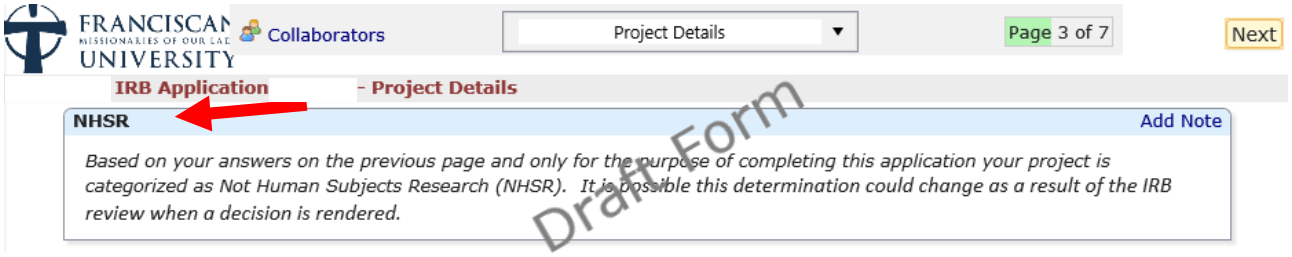
*You MUST FIRST receive the confirmation email BEFORE the new contact name appears in the drop-down list to use as the **PI, Faculty Advisor or Study Staff Member(s).***

6.0 Project Details

6.1 HSR vs. NHSR

Based on your answers on the previous screen and only for the purpose of completing this application your project is categorizes as either **HSR** or **NHSR** (**red arrows**) and generates questions and sections to complete. It is possible this determination could change as a result of the IRB review when a decision is rendered.





If your project is categorized as NHSR it has fewer application requirements. All sections that only apply to HSR will automatically be removed from your application.

*NOTE: This tutorial is designed to show all details necessary for **HSR** submissions.*

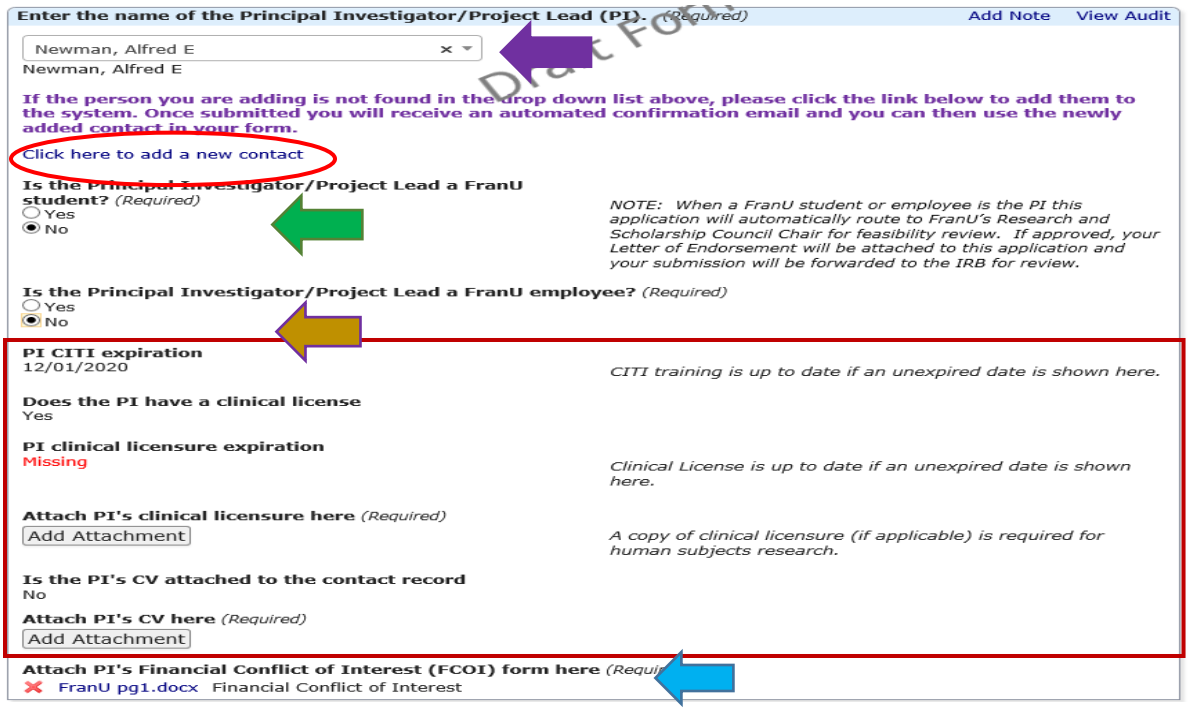
- *Keep in mind that some questions and sections are shown in this tutorial for the benefit of **HSR** submissions but are not needed for **NHSR** projects.*
- *Please ignore/skip sections shown in this tutorial that do not apply to **NHSR** projects, they are automatically removed from the application.*

6.2 Project Title

- Enter the title of your project.

6.3 Principal Investigator/Project Lead (PI)

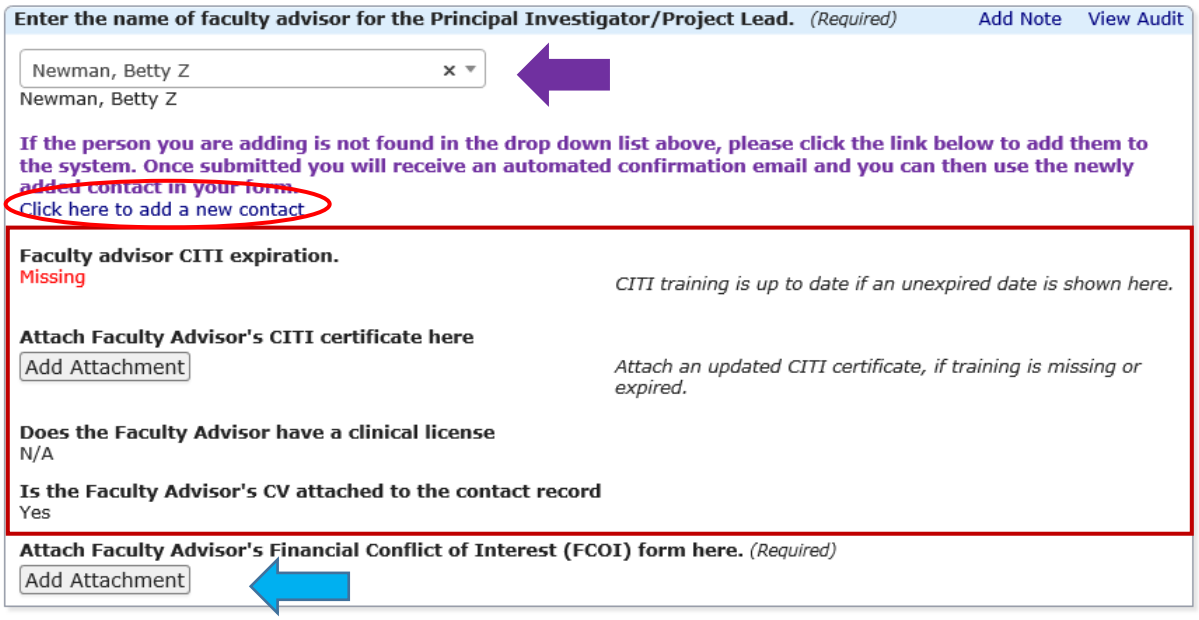
- Start typing the last name of the Principal Investigator/Project Lead (PI) in the space provided to select from the IRBManager contact drop-down list (**purple arrow**).
- If the name is not found in the drop-down list, click the link below (**red circle**) to add new contact. For details see – **5.0 Adding New Contact to IRBManager**. After receiving the confirmation email, you can use the newly added contact by repeating the previous step.
- Is the Principal Investigator/Project Lead a **FranU Student** (**green arrow**)?
    - Faculty Advisor section only appears if the PI is a **FranU Student**.
    - **FranU Students** DO NOT NEED to request feasibility review before submitting your application to the IRB. Once your application is submitted, it is sent for feasibility review and a Letter of Endorsement is automatically attached upon approval.
- Is the Principal Investigator/Project Lead a **FranU Employee** (**gold arrow**)?
    - **FranU Employees** DO NOT NEED to request feasibility review before submitting your application to the IRB. Once your application is submitted, it is sent for feasibility review and a Letter of Endorsement is automatically attached upon approval.
- Details regarding CITI training, licensure and CV are conditioned on the project category of **HSR** or **NHSR** and auto populate in your form from the IRBManager contact record. If information is missing or expired, you are prompted to attach document(s) here (**red box**).
- Attach PI's Financial Conflict of Interest (FCOI) form (**blue arrow**).
    - FCOI template: https://s3.franu.edu/uploads/documents/IRB-Conflict-of-Interest-Form-FranU-2017.pdf?mtime=20190724105247&focal=none



6.4 Faculty Advisor Section

If the PI is a **FranU Student** the Faculty Advisor section appears, otherwise it does not appear.

