Salus IRB
IRBManager User Guides
Completing and Submitting Modification xForms

Salus IRB

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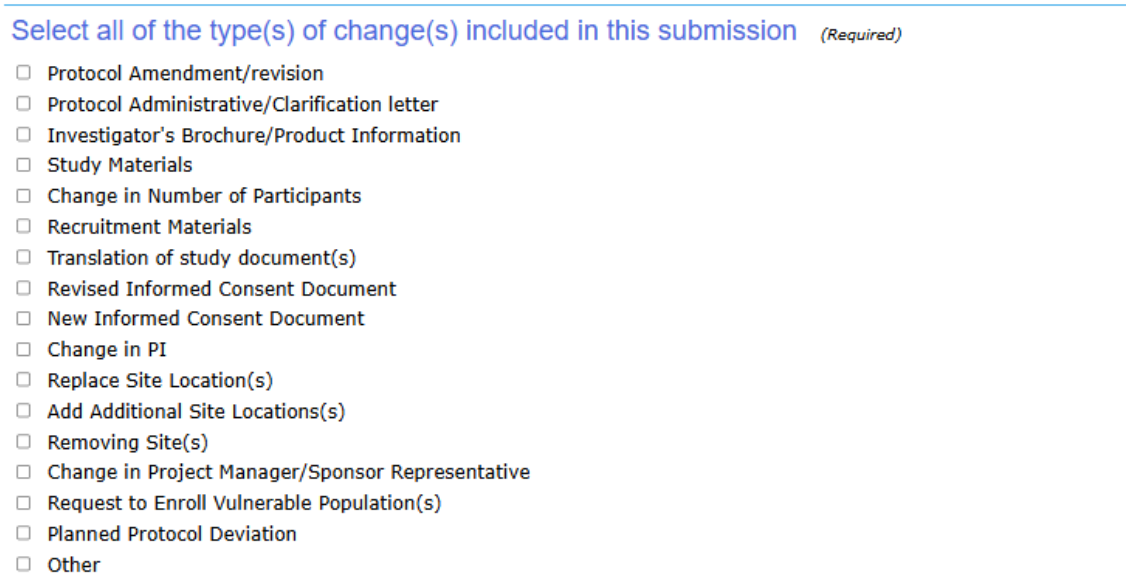
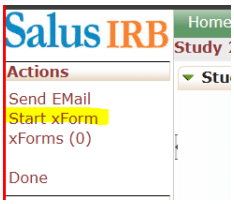
Starting a Modification xForm

The following circumstances require submission of a modification xForm. When submitting, please keep the following in mind:

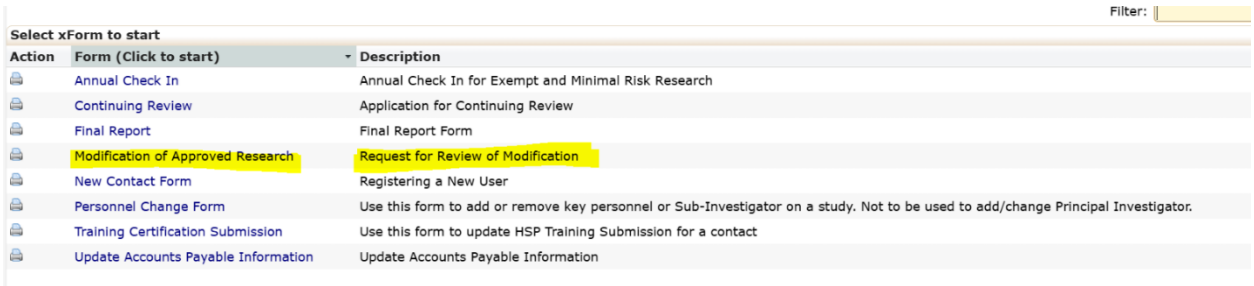
- Modification xForms are to be used for submissions of new and revised materials on an existing and active study or study site.



1. From your IRBManager Dashboard, select the "Studies" tab
2. Select the study or site for which you wish to modify
3. Click on "Start xForm" on the left side



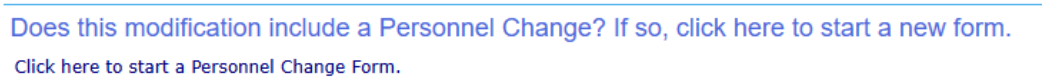
4. Select *Modification of Approved Research*



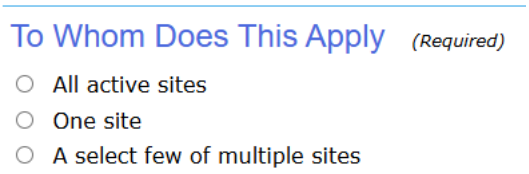
5. Complete and submit the form

Completing the Modification xForm

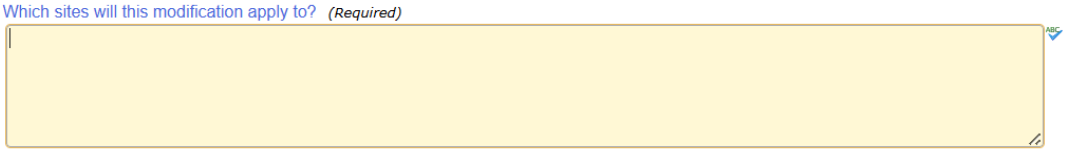
1. If the Modification Submission includes a Personnel Change, this will be your first question on the modification checklist. Click the link on the xForm to start the Personnel Change Form.



