Salus IRB
IRBManager User Guides

Getting Started, General Information, and Submitting

Salus IRB

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Salus IRB

Introduction

IRBManager is an online submission and research management system for Salus IRB. Through IRBManager, you can access all associated forms, documents and letters for studies approved or in process with Salus IRB. You can also make a variety of submissions to Salus IRB through IRBManager's online submission forms called "xForms".

IRBManager is a fully web-based system, which means that users can log in anywhere they have internet access.

Salus IRB implemented IRBManager January 15, 2024, but continued to accept paper forms through January 31, 2024. Documents associated with submissions made prior to the implementation of IRBManager are still available in Salus IRB's previous document distribution platform, GlobeSync.

Salus IRB's IRBManager platform can be accessed via the below link. We recommend bookmarking this link for ease of use.

Salus IRB's IRBManager Link : https://salusirb.my.irbmanager.com/Login.aspx

Definitions and Terms

- PI : Principal Investigator
- PM : Project Manager
- xForm: Submission forms in IRBManager
- Dashboard: Your homepage in IRBManager
- Site or Study-Site Contact: Contact level who can only access the site they have permission to access. For example, a research coordinator who only needs access to their specific site.
- Study Contact: Contact level who can access the PM and all PI sites approved with Salus IRB. For example, a member of the project management team who needs access to information for all study sites.
- HSP or HSR Certificate: Human Subjects Protection or Human Subjects Research training certificate, such as GCP.
- SOP: Standard Operating Procedure
- ICD: Informed Consent Document
- IB: Investigator's Brochure

- Sub-I: Sub-Investigator
- COI: Conflict of Interest
- Study Reference Documents: Current Salus IRB approved Protocol, Device and/or Drug Information documents
- Study-Site Reference Document: Current Salus IRB approved Informed Consent Document(s), English and if applicable, Foreign.

When to Contact Salus IRB for Help

While this guide provides tips and instructions for you to modify IRBManager as needed, there are certain instances where it's best if you contact Salus IRB. We are more than happy to provide further instruction or make certain changes on your behalf.

Reach out via phone: ***(855) 300-0815***

Reach out via email: ***salus@salusirb.com***

- Change in email address – Please contact Salus right away to request this change. For security purposes, only a Salus IRB staff member can make this change.
- Study level contact changes
- Contact changes that will affect a large number of studies: for example, departure of an employee who has access to 5+ studies, sites, etc.
- Your IRBManager account is *locked out* or *deactivated*
- To request an *Exemption* or *HSR* submission form
- To request reporting requirements for Unanticipated Problems, non-reportable events, deviations, and other safety information
- Any time you have a question regarding your study, submission, or IRBManager. We are always happy to help!

Getting Started

IRBManager Link: https://salusirb.my.irbmanager.com/Login.aspx

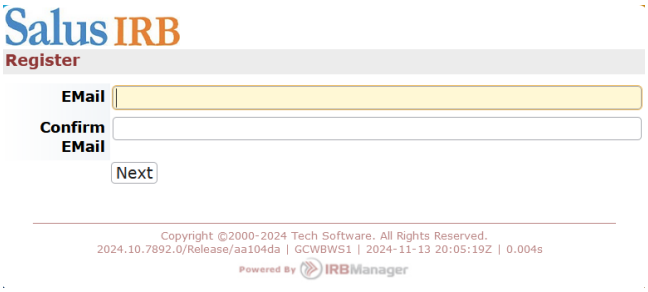
Creating an IRBManager Account

If you have worked with Salus IRB prior to the January 15, 2024, IRBManager implementation, we have already set up an account on your behalf. Please follow the steps in the section "*Resetting Your Password*" to access your account.

Otherwise, new users must first create an IRBManager account. Please follow the directions below in order to create your new user account for IRBManager.

1. IRBManager access link: https://salusirb.my.irbmanager.com/Login.aspx
2. Click on "Click here to register"

3. Enter and confirm your email address and click [Next]



4. Enter the requested information into the registration form
5. Once completed, click [Register]

Resetting Your Password

Please follow the steps below to reset your forgotten password:

1. Click on "Forgot Password"

2. Enter your email address and the code in the image and click [Retrieve]

3. You will receive an email with instructions to reset your password

Adding your Existing Approved Studies to IRBManager

Once logged into IRBManager, you will need to link your contact to your associated, existing studies (if any). Please see “Submitting xForms - *Adding Personnel to a Study-Site*" to be added as a study-site contact or contact Salus IRB to be added as a study level contact. For security purposes, an existing associated contact must approve the addition of new contacts to the study or study-site.

If you do not have existing approved studies and would like to submit, please see “Submitting a New Study”.