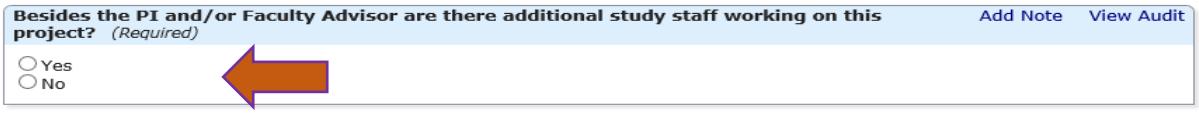
- Start typing the last name of the Faculty Advisor in the space provided to select from the IRBManager contact drop-down list (**purple arrow**).
- If the name is not found in the drop-down list, click the link below (**red circle**) to add new contact. For details see **– 5.0 Adding New Contact to IRBManager**. After receiving the confirmation email, you can use the newly added contact by repeating the previous step.
- Details regarding CITI training, licensure and CV are conditioned on the project category of **HSR** or **NHSR** and auto populate in your form from the IRBManager contact record. If information is missing or expired, you are prompted to attach document(s) here (**red box**).
- Attach Faculty Advisor's Financial Conflict of Interest (FCOI) form (**blue arrow**).
    - FCOI template: https://s3.franu.edu/uploads/documents/IRB-Conflict-of-Interest-Form-FranU-2017.pdf?mtime=20190724105247&focal=none



6.5 Study Staff Members

Are there additional members working on this project besides the PI and Faculty Advisor?

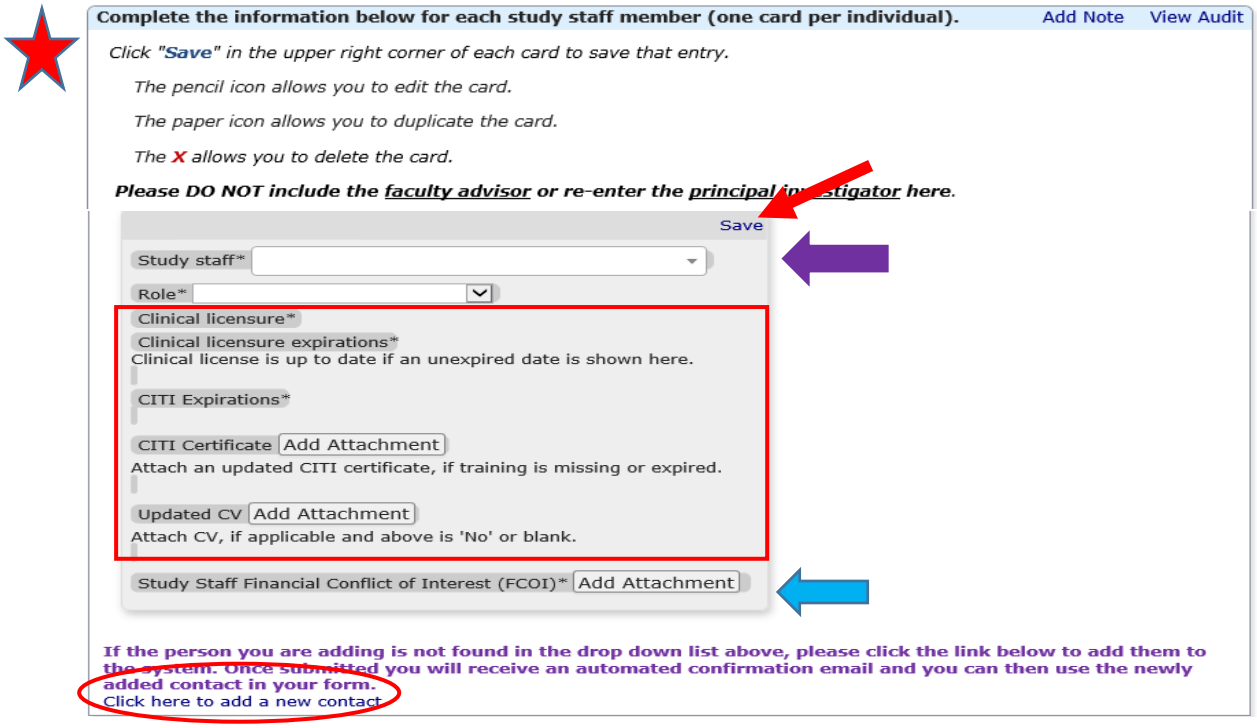
- If "Yes" is selected (**gold arrow**) you are provided space to furnish information for each project member (**red star**). If "No" is selected the study staff section does not appear.



DO NOT re-enter principal investigator or faculty advisor here.

Complete the information for each project member (**one card per individual**).

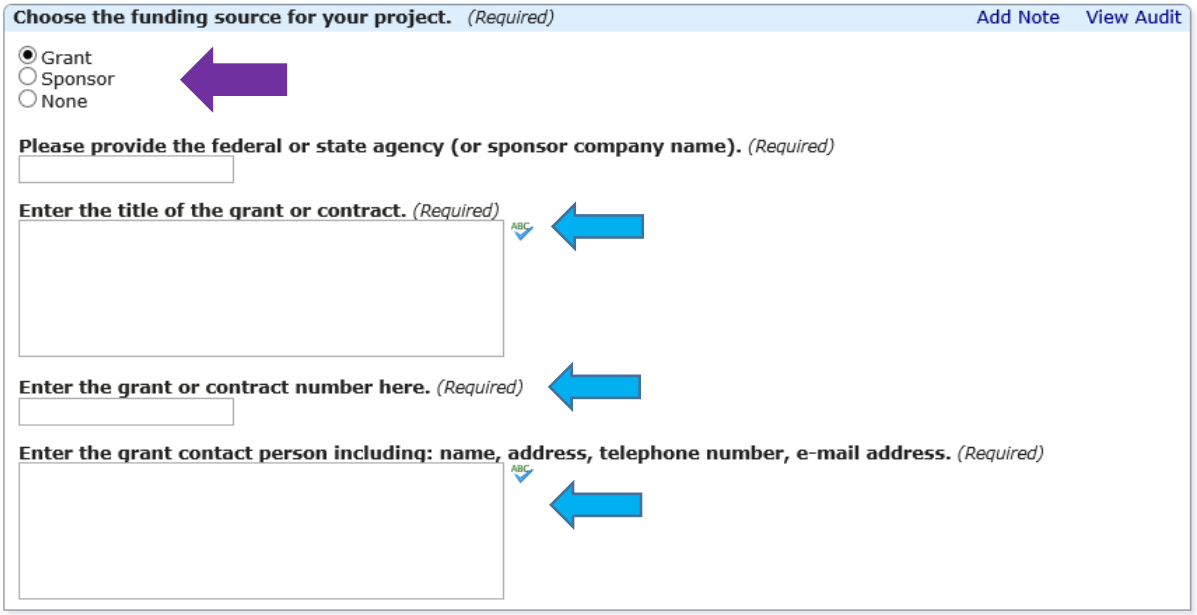
- Start typing the last name of the study staff member in the space provided to select from the IRBManager contact drop-down list (**purple arrow**).
- If the name is not found in the drop-down list, click the link below (**red circle**) to add new contact. For details see – **5.0 Adding New Contact to IRBManager**. After receiving the confirmation email, you can use the newly added contact by repeating the previous step.
- Details regarding CITI training, licensure and CV are conditioned on the project category of **HSR** or **NHSR** and auto populate in your form from the IRBManager contact record. If information is missing or expired, you are prompted to attach document(s) here (**red box**).
- Attach Study Staff Member's Financial Conflict of Interest (FCOI) form where specified on their individual card (**blue arrow**).
  - FCOI template: https://s3.franu.edu/uploads/documents/IRB-Conflict-of-Interest-Form-FranU-2017.pdf?mtime=20190724105247&focal=none
- Click "**Save**" in the upper right corner of each card to save that entry (**red arrow**) and enter additional staff members on the next blank card if applicable.



6.6 Funding Source

Indicate funding source of your project

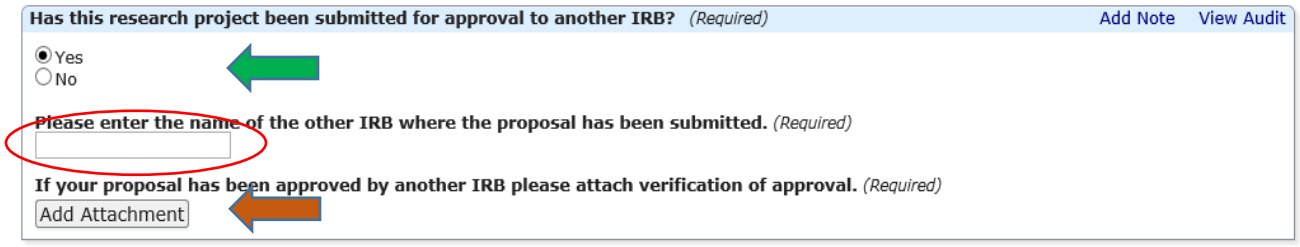
- If “Grant” or “Sponsor” is selected (**purple arrow**) the funding detail section appears (**blue arrows**).
- If “None” is selected the funding detail section does not appear.