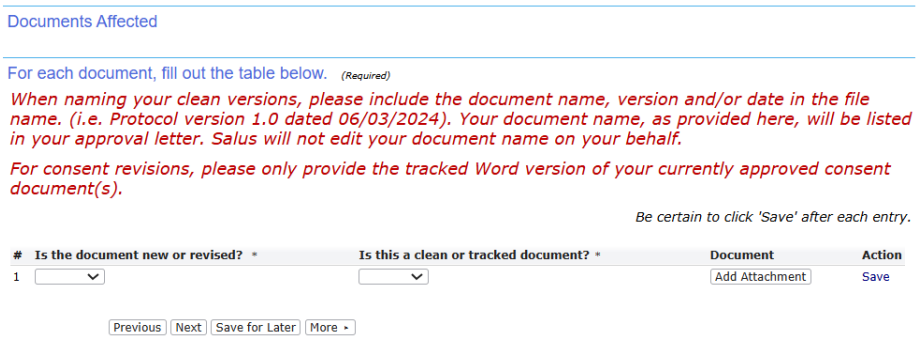
2. ***(Multi-Site Question)*** *To whom does this apply?*
   - *Select: All Active; One Site or Select a few of multiple sites*



   - Note: If "One Site" or a "Select Few of Multiple Sites" is selected, please provide the site(s) information in the text box below.

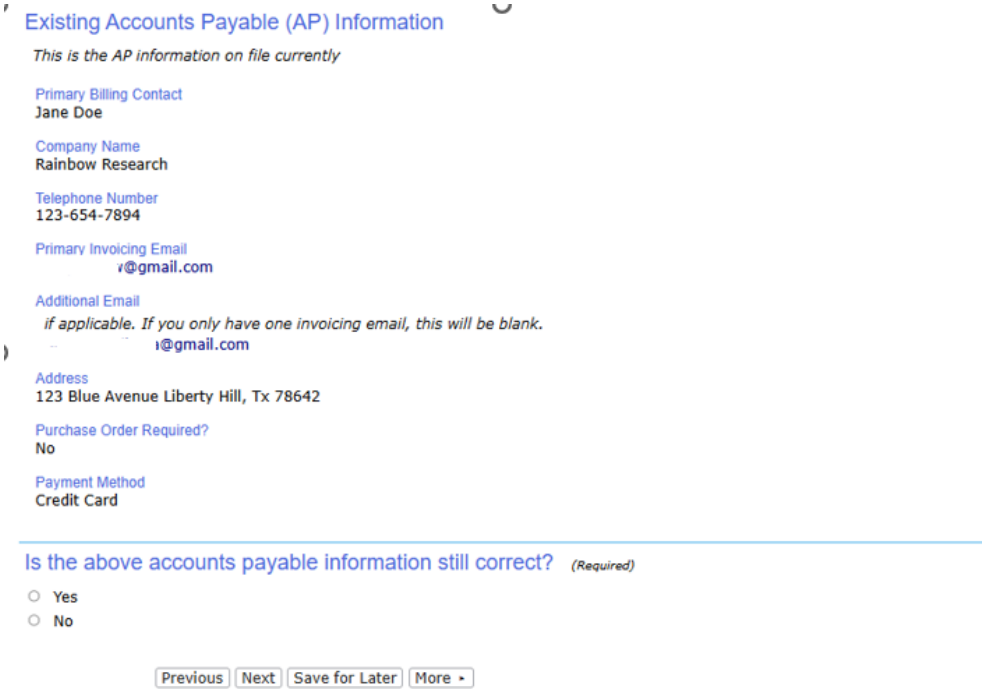


3. Once page 1 is complete, click NEXT at the bottom of the form to page 2.
   - Please attach all necessary documents here (see screenshot).
   - First drop down: Is the document New or Revised?
   - Select clean or tracked document
     - Note: please follow the instructions below on how to submit documents, new and revised.
   - Attach document
   - Click save



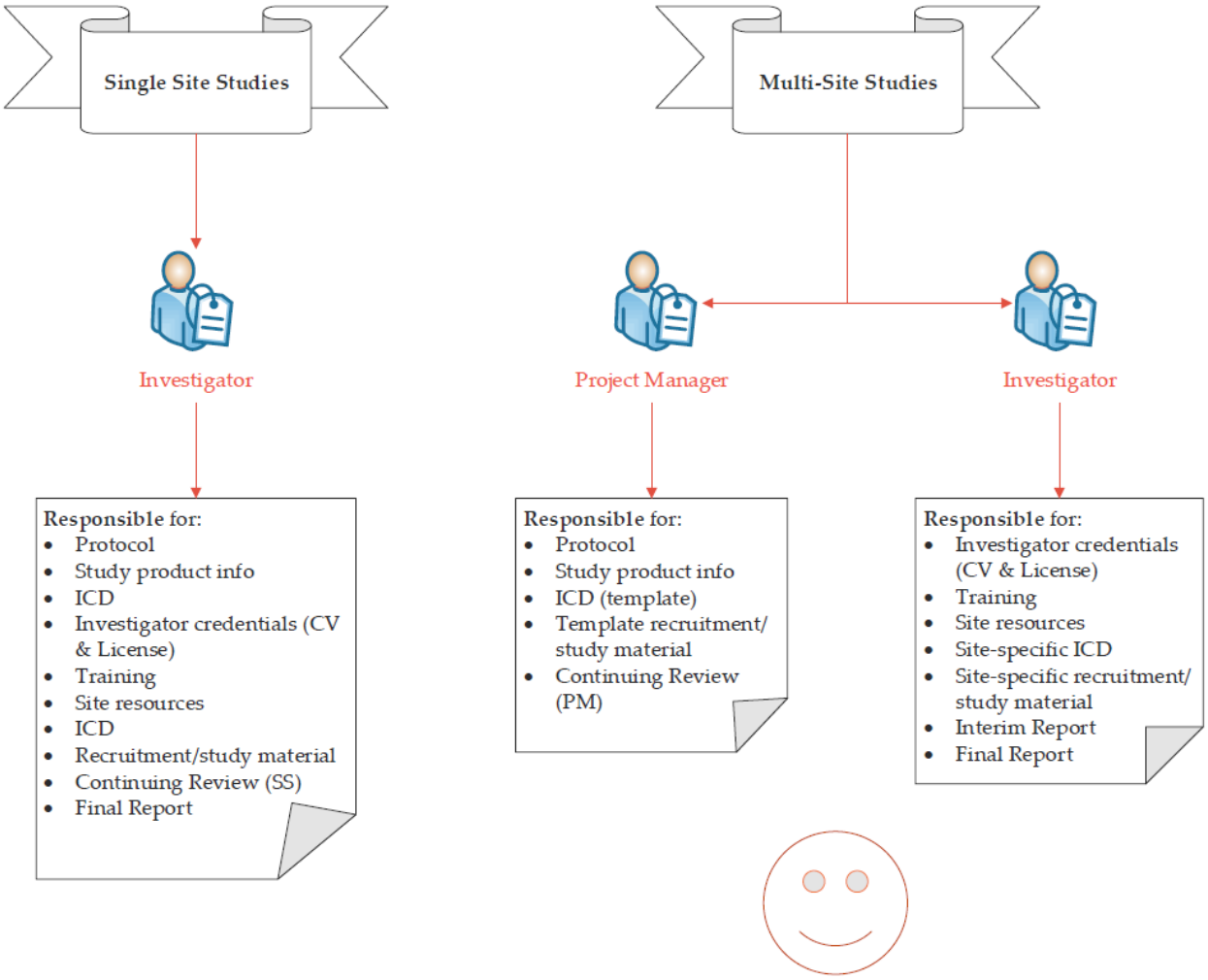
4. When you have finished attaching all documents, click NEXT into page 3 of the xForm.
    - Please list any additional information the site feels Salus IRB should be aware of here.