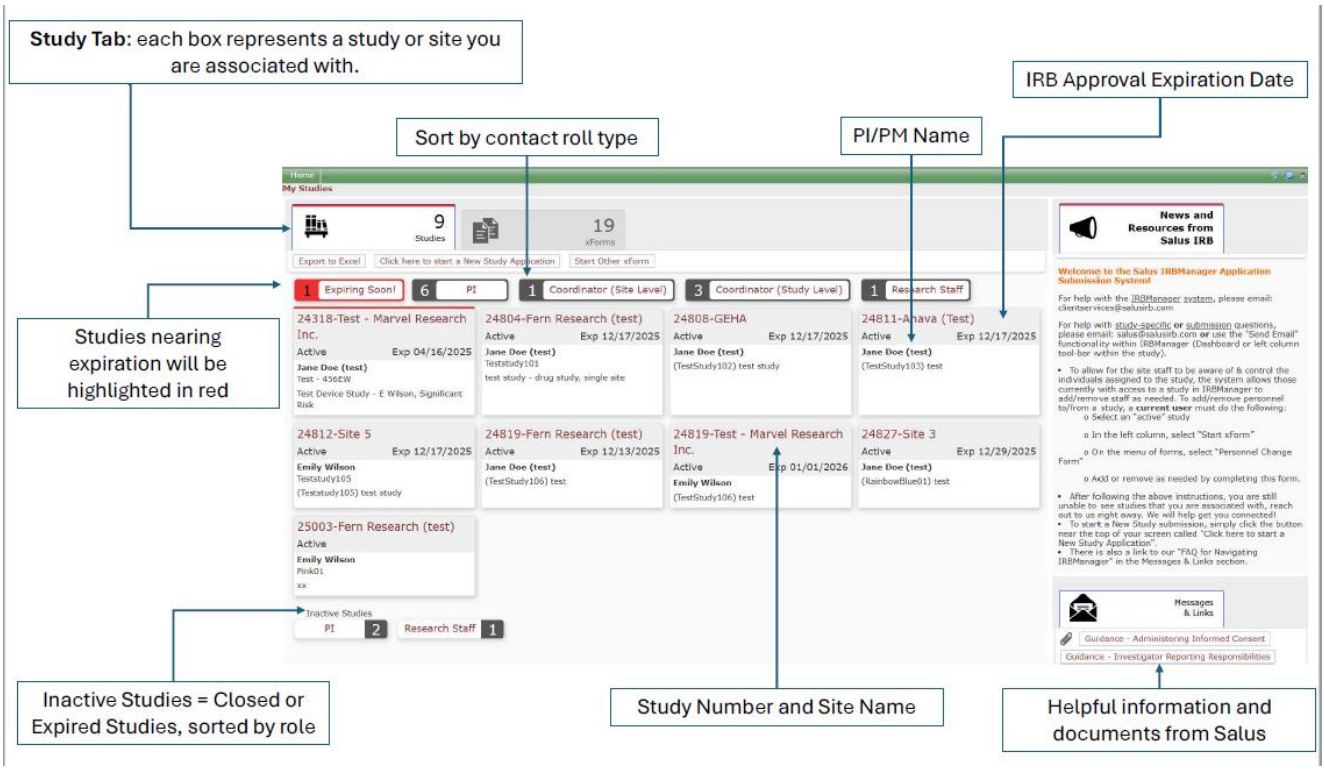
Tips for Navigating IRBManager

IRBManager is organized by study and study-site. When you log into IRBManager, you will see your Dashboard. Your dashboard is specific to you and shows all of the studies, sites, and xForms for which you are associated.

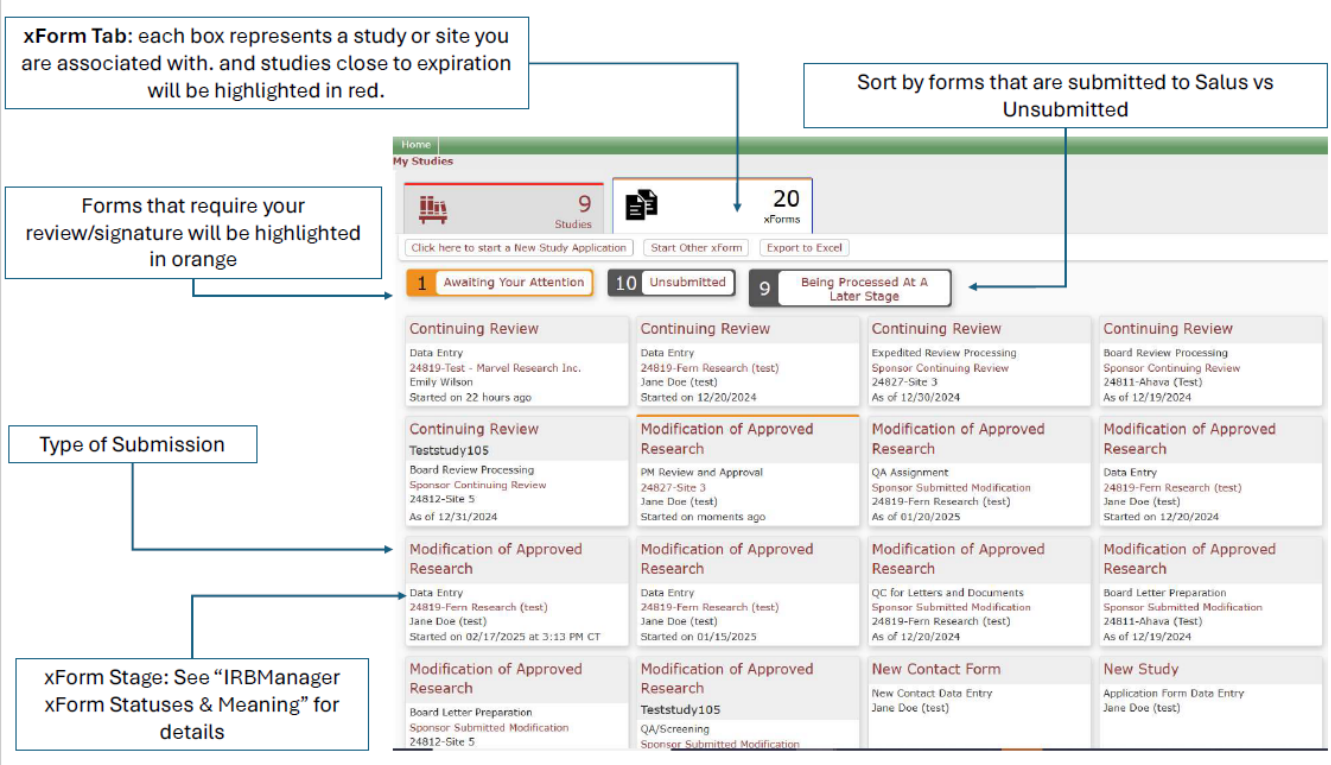
Study specific xForms such as *Continuing Reviews* or *Modifications* are located under each study, while generic xForms such as *New Study* or *HSP Training* are located on your Dashboard.