6.7 Other IRB

Has this research project been submitted for approval to another IRB?

- If “Yes” is selected (**green arrow**) space to list other IRB (**red circle**) and place to attach their approval document (**gold arrow**) appears.
- If “No” is selected the detail section does not appear.



6.8 General Purpose

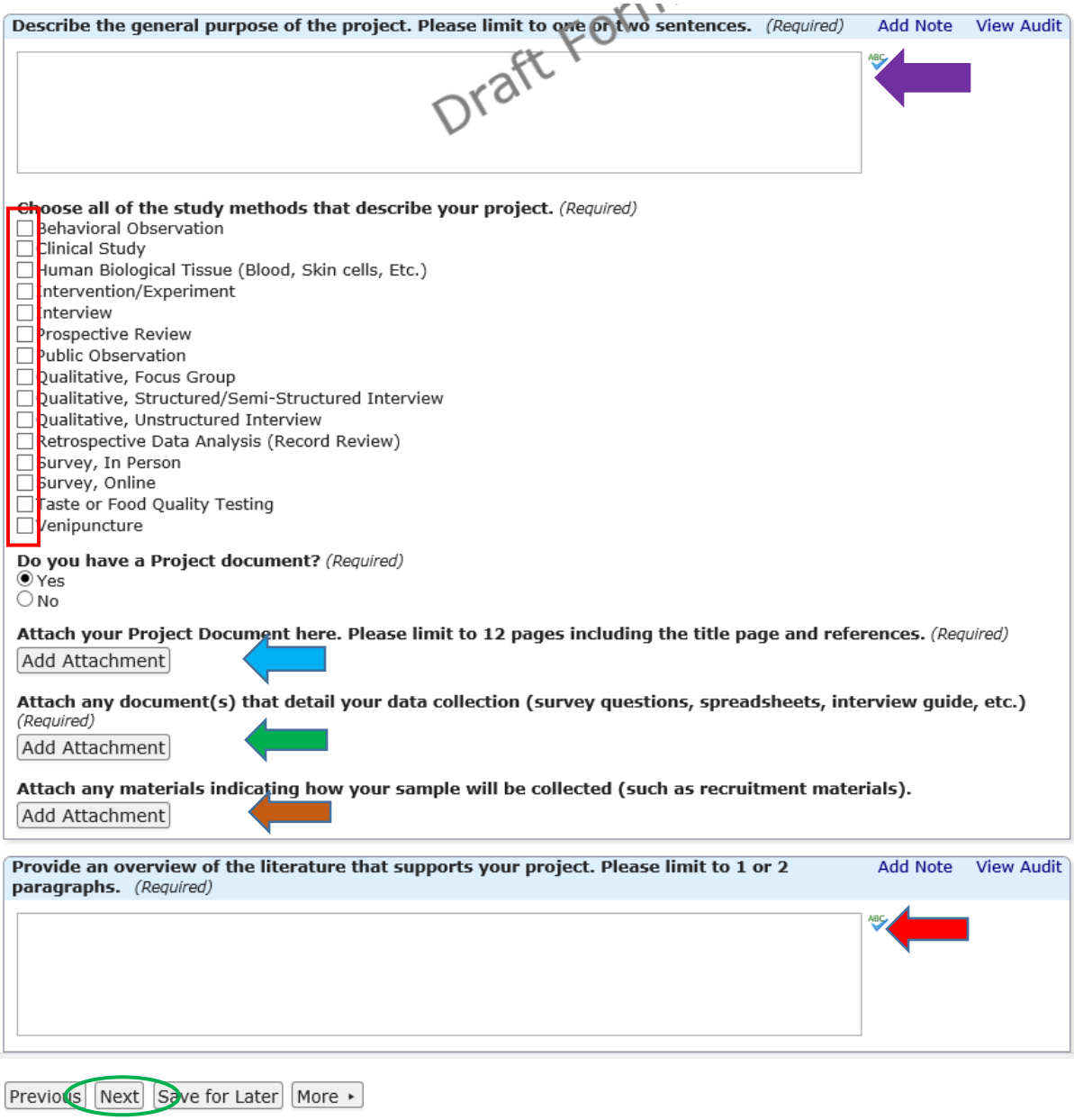
- This section is conditioned on your project category of **HSR** or **NHSR** (examples follow).

6.9 Example of HSR questions

- Briefly describe the general purpose of the project, *1-2 sentence limit* (**purple arrow**).
- Choose **ALL** the study methods that describe your project (**red box**).
- Attach protocol - *12 page limit* (**blue arrow**). If you do not have a protocol document, attach a more detailed description of the project, including sufficient details about the methods.
- Attach data collection details: survey questions, interview guides, etc. (**green arrow**).
- Attach materials indicating how your sample is collected such as recruitment materials , if applicable (**gold arrow**).

6.10 Example of NHSR questions

- Briefly describe the general purpose of the project, *1-2 sentence limit* (**purple arrow**).
- Choose **ALL** the study methods that describe your project (**red box**).
- If you have a project document, space to attach appears (**blue arrow**).
- Attach data collection details: survey questions, interview guides, etc. (**green arrow**).
- Attach materials indicating how your sample is collected such as recruitment materials, if applicable (**gold arrow**).
- Provide an overview of the literature that supports your project (**red arrow**).

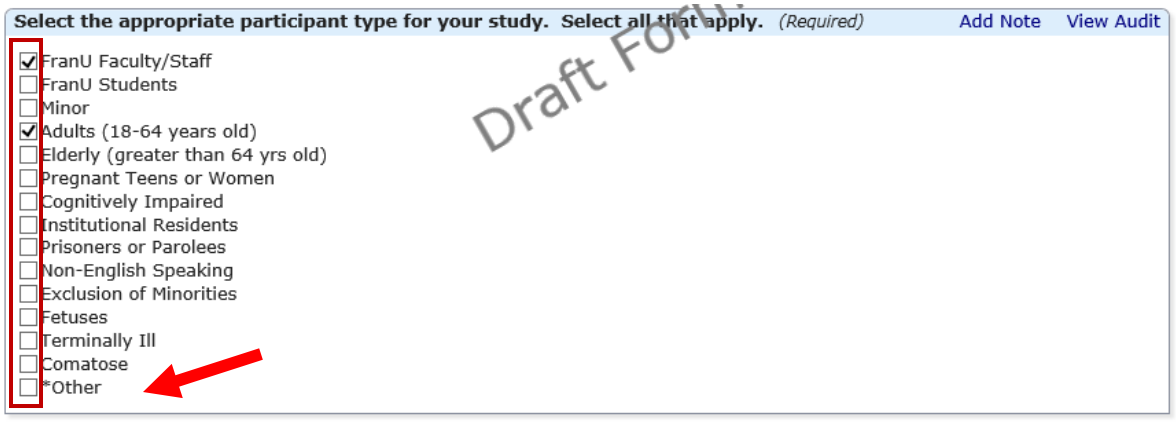


- Click "**Next**" at the top or bottom of the screen to proceed to the next screen.

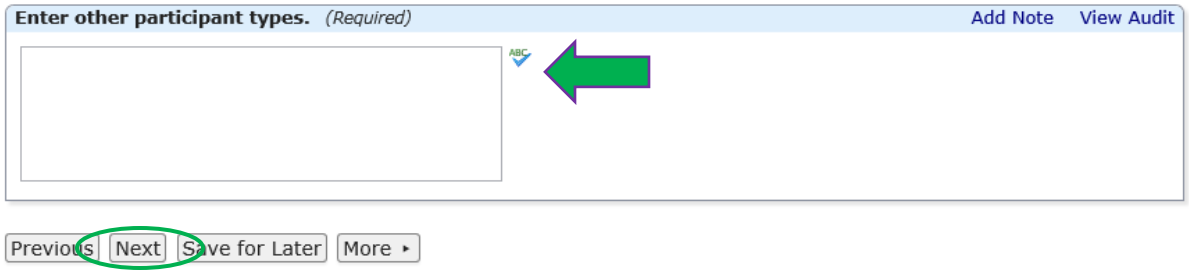
7.0 Participant Population

7.1 Participant Types

- Select ALL appropriate participant types for your project (**red box**).



- If "Other" is selected above (**red arrow**), space to list other participant types appears (**green arrow**), otherwise it does not appear.