5. Click NEXT, to page 4 of the xForm. This page will ask the study to verify the billing/account information.
    - Ensure ALL Accounts Payable (AP) Information is correct and up to date. If the information is incorrect, select NO. This will prompt the xForm to allow you to enter correct information.



6. Final Step: SUBMIT
    - Note: if the PI is not the person creating the xform, the form will be routed to the PI for review and signature prior to final submission to Salus for review (see “IRBManager User Instructions for Site PIs”)

Multi-Site and Single-Site Modification Flowchart:



Things to Keep In Mind

When submitting Modifications, please ensure your documents follow the list of Salus IRB requirements below.

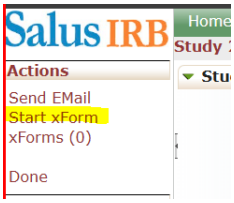
- IMPORTANT: ALL documents submitted for review and approval by Salus IRB require a **Version # and/or Date** to be included in the document and in the document file name.
- Revised Informed Consent Document(s): Must be submitted on Salus IRB previously approved and locked version. Salus IRB will not accept revisions made to a MSWord document that does not require Salus IRB password protection to unlock.

- Revised/Amended Protocol: Submit a clean version of the document. Submit a tracked and/or SOC version of the document. Tracked and/or SOC must always be provided.
- Revised Investigator's Brochure: Submit a clean version of the document. Submit a tracked and/or SOC version of the document. Tracked and/or SOC must always be provided.
- Study Material: All Study Materials must be submitted as a MSWord document. For revisions, submit a clean AND tracked document. If a tracked document cannot be provided, please provide a detailed list of all revisions to the document in the additional comments section of the xForm.
- Recruitment Material: All Recruitment Material must be submitted as a MSWord document. All revised recruitment materials must be submitted with a clean AND tracked document. If a tracked document cannot be provided, please provide a detailed list of all revisions to the document in the additional comments section of the xForm.
- Client Translated Study Documents: If your study is a client translated study/site, please ensure the following:
    - Include all translated documents alongside corresponding translation certificates.
    - Ensure all file names contain a version # and/or date that Salus IRB will be able to locate on the document itself.
- Change in Principle Investigator/Project Manager:
    - Ensure new investigator's documents are submitted as applicable (license, HSP certificate, CV, etc.)
- Adding/Removing/Changing Research Sites/Locations:
    - Salus IRB will modify any active ICDs to reflect the research site/location modifications. Please only select "ICD revisions" if changes *other than* location are requested.
- File Naming: Salus IRB will not re-name your files, therefore your document name, as provided on the xForm, will be listed in the approval letter. When naming your clean versions, please include the document name, version and/or date in the file name. The only exception is that Salus IRB will rename ICDs upon approval, thus you do not need to rename any ICDs submitted for modification.
    - Examples of how documents should be named:*Protocol Version 1.0 dated 06/03/2024*
    - *Protocol Clarification Letter dated 22 December 2021*
    - *Subject Calendar Version 2 dated 25-Jan-25*
    - *Subject Calendar V2*
    - *AdSet V2 dated 22-Feb-25*

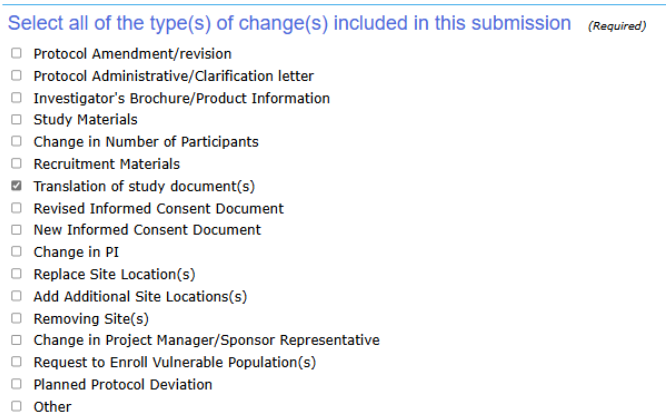
- *AdSet Version 2.0*
- *Drug Diary: Daily Dosing 3 Days on and 4 Days Off for Cycle X dated 01-25-2025*
- *Drug Diary: Daily Dosing 3 Days on and 4 Days off for Cycle X*
- *Investigator's Brochure Edition 5.0 dated 1-23-24*
- *Investigator's Brochure Edition 5.0*

Submitting Modification xForm for Translation Request

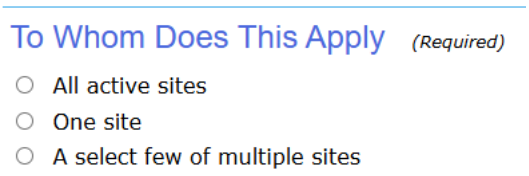
1. First, please ensure that your study and/or site is approved to enroll Non-English-Speaking Participants. If your study/site is NOT approved to do so, please follow the instructions for "Requesting to Enroll Vulnerable Populations" as detailed later in this document.
2. Start Modification xForm



