

Salus IRB

IRBManager User Guides

Getting Started, General Information, and Submitting

Table of Contents

Introduction -----	3
Definitions and Terms -----	3
When to Contact Salus IRB for Help -----	4
Getting Started-----	5
Creating an IRBManager Account -----	5
Resetting Your Password -----	6
Adding your Existing Approved Studies to IRBManager-----	6
Tips for Navigating IRBManager-----	7
IRBManager Dashboard -----	7
Locating the Roster -----	8
Locating Reference Documents -----	9
Locating Event Attachments/Approval Documents -----	10
Submitting an xForm-----	11
Tips for xForms-----	11
IRBManager xForm Statuses and Meanings -----	12
Submitting a New Study-----	13
Submitting a Continuing Review for Multi-Site PM or Single-Site Study -----	13
Submitting a Continuing Review for Additional Investigators -----	14
Submitting an Annual Check-In-----	15
Submitting a Final Report -----	15
Updating AP Information -----	16
Submitting a Modification-----	17
Uploading a Training Certificate -----	17
Registering a New User in IRBManager on their Behalf -----	18
Adding Personnel to a Study-Site-----	18

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

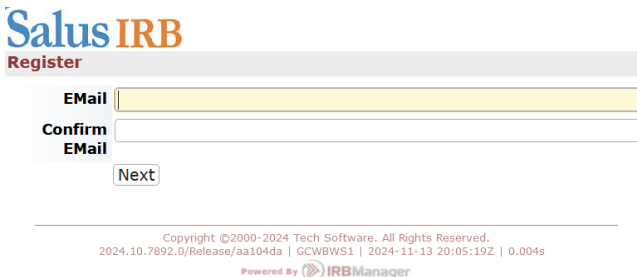
If you have worked with Salus IRB prior to the January 15, 2024, IRBManager implementation, we have already set up an account on your behalf. Please follow the steps in the section “*Resetting Your Password*” to access your account.

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]

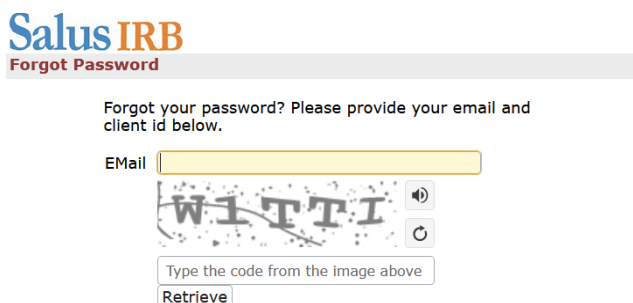
Resetting Your Password

Please follow the steps below to reset your forgotten password:

1. Click on "Forgot Password"

The image shows the Salus IRB Login page. At the top is the Salus IRB logo. Below it is a 'Login' section with fields for 'Email address', 'Password', and 'Client'. The 'Client' field is pre-filled with 'SalusIRB'. There are 'Login' and 'Forgot Password?' buttons. Below the login fields is a link: 'Don't have an account? Click here to register.' At the bottom, there is a copyright notice: 'Copyright ©2000-2025 Tech Software. All Rights Reserved. 2025.2.8051.0/Release/e1e893f | GCWBWS1 | 2025-03-06 22:01:57Z | 0.005s' and a 'Powered By IRBManager' logo.

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

The image shows the Salus IRB 'Forgot Password' page. At the top is the Salus IRB logo and the text 'Forgot Password'. Below this is a message: 'Forgot your password? Please provide your email and client id below.' There is an 'Email' field. Below the email field is a CAPTCHA image showing the word 'WITTI' with a speaker icon and a refresh icon. Below the CAPTCHA is a text input field with the placeholder 'Type the code from the image above' and a 'Retrieve' button.

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

Study Tab: each box represents a study or site you are associated with.

Sort by contact roll type

PI/PM Name

IRB Approval Expiration Date

Studies nearing expiration will be highlighted in red

Inactive Studies = Closed or Expired Studies, sorted by role

Study Number and Site Name

Helpful information and documents from Salus

The dashboard displays a grid of study cards. Each card shows the study number, site name, status (Active/Inactive), PI/PM name, and expiration date. Cards for studies nearing expiration are highlighted in red. The dashboard also includes a sidebar with navigation links and a right-hand panel with news and resources.