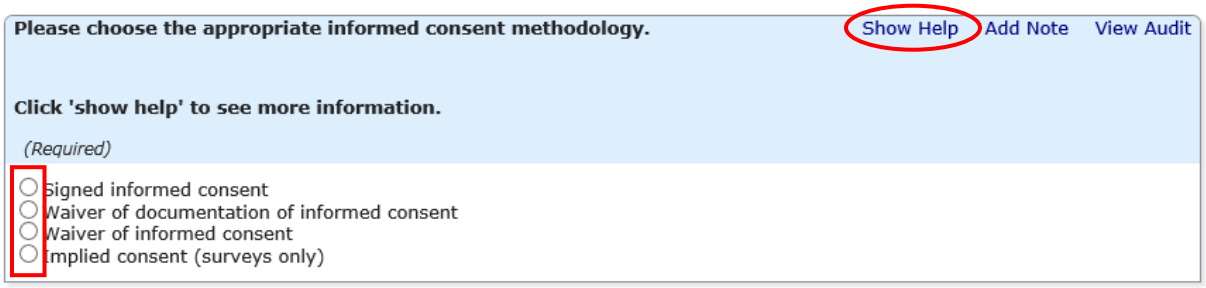
- Click "**Next**" at the top or bottom of the screen to proceed to the next screen.

7.2 Informed Consent Methodology

For projects categorized as **HSR** choose appropriate informed consent methodology (**red box**), otherwise this section does not appear.

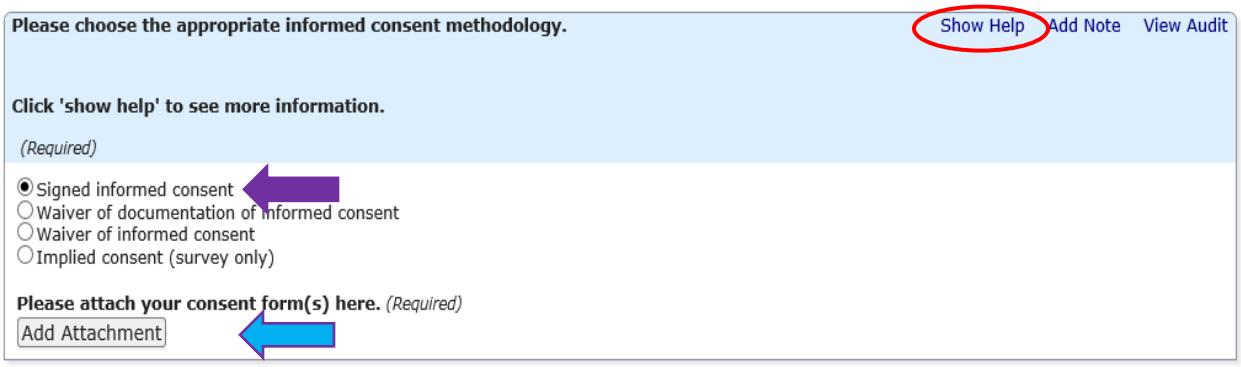
- Signed informed consent
- Waiver of documentation of informed consent
- Waiver of informed consent
- Implied consent (survey only)

*NOTE: Click **"Show Help"** (**red circle**) for additional information on consent methodology. After selecting your methodology, you are prompted to attach information and/or answer additional questions (examples of each method follows).*



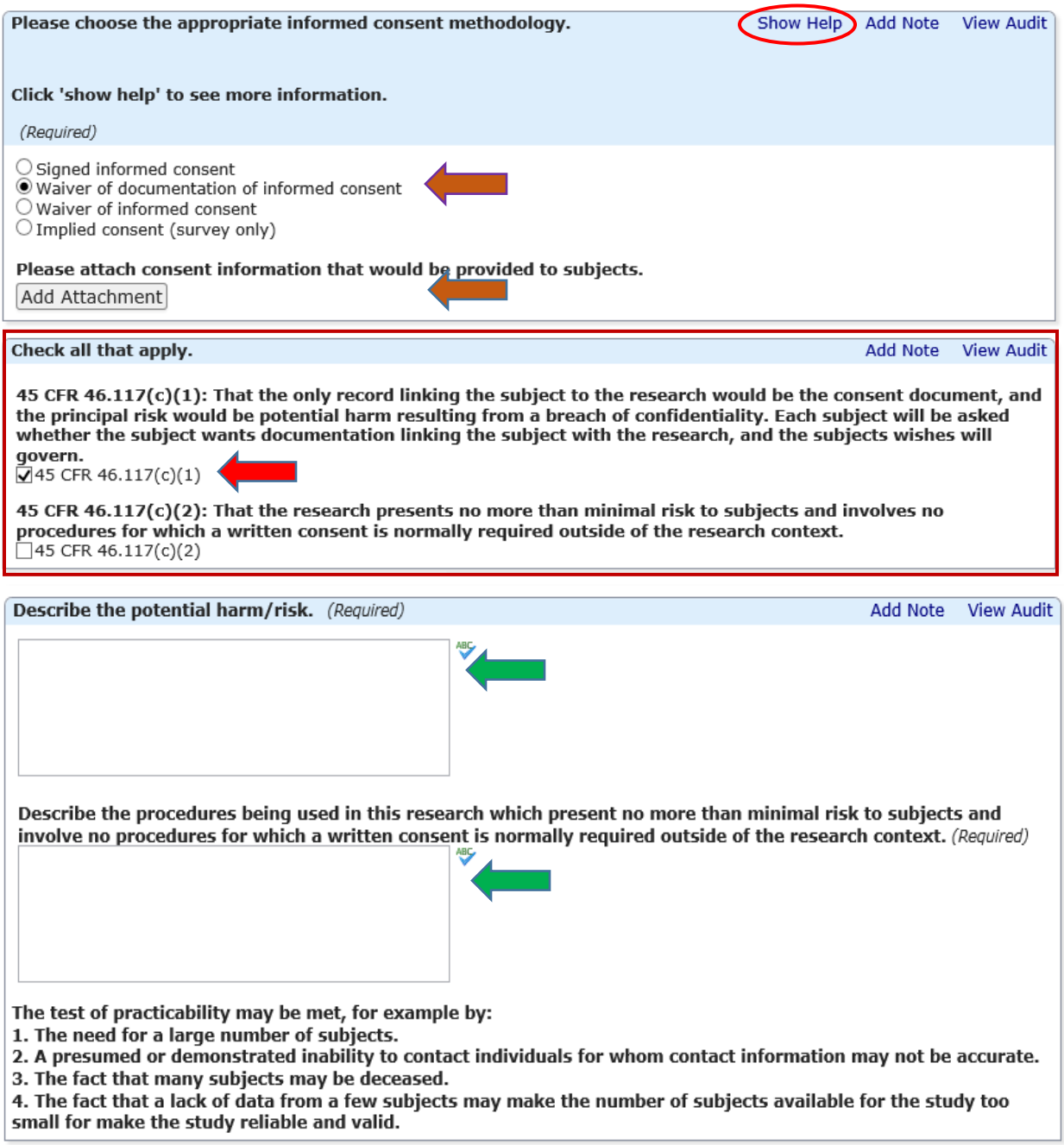
7.3 Signed informed consent

- Select "Signed informed consent" (**purple arrow**)
- Attach consent form(s) here (**blue arrow**)



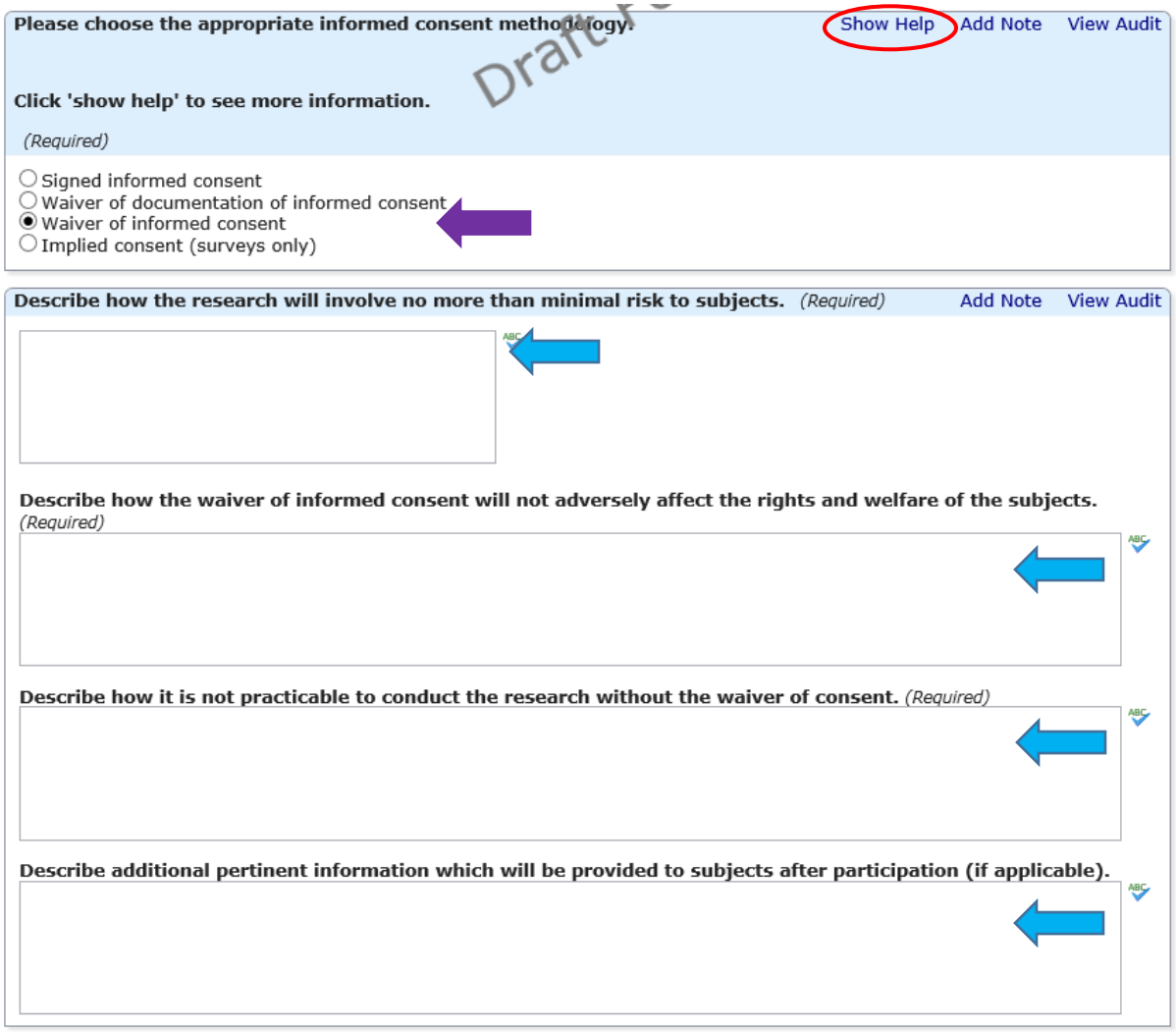
7.4 Waiver of documentation of informed consent