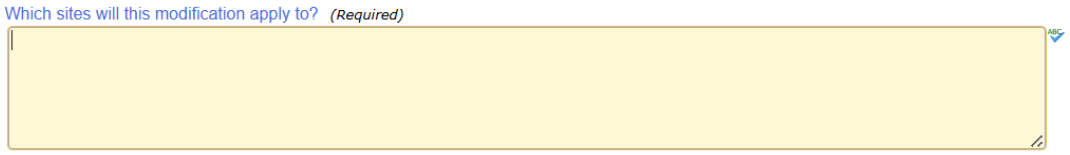
3. Select Translation of Study Document(s)



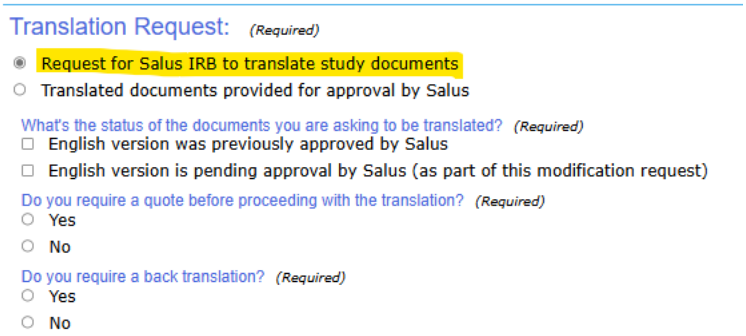
4. ***(Multi-Site Question)*** *To whom does this apply?*
    - *Select: All Active; One Site or Select a few of multiple sites*



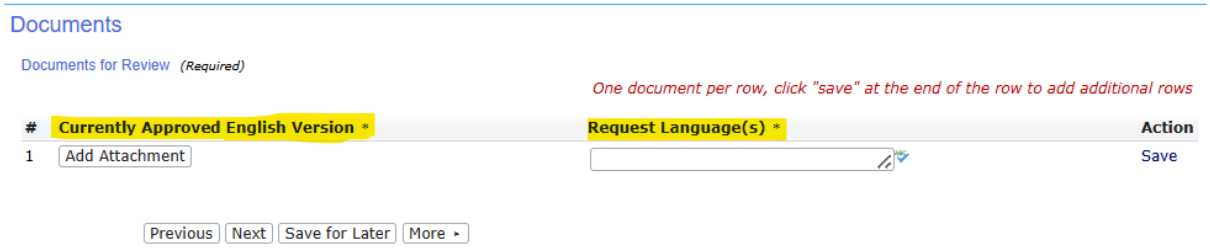
- Note: If "One Site" or a "Select Few of Multiple Sites" is selected, please provide the site(s) information in the text box below.



5. Select Request for Salus IRB to Translate study documents & answer the questions:
   - Do you require a quote? If selected, Salus IRB will send the translation to the vendor and receive a quote. Salus will send this quote via email for the study to confirm. If this option is selected, Salus IRB will not move forward with the translation until you have accepted the quote.
   - Do you require a back translation?



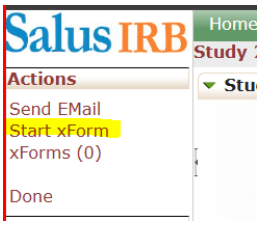
6. **Attach:** Currently approved English document (this will be the exact document translated)
7. **Input Requested language:** (Spanish, Chinese, Japanese…etc.)



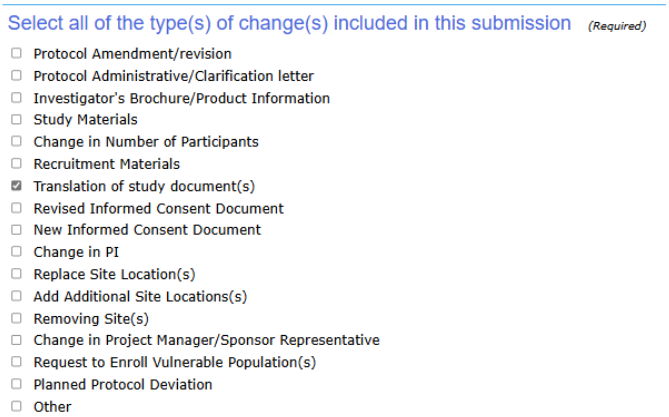
8. Final Step: SUBMIT

Submitting Modification xForm for Client Translated Study Document(s)

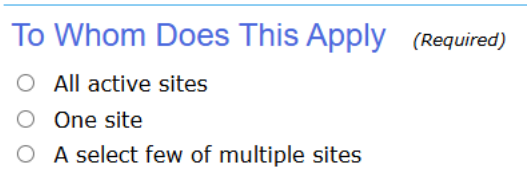
1. First, please ensure that your study and site are approved to enroll Non-English-Speaking Participants. If your study/site is NOT approved to do so, please follow the instructions for "Requesting to Enroll Vulnerable Populations" as detailed later in this document.
2. Start Modification xForm



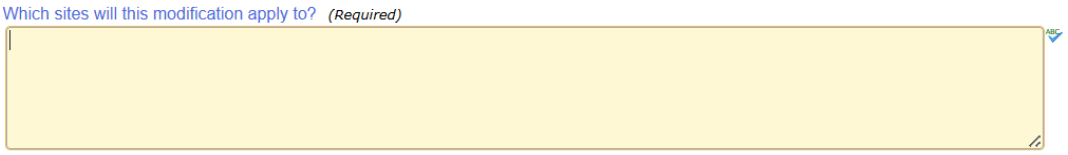
3. Select Translation of Study Document(s)