All documents, submission forms, and approval letters can be found under each study. See "Locating Reference Documents" or "Locating Event Attachments/Approval Documents" in this guide for more information.

IRBManager Dashboard

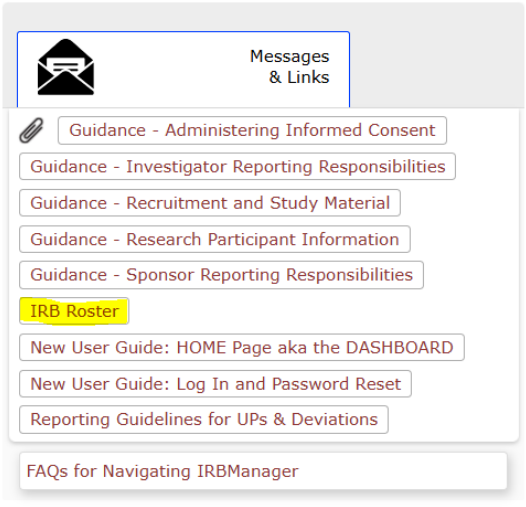


Version 1.0
Date: 10 March 2025



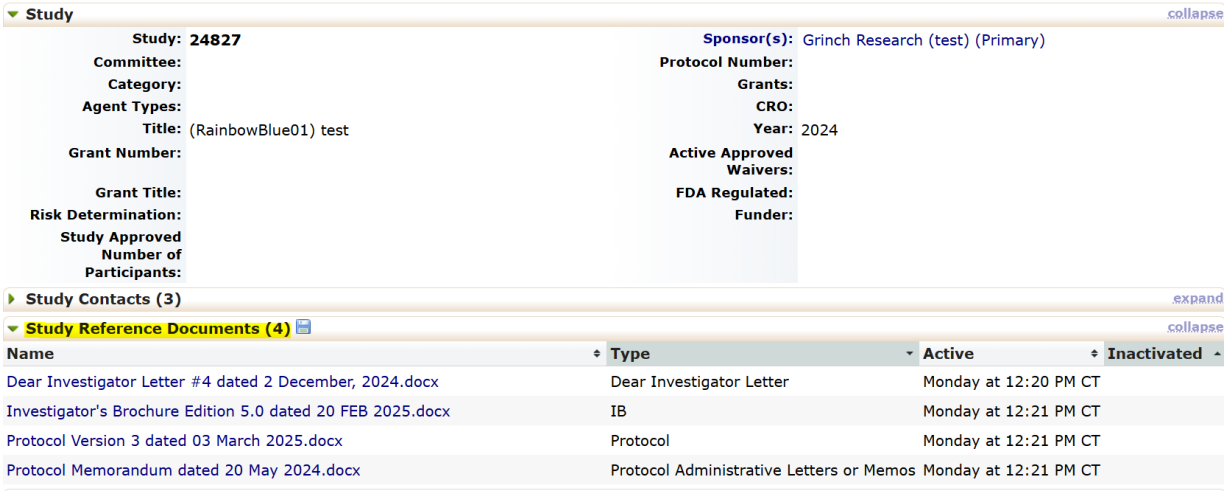
Locating the Roster

From your IRBManager Dashboard, scroll down to view *Messages and Links* in the right column. The current Salus Roster can be accessed by clicking on "IRB Roster".



Locating Reference Documents

Study Reference Documents: To locate current/approved Protocol Information, Device and/or Drug Information.