- Select “Waiver of documentation of informed consent” and attach consent information provided to subjects (**gold arrows**).
- Select ALL that apply (**red box**). If “45 CFR 46.117 (c)(1)” is selected (**red arrow**), a place to describe the potential harm/risk appears (**green arrows**), otherwise it does not appear.



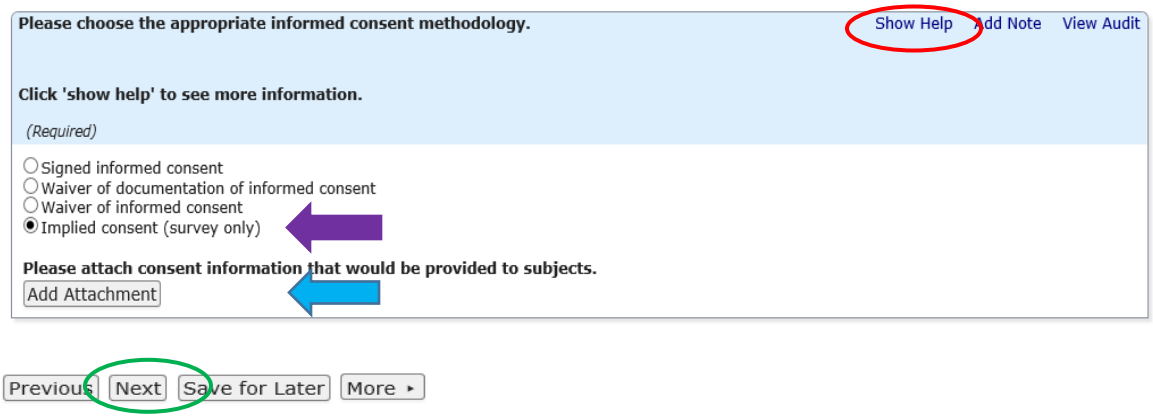
7.5 Waiver of informed consent

- Select “Waiver of informed consent” (**purple arrow**) and answer questions (**blue arrows**).



7.6 Implied consent

- Select “Implied consent” (**purple arrow**) and attach consent information (**blue arrow**).

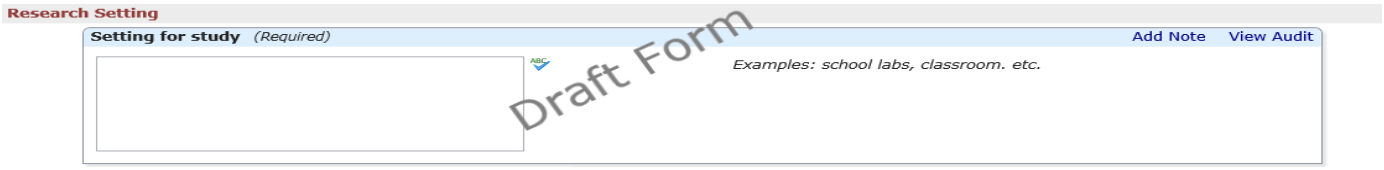


- Click “**Next**” at the top or bottom of the screen to proceed to the next screen.

8.0 Research Setting

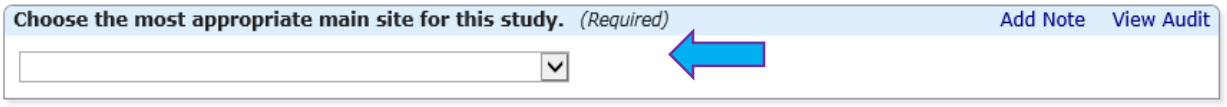
8.1 Setting for Study

- Describe the setting for your study



8.2 Main Site

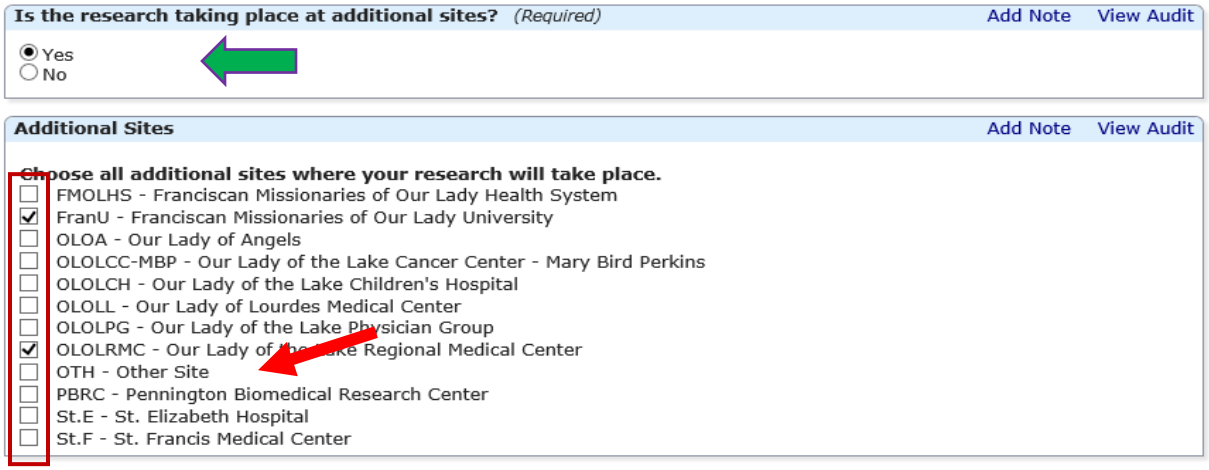
- Choose the most appropriate main site for your project from the drop-down (**blue arrow**).



- If "other" is selected space to specify an "other" main site appears (**gold arrow**), otherwise it does not appear.

8.3 Additional Sites

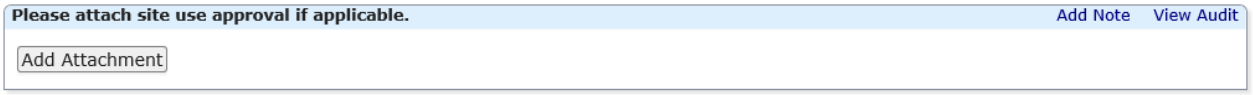
- Is the research taking place at additional site(s) (**green arrow**)?
- If "Yes" is selected a place to select **ALL** additional sites appears (**red box**), otherwise it does not appear.



- If "OTH – Other Site" is selected from above list (**red arrow**), space to enter "other" additional site(s) appears (**purple arrow**), otherwise it does not appear.

8.4 Site Use Approval

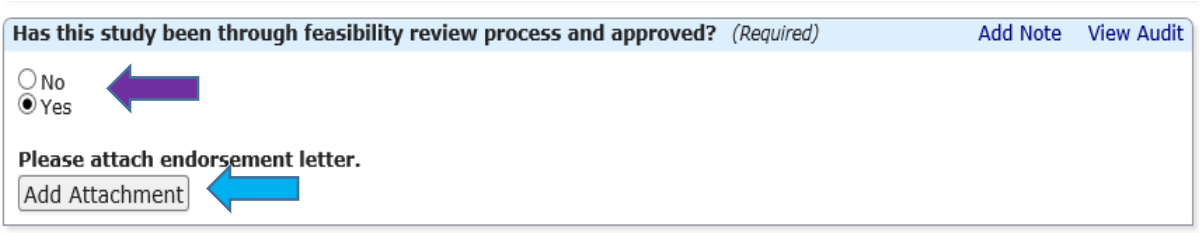
- Study sites off-campus or not affiliated with FranU, OLOLRMC or FMOLHS need signed authorization from the site. Attach site use approval here (if applicable).