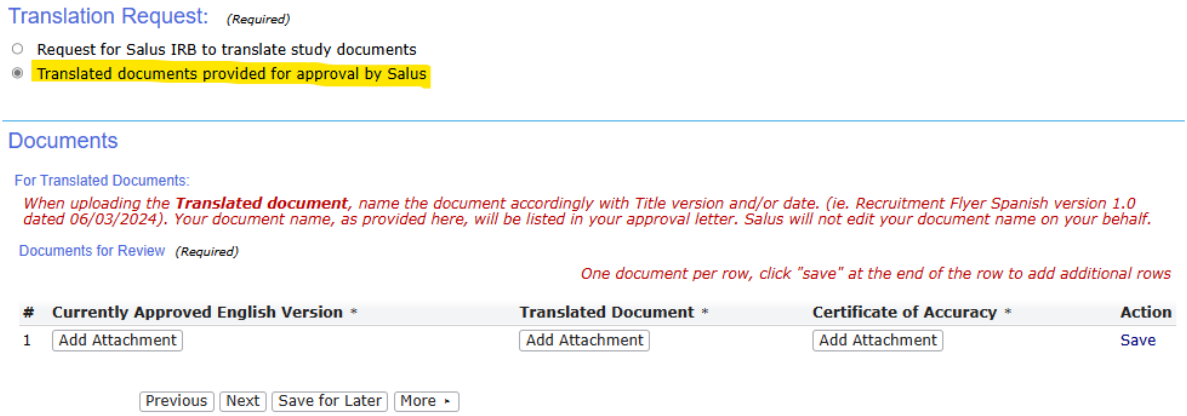
4. ***(Multi-Site Question)*** *To whom does this apply?*
    - *Select: All Active; One Site or Select a few of multiple sites*



- Note: If "One Site" or a "Select Few of Multiple Sites" is selected, please provide the site(s) information in the text box below.



5. Select Translated documents provided for approval by Salus IRB
6. Attach the Salus IRB Approved English Version, the Translated document, and the Certificate of Accuracy/Translation.
    - Ensure the translated document contains a version # and/or date that matches the document.
    - All Client Translated documents must be submitted alongside a Translation Certificate. The Certificate of Translation must contain the document file name, version # and/or date listed on the document.

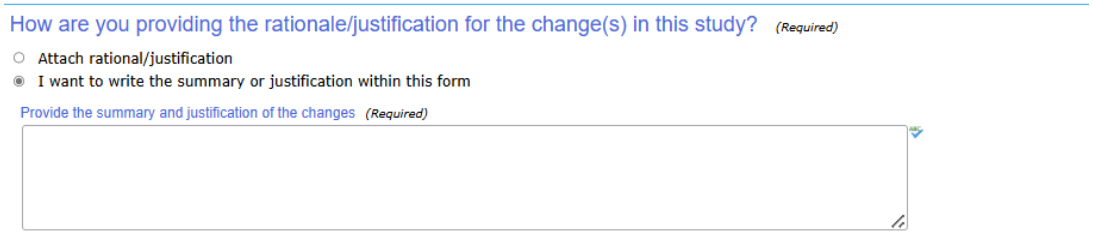


7. Final Step: SUBMIT

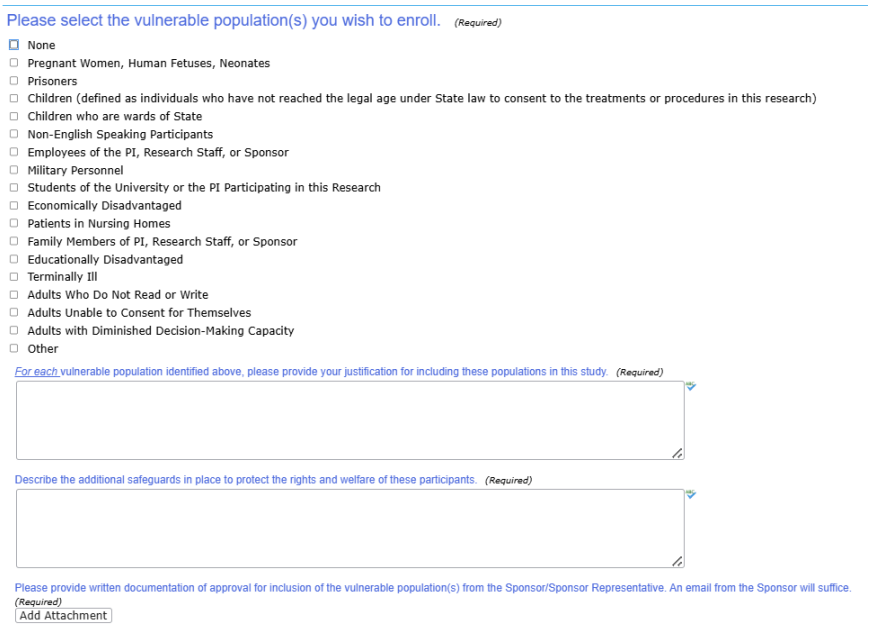
Requesting to Enroll Vulnerable Populations

If the study/site would like to enroll vulnerable populations follow the instructions below.

1. Start Modification xForm
2. Select Request to Enroll Vulnerable Populations
    - *NOTE: If the number of participants to be enrolled in the study is changing and/or you are requesting adding a new vulnerable population, a protocol amendment must also be submitted. Be certain to select 'protocol amendment' in the type of changes.*
    - *If you do not include ICD revisions,you must provide a rational for ICD modification not being necessary.*
    - You may either attach a rationale or write a rationale in the box listed below.



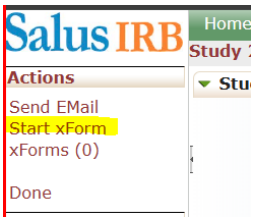
3. Follow the instructions below on the xForm & attach required documentation