Study collapse

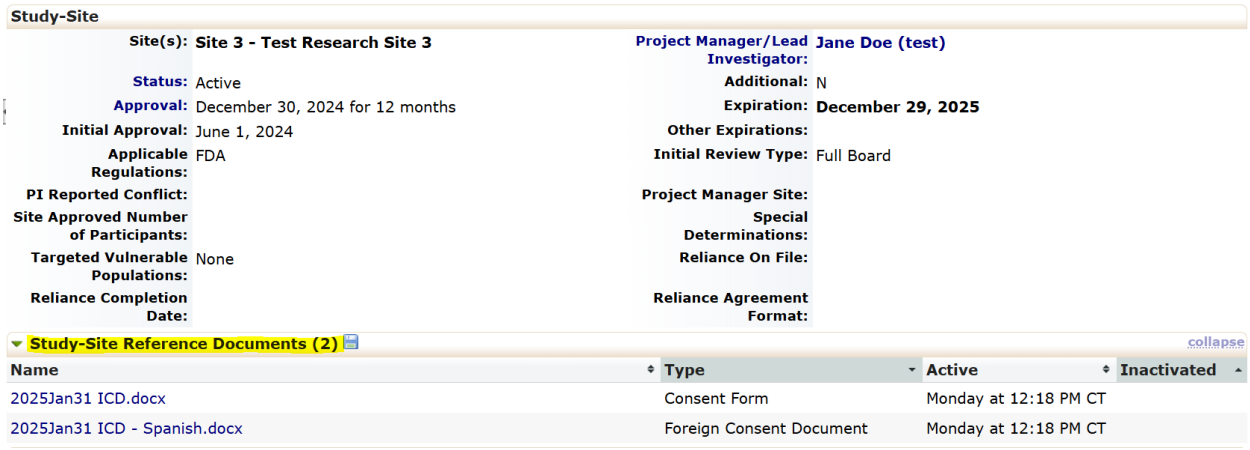
Study:	24827	Sponsor(s):	Grinch Research (test) (Primary)
Committee:		Protocol Number:	
Category:		Grants:	
Agent Types:		CRO:	
Title:	(RainbowBlue01) test	Year:	2024
Grant Number:		Active Approved Waivers:	
Grant Title:		FDA Regulated:	
Risk Determination:		Funder:	
Study Approved Number of Participants:			

Study Contacts (3) expand

Study Reference Documents (4) collapse

Name	Type	Active	Inactivated
Dear Investigator Letter #4 dated 2 December, 2024.docx	Dear Investigator Letter	Monday at 12:20 PM CT	
Investigator's Brochure Edition 5.0 dated 20 FEB 2025.docx	IB	Monday at 12:21 PM CT	
Protocol Version 3 dated 03 March 2025.docx	Protocol	Monday at 12:21 PM CT	
Protocol Memorandum dated 20 May 2024.docx	Protocol Administrative Letters or Memos	Monday at 12:21 PM CT	

Study-Site Reference Documents: To locate current/approved Informed Consent Document(s), English and Foreign versions.



Study-Site

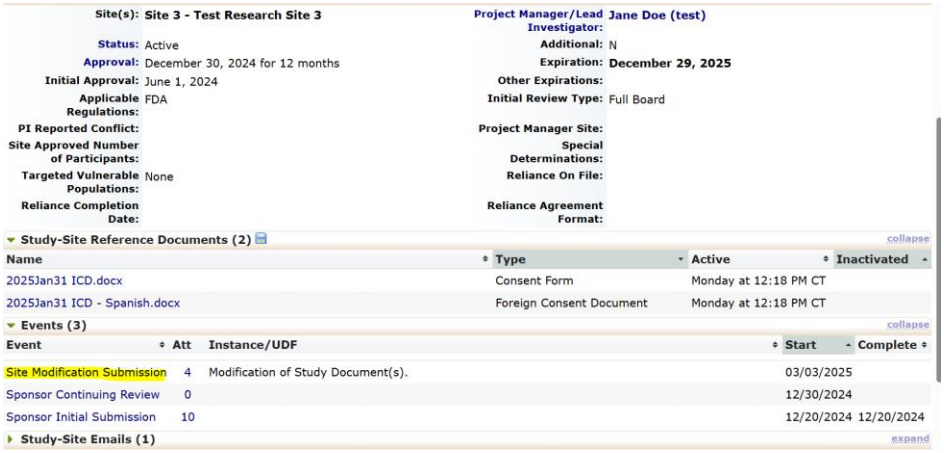
Site(s):	Site 3 - Test Research Site 3	Project Manager/Lead Investigator:	Jane Doe (test)
Status:	Active	Additional:	N
Approval:	December 30, 2024 for 12 months	Expiration:	December 29, 2025
Initial Approval:	June 1, 2024	Other Expirations:	
Applicable Regulations:	FDA	Initial Review Type:	Full Board
PI Reported Conflict:		Project Manager Site:	
Site Approved Number of Participants:		Special Determinations:	
Targeted Vulnerable Populations:	None	Reliance On File:	
Reliance Completion Date:		Reliance Agreement Format:	

Study-Site Reference Documents (2) collapse

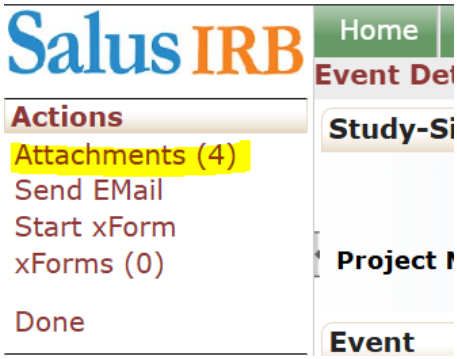
Name	Type	Active	Inactivated
2025Jan31 ICD.docx	Consent Form	Monday at 12:18 PM CT	
2025Jan31 ICD - Spanish.docx	Foreign Consent Document	Monday at 12:18 PM CT	

Locating Event Attachments/Approval Documents

1. Looking for your approval documents? Navigate to Study/Site Home Page and select the event for which you would like to locate approval documents