8.5 Feasibility Review

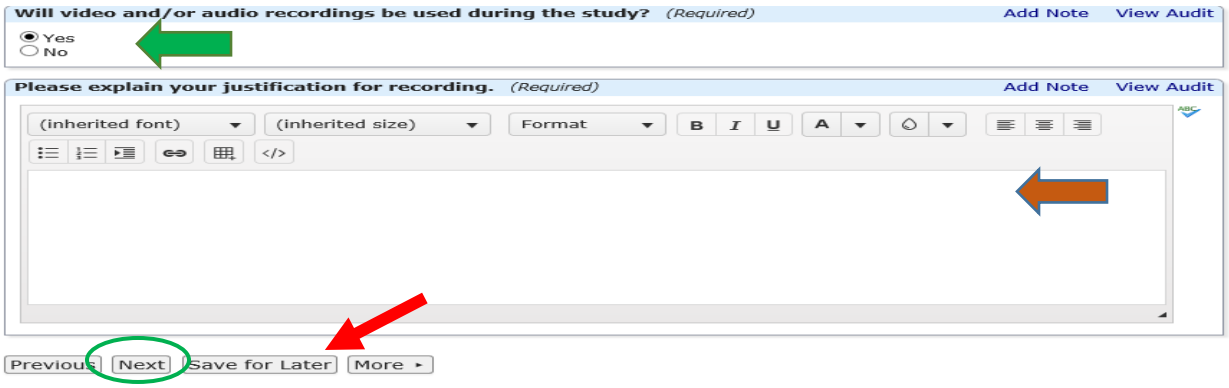
*NOTE: If the Principal Investigator/Project Lead is a **FranU Student or Employee** the following feasibility section does NOT appear. You DO NOT NEED to request feasibility review before submitting your application to the IRB. Once your application is submitted, it is sent for feasibility review and a Letter of Endorsement is automatically attached upon approval.*

- Has this study been through feasibility review process and approved?
- If "Yes" is selected a place to attach your endorsement letter is provided (**purple arrow**), otherwise it does not appear.
- Attach endorsement letter here (**blue arrow**).
- If "No" is selected the remainder of the application can be filled out using the "Navigation Drop-Down" (top of the screen), but **feasibility approval is needed before you can submit this application.** "Save for Later" at the bottom of the screen (**red arrow**) allows you to save your progress and return later from your **Dashboard.**



8.6 Video or audio recordings

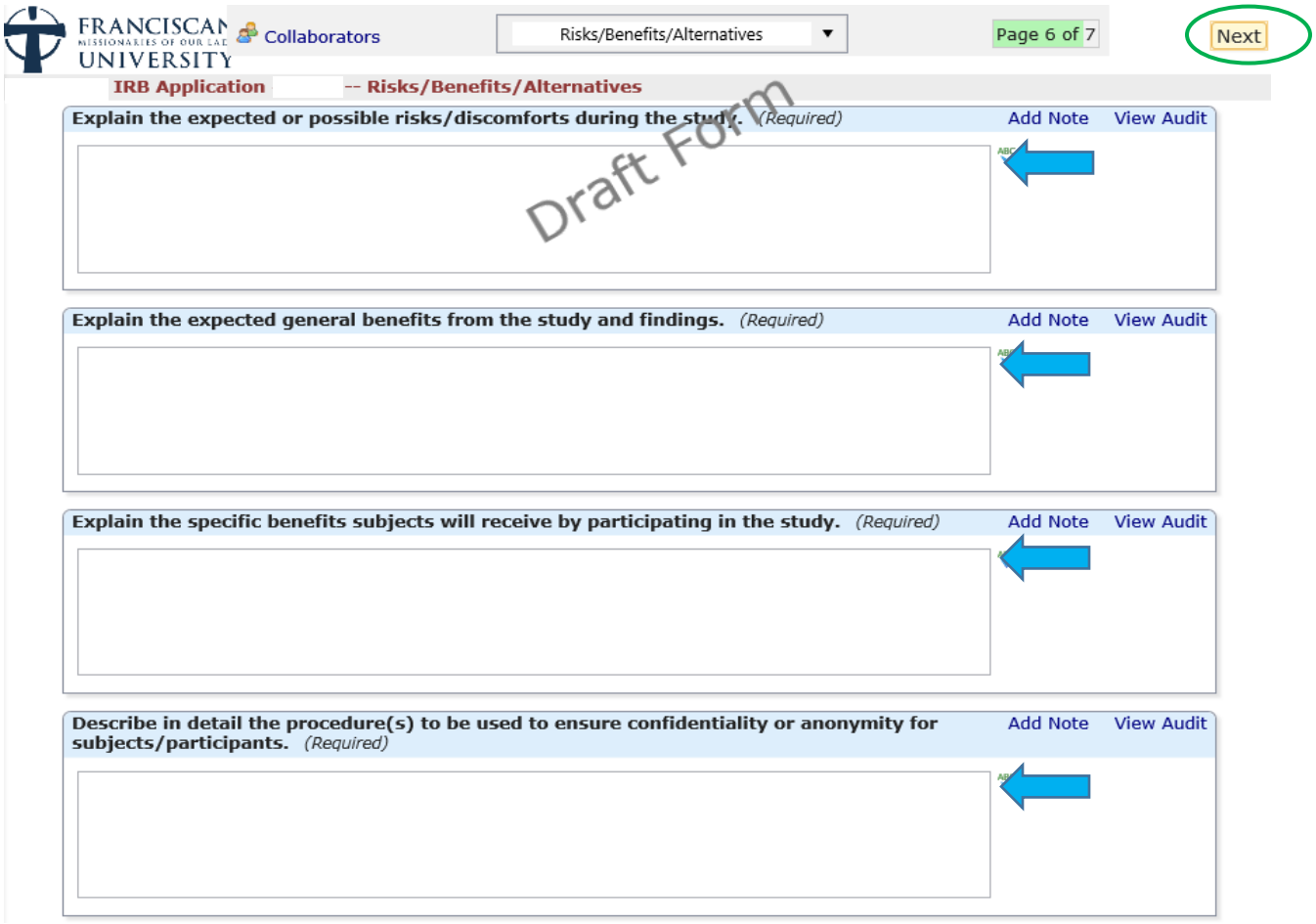
- If video and/or audio recordings are used select "Yes" (**green arrow**) and provide justification (**gold arrow**). If "No" is selected the justification section does not appear.



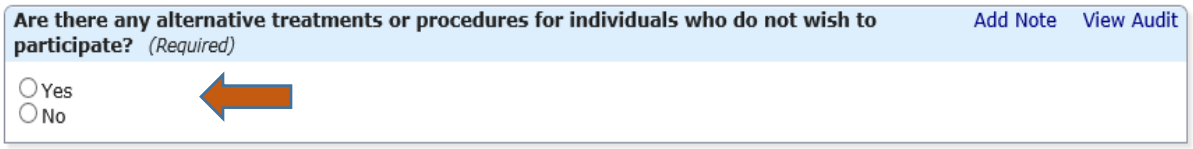
- Click "**Next**" at the top or bottom of the screen to proceed to the next screen.

9.0 Risks/Benefits/Alternatives

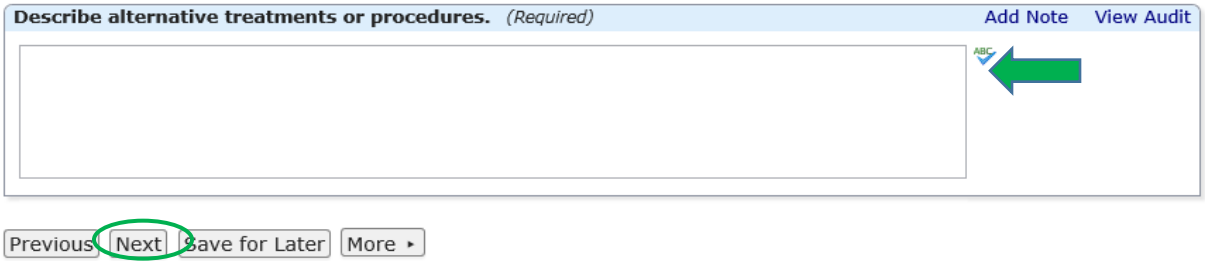
- Each of the following sections require your input (**blue arrows**).



- Are there any alternative treatments or procedures for individuals who **do not wish to participate** (**gold arrow**)?



- If "Yes" is selected a place to describe alternative treatments or procedures appears (**green arrow**), otherwise it does not appear.