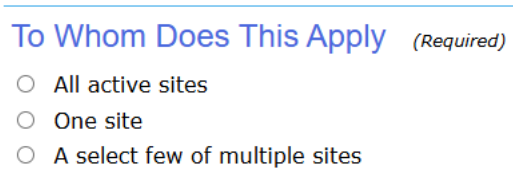
4. Final Step: SUBMIT

Submitting a PI Change

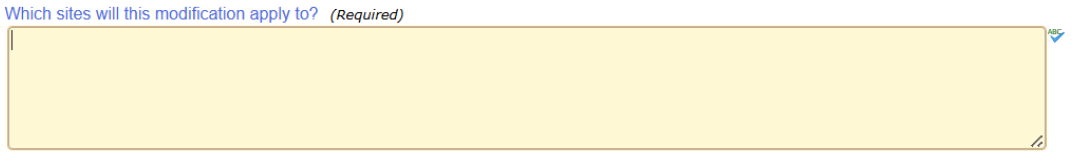
1. Start a Modification xForm



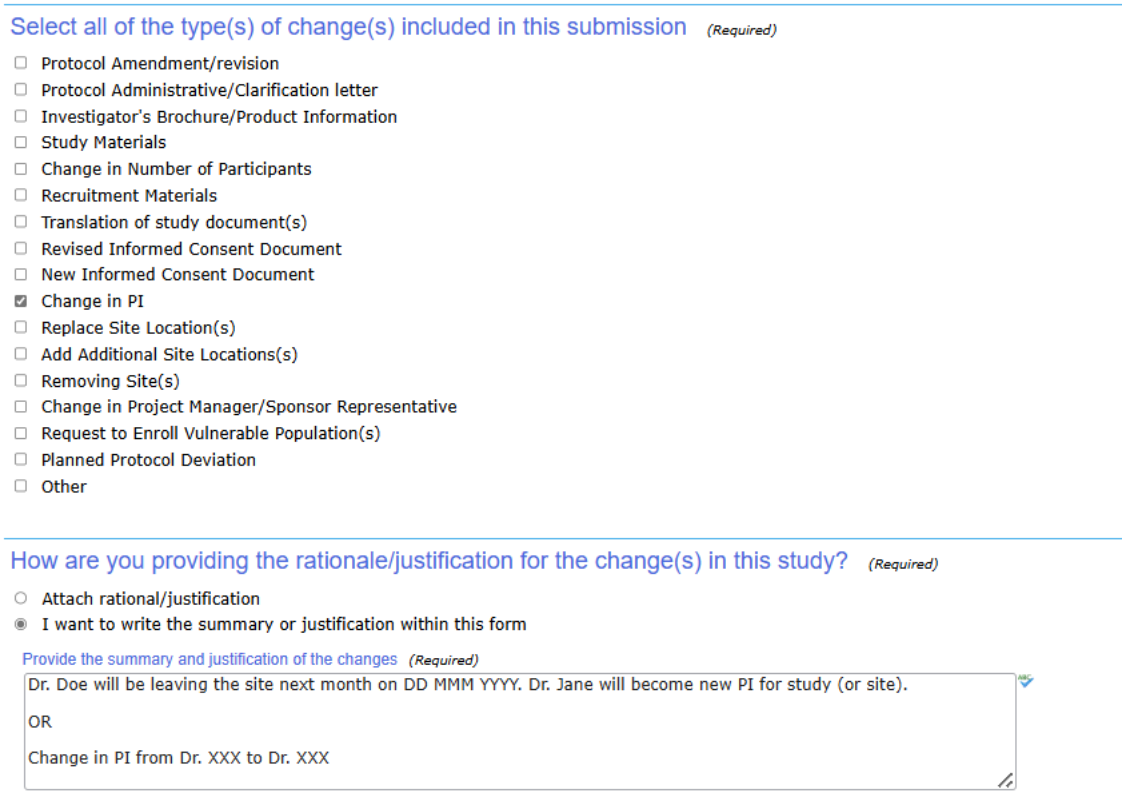
2. ***(Multi-Site Question)*** *To whom does this apply?*
    - *Select: All Active; One Site or Select a few of multiple sites*



    - Note: If “One Site” or a “Select Few of Multiple Sites” is selected, please provide the site(s) information in the text box below.



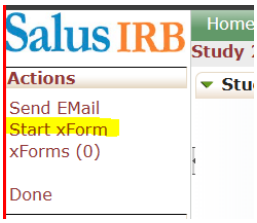
3. Select “Change in PI” from the list below and provide rationale/justification.
    - Rationale/Justification may be written in like so or you may attach a document.



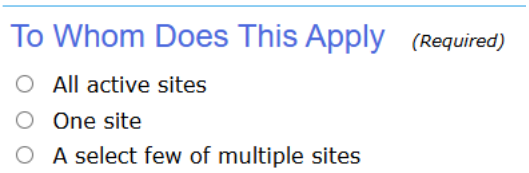
4. Answer all questions prompted & provide all required documentation.
5. Final Step: SUBMIT

Submitting a Site Change

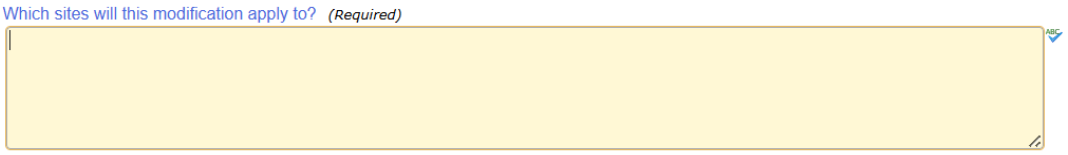
1. Start a Modification xForm



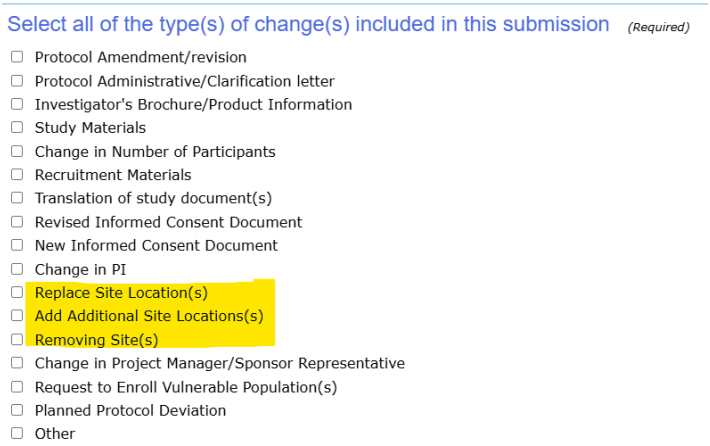
2. ***(Multi-Site Question)*** *To whom does this apply?*
    - *Select: All Active; One Site or Select a few of multiple sites*



- Note: If "One Site" or a "Select Few of Multiple Sites" is selected, please provide the site(s) information in the text box below.