2. Once you are in the event, navigate to the left side panel. Select Attachments



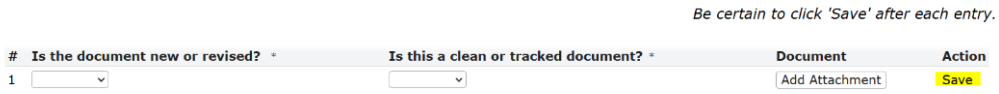
3. Event Attachments + Approval Documents can be opened or saved onto your computer

Salus IRB

Submitting an xForm

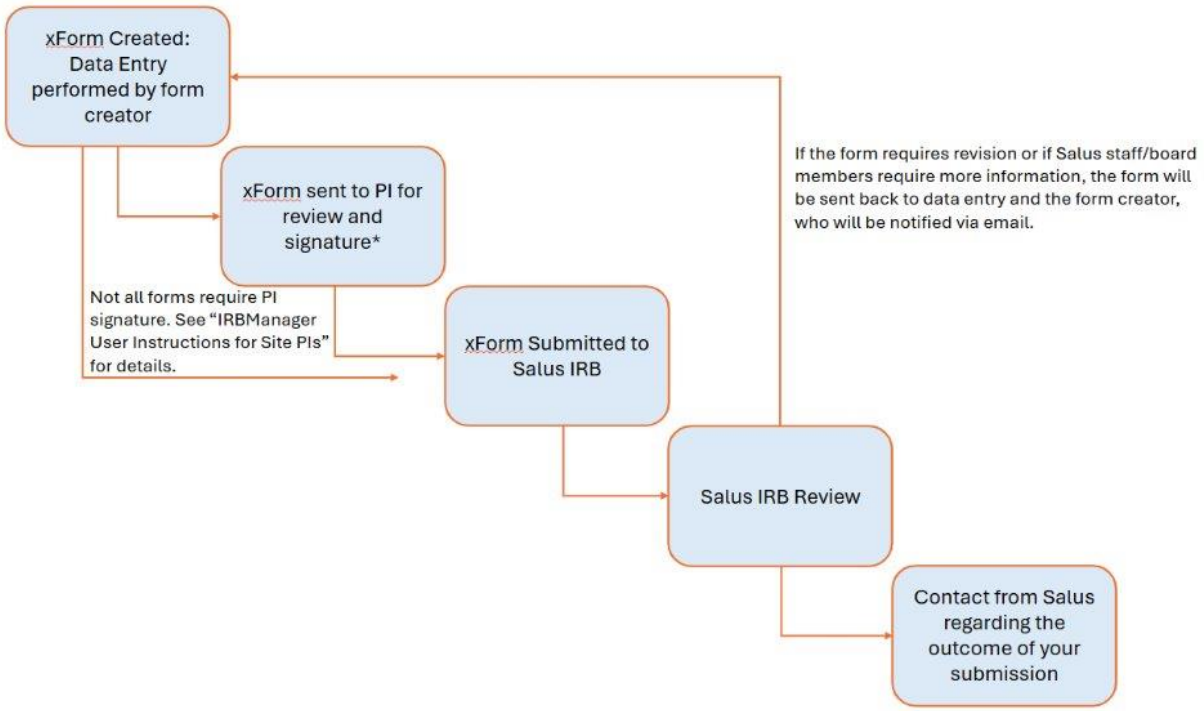
Tips for xForms

- Read all instructions on the xForm – Forms will provide detailed instruction regarding required attachments. By following xForm instructions and submitting all required documents, Salus is less likely to have to return the form with requests for additional information, confirmation, or clarification.
- Click “next” all the way to the end of the form when you can select “submit”. If you have not clicked “submit” the form will not move to the next stage.
- When a table is provided for document upload, click “Save” after attaching each individual document.



- Some forms require PI review and signature prior to final submission to Salus for review. If someone other than the PI creates the xForm, the PI will receive an email after the form creator hits “submit”. The email will prompt the PI to review and approve the submission for it to be sent to the IRB.

Timeline of an xForm



IRBManager xForm Statuses and Meanings

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.

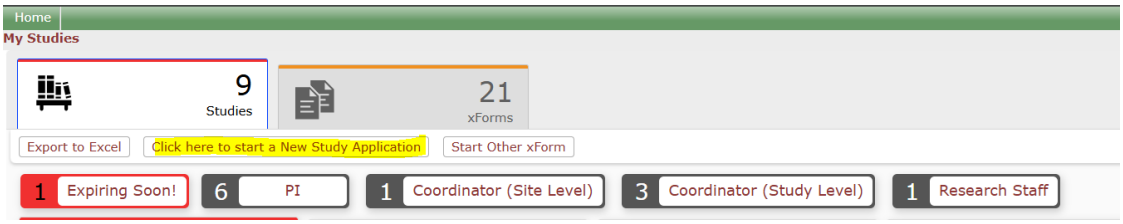
QC Expedited Pre-Approval	Your submission is in review by admin staff.
Expedited Review	Your submission is in review by a board member.
Expedited Review Processing	An admin staff is preparing to send out the board member's review outcome to you.
Awaiting Board Meeting	The submission has been assigned 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.

Submitting a New Study

This form is not to be used for Exemption or HSR Determinations, contact Salus IRB for submission instructions.