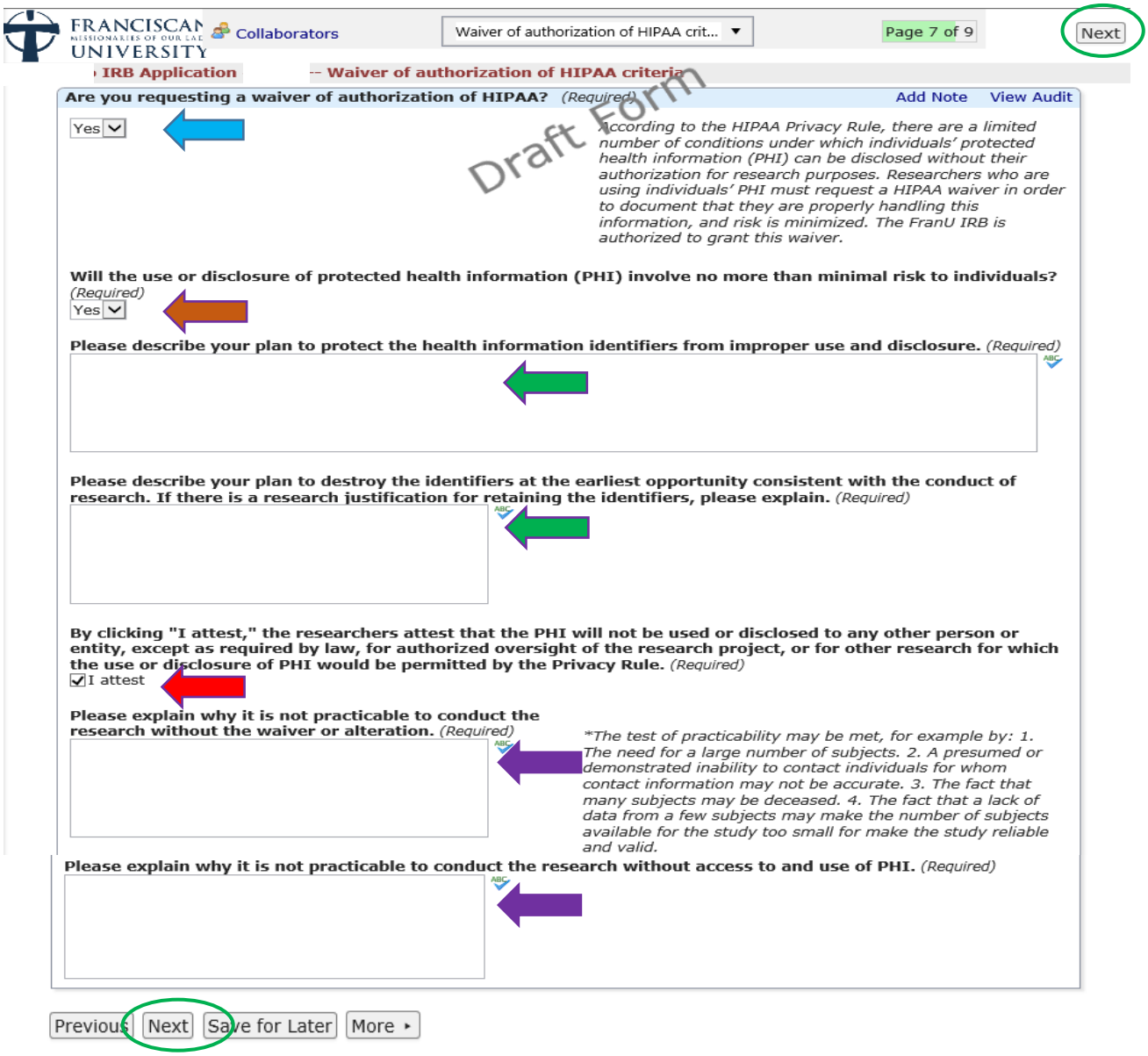


- Click "**Next**" at the top or bottom of the screen to proceed to the next screen.

10.0 Waiver of authorization of HIPAA criteria

Select "Yes" if you are requesting a waiver of authorization of HIPAA (**blue arrow**) and provide the additional information related to the use of protected health information (PHI). If "No" is selected the additional information section does not appear.

- Select "Yes" (**gold arrow**) if the study involves no more than minimal risk to individuals.
- Describe your plan to protect health information identifiers from improper use and disclosure, and your plan to destroy the identifiers at the earliest opportunity or justification for retaining any identifiers (**green arrows**).
- Read statement and if you agree, select "I attest" (**red arrow**).
- Explain why it is not practical to conduct study without a waiver or alteration and without access to and use of PHI (**purple arrows**).

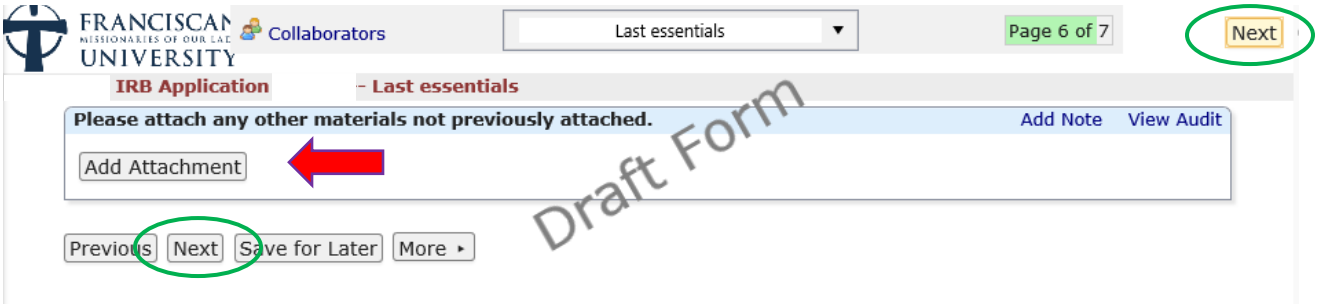


- Click "**Next**" at the top or bottom of the screen to proceed to the next screen.

11.0 Last Essentials

11.1 Other materials not previously attached

- This section allows you to attach other material you feel is important to your study but was not previously attached (**red arrow**).

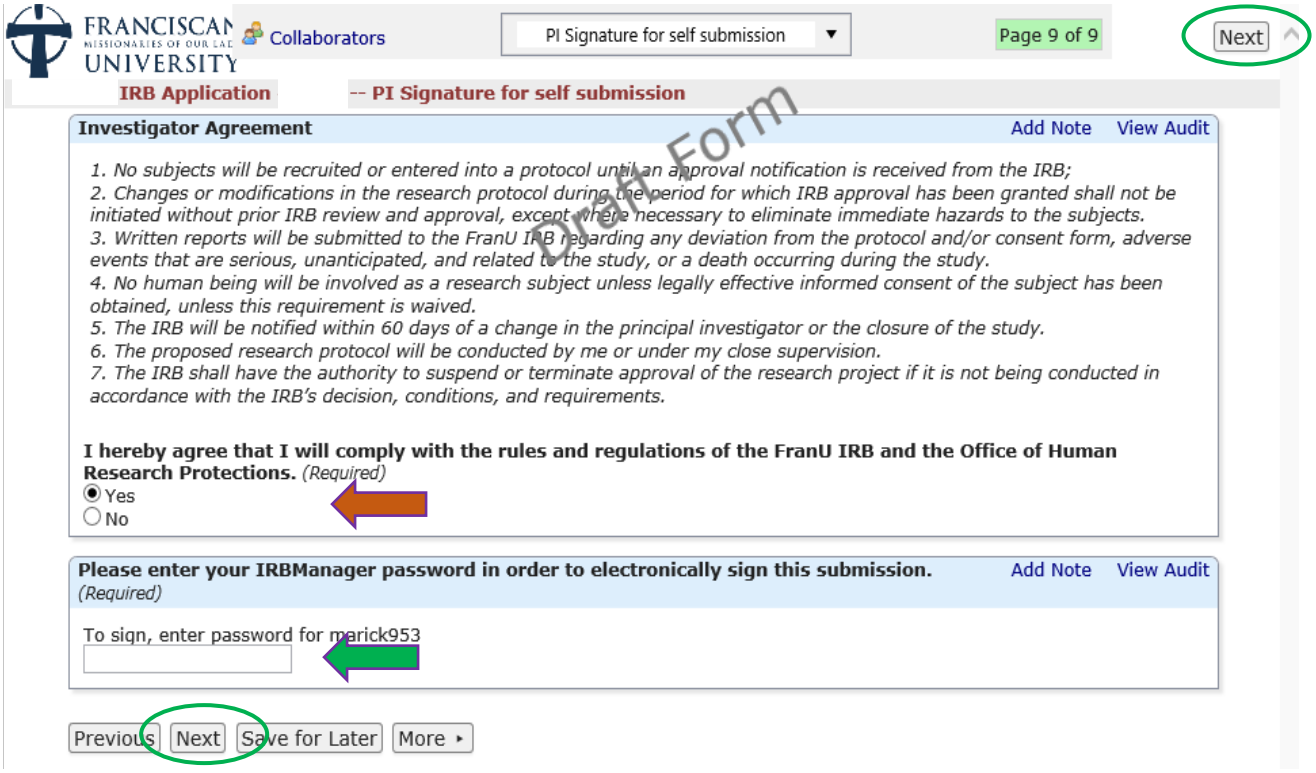


- Click "**Next**" at the top or bottom of the screen to proceed to the next screen.