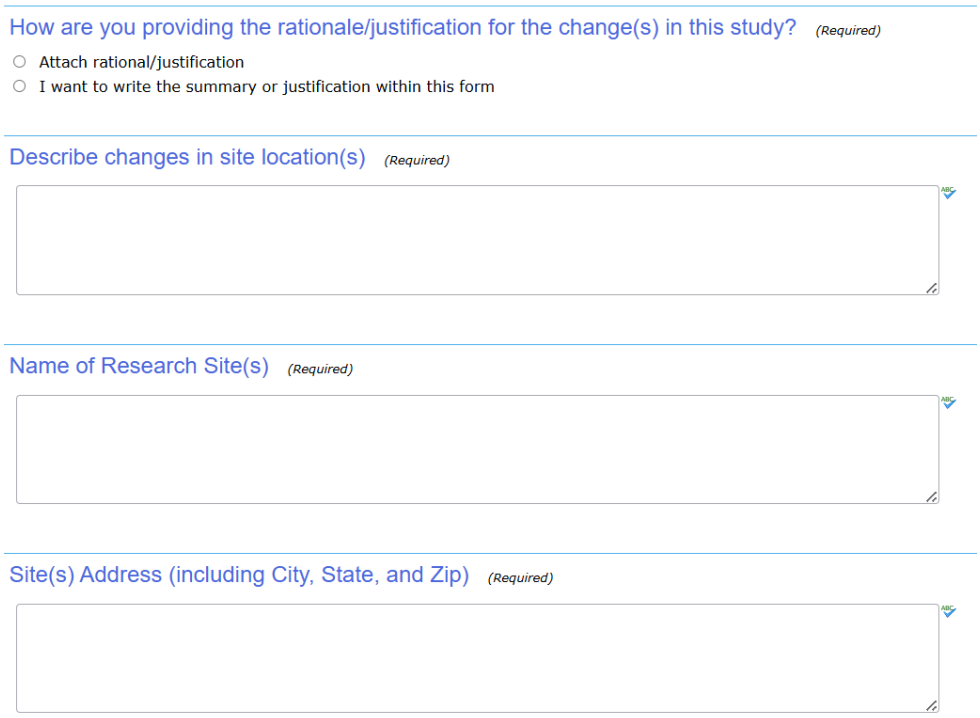


3. Select the Type of Change:
    - Replace Site Location(s)
    - Add Additional Site Location(s)
    - Removing Site(s)

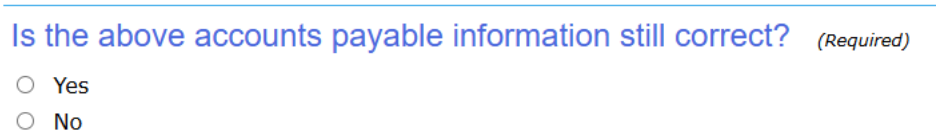


Replace Site Location(s):

1. Provide All Information Required Below:
    - Attach a rational/justification document OR provide a written summary/justification of the change in the text box provided.
    - Describe the changes in site location(s)
    - List Name of Research Site(s)
    - Provide full site(s) address



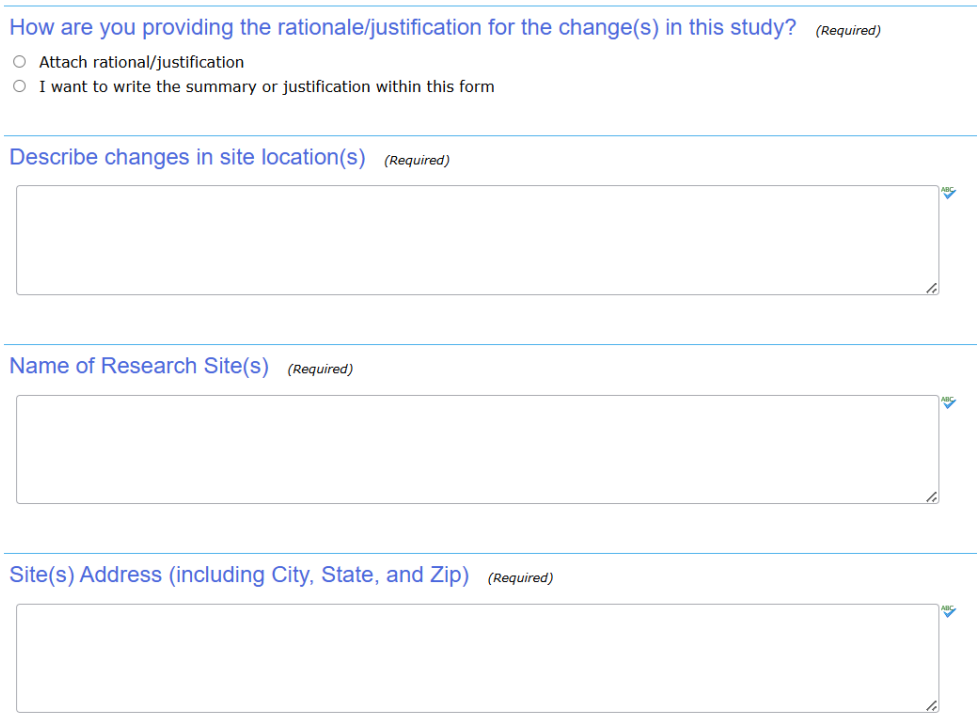
2. Confirm the above accounts payable information is still correct.