To submit a new study:

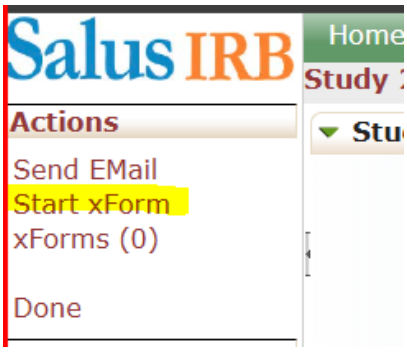
1. Log into IRBManager
2. Click on [Click Here to Start a New Study Application]



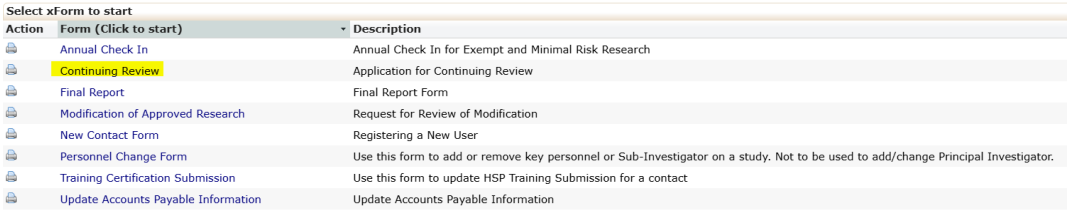
3. Follow the instructions to complete the *New Study* xForm
4. Note: if the PI is not the person creating the xForm, the form will be routed to the PI for review and signature prior to final submission to Salus for review (see "IRBManager User Instructions for Site PIs")

Submitting a Continuing Review for Multi-Site PM or Single-Site Study

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



4. Select *Continuing Review*

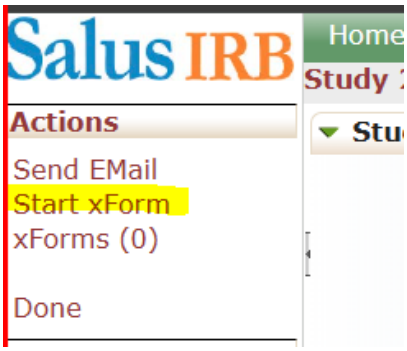


5. Complete and submit the form
6. Note: if the PI is not the person creating the xForm, the form will be routed to the PI for review and signature prior to final submission to Salus for review (see "IRBManager User Instructions for Site PIs")

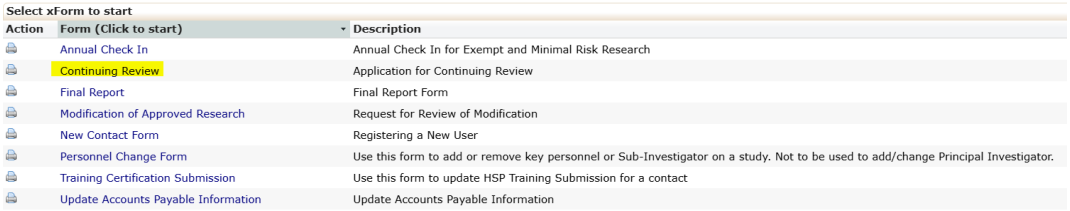
Submitting a Continuing Review for Additional Investigators

1. From your IRBManager Dashboard, select the "Studies" tab
2. Select the study or site for which you wish to submit a continuing review

3. Select "Start xForm" on the left side



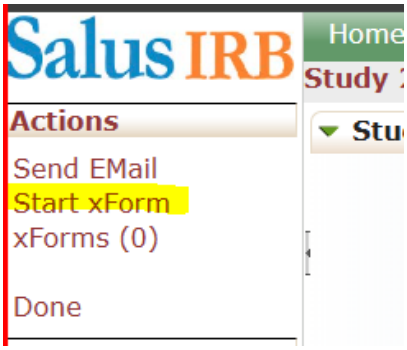
4. Select *Continuing Review* (IRBManager will automatically select the correct continuing review form for you to complete)



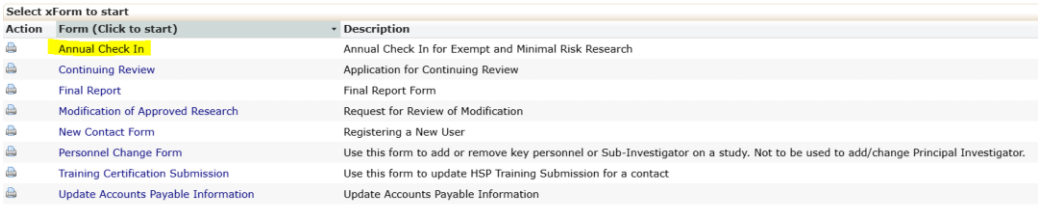
5. Complete and submit the form
6. Note: if the PI is not the person creating the xForm, the form will be routed to the PI for review and signature prior to final submission to Salus for review (see "IRBManager User Instructions for Site PIs")