12.0 PI Signature for self-submission

This section shows how the PI signs for self-submission.

- Read and agree to Investigator Agreement (**gold arrow**)
- Electronically sign application using your IRBManager password (**green arrow**).

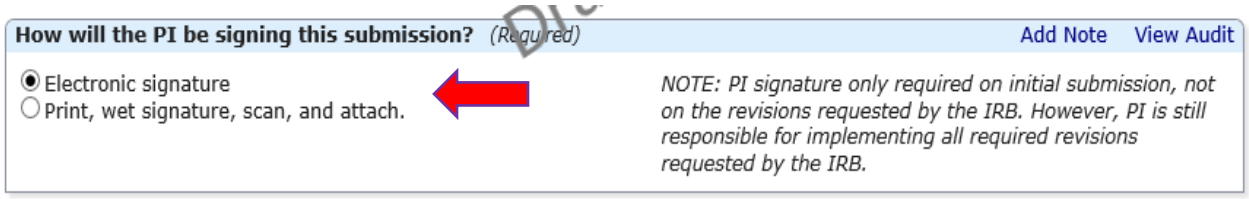


- Click "**Next**" at the top or bottom of the screen to proceed to **check and submit form** screen.

12.1 How will the PI sign when submitted by others?

*NOTE: Coordinators and Research Directors - **When the submitter is NOT the PI** the application routes to the PI for review and signature. If submitter is the PI, these steps will not appear.*

- Select the appropriate option for the PI's signature (**red arrow**).

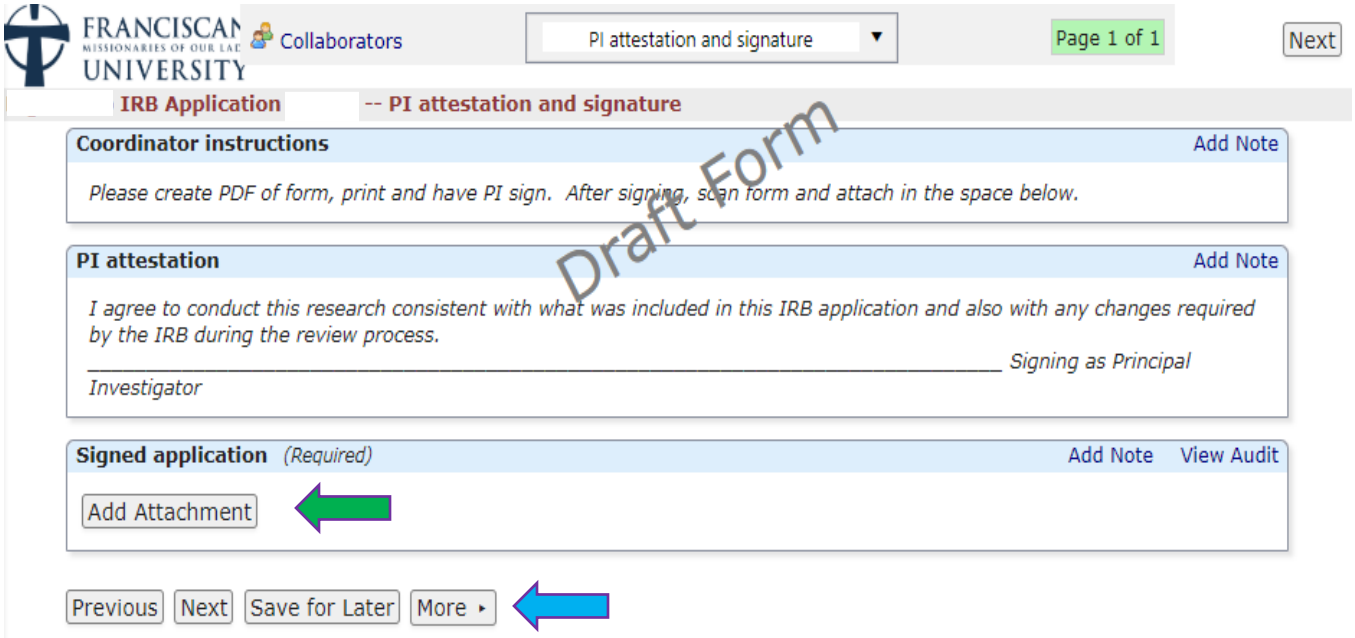


- If "electronic signature" is selected the PI receives an email with a link to the form to review and electronically sign using IRBManager password.
- If "Print, wet signature, scan and attach" is selected follow the steps in 12.2 below.

12.2 Print, wet signature, scan and attach.

Use this option when the PI does not have access to electronically sign. This allows PI's wet signature to be scanned and attached.

- Create PDF of form using "More" button below (**blue arrow**), print and have PI sign.
- Scan signed form and attach in the space provided (**green arrow**).



- Click "**Next**" at the top or bottom of the screen to proceed to **check and submit form** screen.

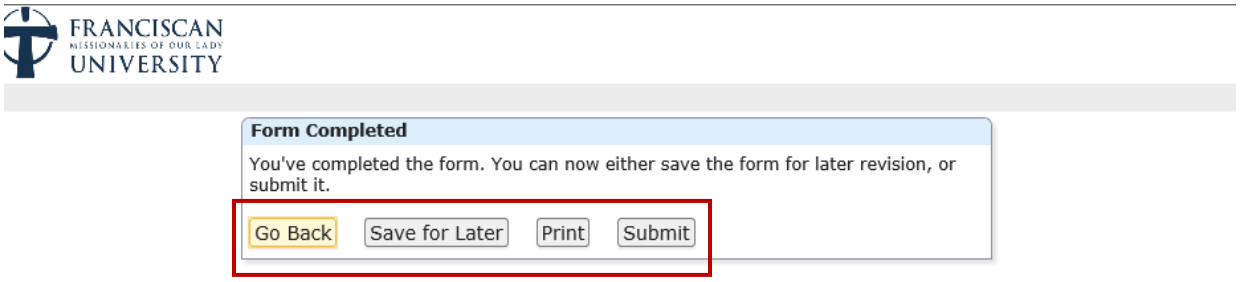
13.0 Form Complete and Submit

Once you reach the submission screen you have several options (**red square**).

- **Go Back** – return to prior screen(s).
- **Save for Later** – save and exit your form. You may return later from your **Dashboard.**
- **Print** – print a PDF of your form.
- **Submit** – submit your form.

After selecting "**Submit**" the system checks for all required elements.

- If you provided all required elements your form is sent to IRB for review. You may close this window.
- If you missed any required elements a list of issues is created to correct before you can submit your form (**green box**).
- Click on the page name link to jump to that screen and correct issues (**blue arrow**).
- After correcting all issues, select "**Submit**" again and your form is sent to IRB for review. You may close this window.



14.0 What's Next?

- After your application is submitted, an automated email is generated to the owner of each stage with a link to the form as it advances.

    1. Application data entry
        Stage Owner - ***Submitter/PI***
    2. Faculty Advisor Review (if applicable)
        Stage Owner - ***Faculty Advisor***
    3. IRB Office Review
        Stage Owner – ***FranU IRB Office*** *(IRB@franu.edu)*
    4. FranU Feasibility Review (if applicable)
        Stage Owner **-** ***FranU Research & Scholarship Council Chair*** *(RSC@franu.edu)*
    5. IRB Chair Review
        Stage Owner – ***FranU IRB Chair*** *(IRB@franu.edu)*
    6. IRB Member Review
        Stage Owner(s) – ***FranU IRB Committee Member(s)*** *assigned by IRB Chair*
    7. IRB Full Board Review (if applicable)
        Stage Owner – ***FranU IRB Office***
    8. Post Review Processing
        Stage Owner – ***FranU IRB Office*** *(IRB@franu.edu)*
    9. Notify PI of Approval
        Stage Owner – ***FranU IRB Office*** *(IRB@franu.edu)*

- Once your application is submitted, you can see the "initial submission" link on your **Dashboard**. To check the progress of your application in IRBManager return to your **Dashboard** and click on your application.
- Access to update applications is restricted to the owner of each stage (see above). In other words, no one can make changes or add notes to the form unless they are the owner of the current/active stage.
- Forms may be returned to the Submitter/PI during any review stage if additional information or further explanation is needed. In the event this happens, an automated email is generated to the PI/Submitter with a link to the form. A link to your form is also available on your **Dashboard**. Once the form is resubmitted it routes back through all stages again.
- The usual turnaround from submission to assigning reviewers is five business days with most decisions rendered within 30 days.

Email IRB@franu.edu for questions or assistance.