3. Final Step: SUBMIT

Add Additional Site Location(s):

1. Provide All Information Required Below:
    - Attach a rational/Justification document OR provide a written summary/justification of the change in the text box provided.
    - Describe the changes in site location(s)
    - List Name of Research Site(s)
    - Provide full site(s) address


How are you providing the rationale/justification for the change(s) in this study? *(Required)*

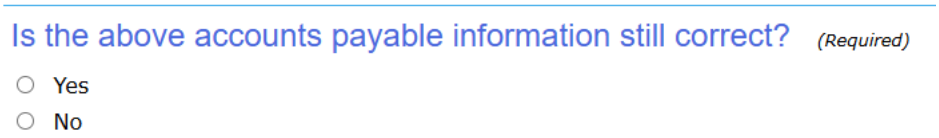
- Attach rational/justification
- I want to write the summary or justification within this form

Describe changes in site location(s) *(Required)*

Name of Research Site(s) *(Required)*

Site(s) Address (including City, State, and Zip) *(Required)*

2. Confirm the above accounts payable information is still correct.


Is the above accounts payable information still correct? *(Required)*

- Yes
- No

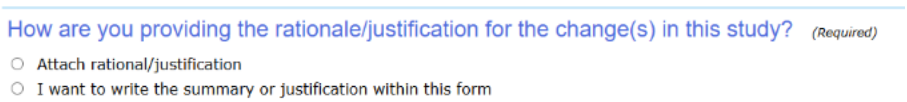
3. Final Step: SUBMIT

Removing Site Location(s):

1. Provide All Information Required Below:
    - Attach a rational/Justification document OR provide a written summary/justification of the change in the text box provided.

RESEARCH SITE(s) BEING REMOVED/REPLACED:

- Describe the changes in site location(s)
- List Name of Research Site(s)
- Provide full site address(es)


How are you providing the rationale/justification for the change(s) in this study? *(Required)*

- Attach rational/justification
- I want to write the summary or justification within this form

RESEARCH SITE(S) BEING REMOVED/REPLACED

Describe changes in site location(s) *(Required)*

Name of Research Site(s) *(Required)*

Site(s) Address (including City, State, and Zip) *(Required)*

2. Confirm the above accounts payable information is still correct.

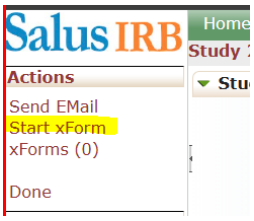
Is the above accounts payable information still correct? *(Required)*

- ○ Yes
- ○ No

3. Final Step: SUBMIT

Submitting a Planned Protocol Deviation

1. Start a Modification xForm



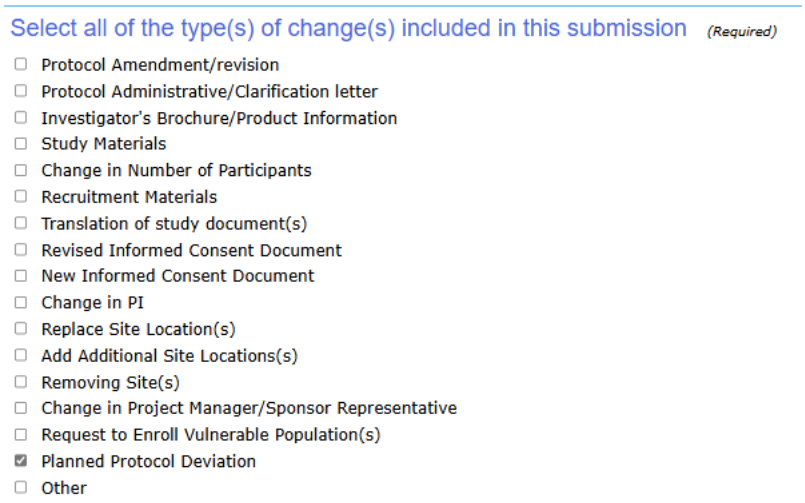
2. ***(Multi-Site Question)*** *To whom does this apply?*
   - *Select: All Active; One Site or Select a few of multiple sites*

To Whom Does This Apply *(Required)*

- ○ All active sites
- ○ One site
- ○ A select few of multiple sites

- Note: If “One Site” or a “Select Few of Multiple Sites” is selected, please provide the site(s) information in the text box below.

3. *Select “Planned Protocol Deviation”*



4. *Next Page - Ensure all questions are addressed below:*
    - *You may either attach a rational/justification or you may write a summary or justification within the form in the box provided.*

Planned Protocol Deviation

A prospective, intentional deviation from the IRB-approved protocol (for details on details on reporting these events, see the Reporting Guidelines for Unanticipated Problems, Deviations, and Other Safety Information)

If the planned deviation is to remove an immediate apparent hazard or risk of harm to participants or others, you must use the problem reporting form.

Describe the planned protocol deviation: *(Required)*

Describe how the deviation is not consistent with the approved protocol *(Required)*

Provide written documentation of the Sponsor's approval of this deviation *(Required)*

Add Attachment

How are you providing the rationale/justification for the change(s) in this study? *(Required)*

- ○ Attach rational/justification
- ◉ I want to write the summary or justification within this form

Provide the summary and justification of the changes *(Required)*

5. *Verify the Existing Accounts Payable Information is still correct*
6. Final Step: SUBMIT

Salus IRB

WHAT IS THE STATUS OF MY SUBMISSION?

Form Stage	Stage Meaning
Application Form Data Entry	The application form is with the research team and you are able to make edits or enter in new data/ information.
PI Signature for Coordinator Submission	The application form was completed by somebody other than the PI. The form is waiting for the PI to review and approve the submission to the IRB. The IRB does not receive the submission until the PI has signed off.
Main Sponsor Contact Signature	A multi-site study main submission was completed by somebody other than the Project Manager/ PI. The form is waiting for the lead PM/PI to review and approve the submission to the IRB. The IRB does not receive the submission until the lead PM/PI has signed off.
QA Assignment	The IRB has received your submission and will assign it to an admin staff member for review.
QA/Screening	Your submission is in review by admin staff.
QC Expedited Pre-Approval	Your submission is in review by admin staff.
Expedited Review	Your submission is in review by a board member.
Expedited Review Processing	An admin staff is preparing to send the board member's review outcome to you.
Awaiting Board Meeting	The submission has been assigned to an upcoming board meeting.
Board Review Processing	An admin staff is preparing to send out the board's review outcome to you.
Board Letter Preparation	An admin staff is preparing the board review determination letter.
QC for Letters and Documents	An admin staff is reviewing your determination letter.
QA Letter Processing	An admin staff is preparing the review determination letter.