Submitting an Annual Check-In

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



4. Select *Annual Check In*

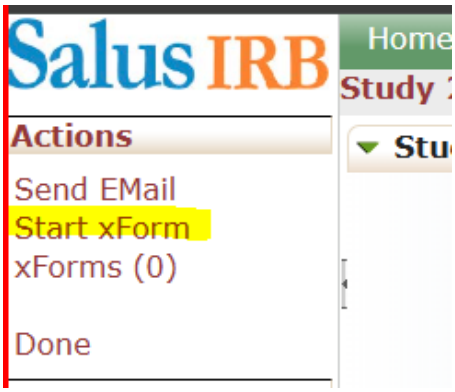


5. Complete and submit the form

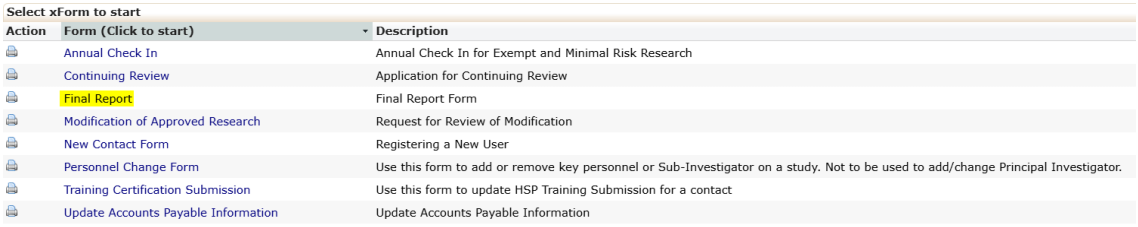
Submitting a Final Report

1. From your IRBManager Dashboard, select the "Studies" tab
2. Select the study or site for which you wish to submit a *Final Report*

3. Select “Start xForm” on the left side



4. Select *Final Report*



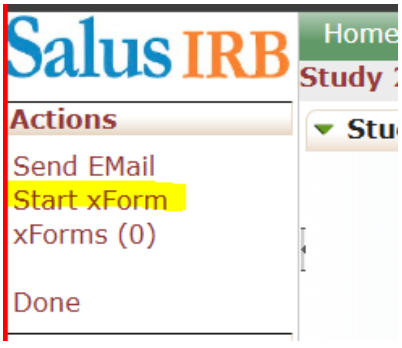
Select xForm to start

Action	Form (Click to start)	Description
	Annual Check In	Annual Check In for Exempt and Minimal Risk Research
	Continuing Review	Application for Continuing Review
	Final Report	Final Report Form
	Modification of Approved Research	Request for Review of Modification
	New Contact Form	Registering a New User
	Personnel Change Form	Use this form to add or remove key personnel or Sub-Investigator on a study. Not to be used to add/change Principal Investigator.
	Training Certification Submission	Use this form to update HSP Training Submission for a contact
	Update Accounts Payable Information	Update Accounts Payable Information

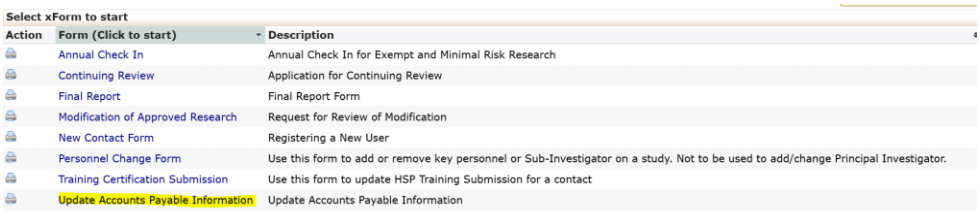
5. Complete and submit the form

Updating AP Information

1. From your IRBManager Dashboard, select the “Studies” tab
2. Select the study or site for which you wish to update the AP information
3. Select “Start xForm” on the left side



4. Select *Update Accounts Payable Information*



Select xForm to start

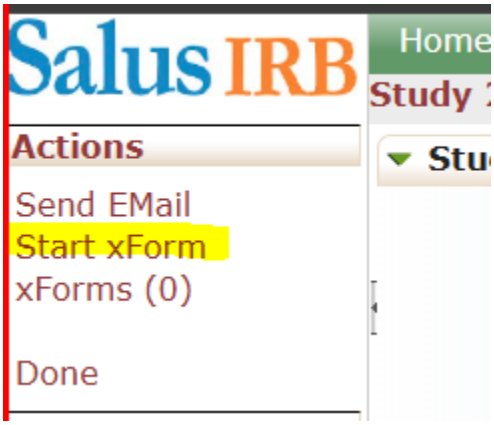
Action	Form (Click to start)	Description
	Annual Check In	Annual Check In for Exempt and Minimal Risk Research
	Continuing Review	Application for Continuing Review
	Final Report	Final Report Form
	Modification of Approved Research	Request for Review of Modification
	New Contact Form	Registering a New User
	Personnel Change Form	Use this form to add or remove key personnel or Sub-Investigator on a study. Not to be used to add/change Principal Investigator.
	Training Certification Submission	Use this form to update HSP Training Submission for a contact
	Update Accounts Payable Information	Update Accounts Payable Information

5. Complete and submit the form

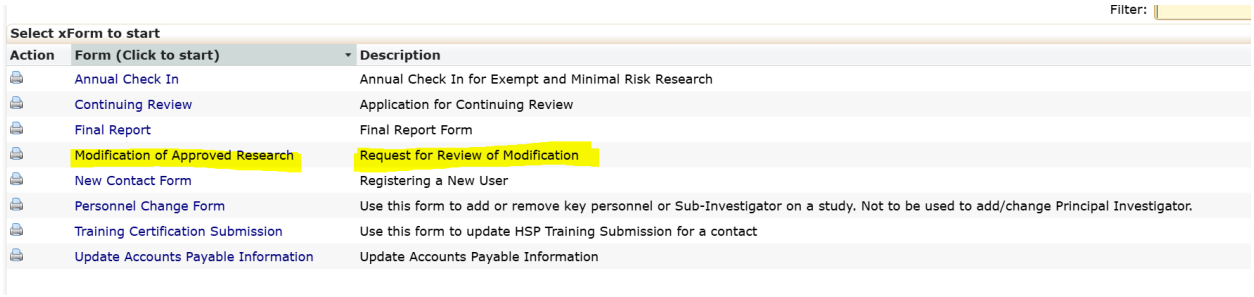
Submitting a Modification

To submit a Modification:

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



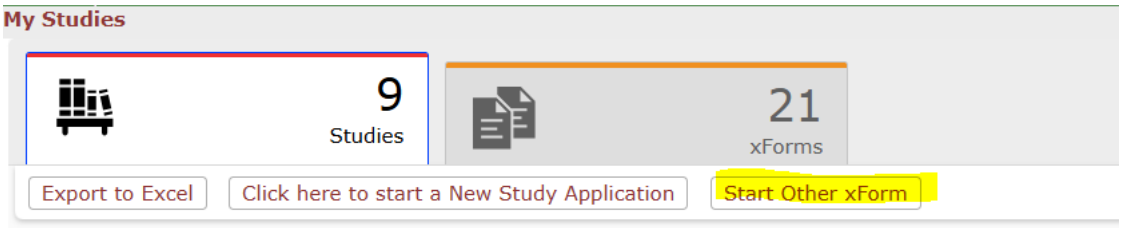
4. Select *Modification of Approved Research*



5. Complete and submit the form
6. For detailed instructions regarding completing the Modification xForm, please see the addendum: **Modifications: A Detailed Instruction Guide.**

Uploading a Training Certificate

1. From your IRBManager Dashboard, select “Start Other xForm”

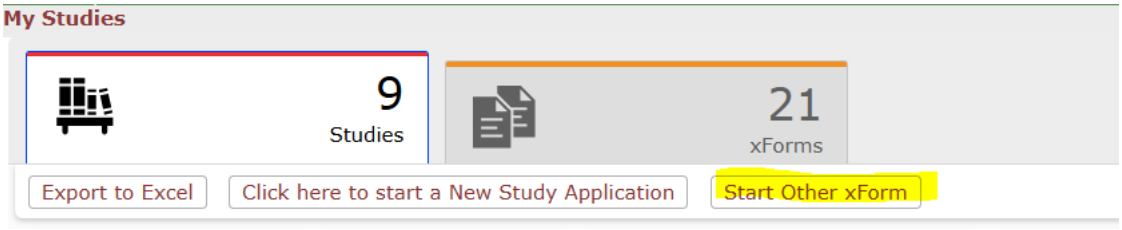


2. Select *Training Certification Submission*

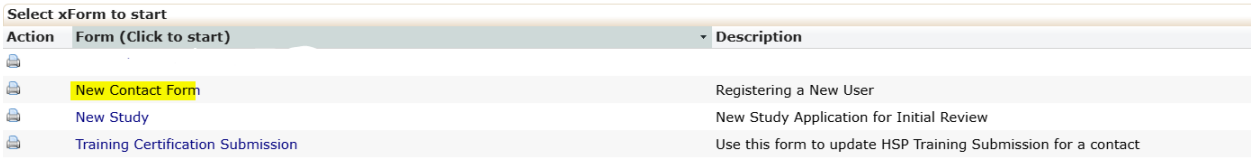
3. Complete and submit the form

Registering a New User in IRBManager on their Behalf

1. From your IRBManager Dashboard, select "Start Other xForm"



2. Select *New Contact Form*



3. Complete and submit the form
4. The new user will receive an automated email from IRBManager notifying them that they are registered with IRBManager.

Adding Personnel to a Study-Site

To allow for the site staff to be aware of & control the individuals assigned to the study, the system will allow those already with access to the study in IRBManager to add/remove staff as needed.

Please *do not* use this form for a PI or PM change as these require a modification form instead.

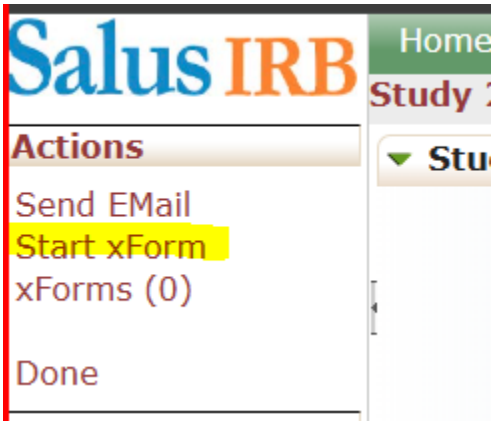
This form is only to be used for *Study-Site* personnel changes. If you need to update your study level personnel, please contact Salus.

Site or Study-Site Contact: Contact level who can only access the site they have permission to access. For example, a research coordinator who only needs access to their specific site.

Study Contact: Contact level who can access the PM and all PI sites approved with Salus IRB. For example, a member of the project management team who needs access to information for all study sites.

To add/remove personnel to/from a study-site, an active user must do the following:

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



4. Select *Personnel Change*
5. Follow the form instructions to add or remove contacts as needed
6. If you are adding an individual who is not already registered with IRBManager, you will be given instructions to create their IRBManager contact on their behalf.
7. Personnel who are added to a study-site will receive an email notification of this change
8. 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")