Study Number	Site Name	Status	PI/PM Name	Expiration Date
24318-Test - Marvel Research Inc.	Active	Jane Doe (test)	Exp 04/16/2025	
24804-Fern Research (test)	Active	Jane Doe (test)	Exp 12/17/2025	
24808-GEHA	Active	Jane Doe (test)	Exp 12/17/2025	
24811-Anava (Test)	Active	Jane Doe (test)	Exp 12/17/2025	
24812-Site 5	Active	Emily Wilson	Exp 12/17/2025	
24819-Fern Research (test)	Active	Jane Doe (test)	Exp 12/13/2025	
24819-Test - Marvel Research Inc.	Active	Emily Wilson	Exp 01/01/2026	
24827-Site 3	Active	Jane Doe (test)	Exp 12/29/2025	
25003-Fern Research (test)	Active	Emily Wilson		

xForm Tab: each box represents a study or site you are associated with. and studies close to expiration will be highlighted in red.

Sort by forms that are submitted to Salus vs Unsubmitted

Forms that require your review/signature will be highlighted in orange

Type of Submission

xForm Stage: See “IRBManager xForm Statuses & Meaning” for details

The screenshot shows the 'My Studies' dashboard. At the top, there are two tabs: 'Studies' (9) and 'xForms' (20). Below the tabs are three buttons: 'Click here to start a New Study Application', 'Start Other xForm', and 'Export to Excel'. The main area displays a grid of study cards. The first card is highlighted in orange and labeled '1 Awaiting Your Attention'. The second card is labeled '10 Unsubmitted'. The third card is labeled '9 Being Processed At A Later Stage'. The grid contains various study types such as 'Continuing Review', 'Modification of Approved Research', 'New Contact Form', and 'New Study'. Each card shows details like 'Data Entry', 'Sponsor', 'Site', and 'Started on'.

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”.

Messages & Links

- Guidance - Administering Informed Consent
- Guidance - Investigator Reporting Responsibilities
- Guidance - Recruitment and Study Material
- Guidance - Research Participant Information
- Guidance - Sponsor Reporting Responsibilities
- IRB Roster**
- New User Guide: HOME Page aka the DASHBOARD
- New User Guide: Log In and Password Reset
- Reporting Guidelines for UPs & Deviations
- FAQs for Navigating IRBManager

Locating Reference Documents

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

Study: 24827

Committee:

Category:

Agent Types:

Title: (RainbowBlue01) test

Grant Number:

Grant Title:

Risk Determination:

Study Approved

Number of

Participants:

Sponsor(s): Grinch Research (test) (Primary)

Protocol Number:

Grants:

CRO:

Year: 2024

Active Approved

Waivers:

FDA Regulated:

Funder:

Study Contacts (3)

Study Reference Documents (4)

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

Status: Active

Approval: December 30, 2024 for 12 months

Initial Approval: June 1, 2024

Applicable Regulations: FDA

PI Reported Conflict:

Site Approved Number of Participants:

Targeted Vulnerable Populations: None

Reliance Completion Date:

Project Manager/Lead Investigator: Jane Doe (test)

Additional: N

Expiration: December 29, 2025

Other Expirations:

Initial Review Type: Full Board

Project Manager Site:

Special Determinations:

Reliance On File:

Reliance Agreement Format:

▼ Study-Site Reference Documents (2)

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

Site(s): Site 3 - Test Research Site 3 Status: Active Approval: December 30, 2024 for 12 months Initial Approval: June 1, 2024 Applicable Regulations: FDA PI Reported Conflict: Site Approved Number of Participants: Targeted Vulnerable Populations: None Reliance Completion Date:	Project Manager/Lead Investigator: Jane Doe (test) Additional: N Expiration: December 29, 2025 Other Expirations: Initial Review Type: Full Board Project Manager Site: Special Determinations: Reliance On File: Reliance Agreement Format:
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Study-Site Reference Documents (2)			
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	

Events (3)			
Event	Att	Instance/UDF	Start - Complete
Site Modification Submission	4	Modification of Study Document(s).	03/03/2025
Sponsor Continuing Review	0		12/30/2024
Sponsor Initial Submission	10		12/20/2024 12/20/2024

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

Salus IRB Actions Attachments (4) Send EMail Start xForm xForms (0) Done	Home Event Details Study-Site Project Information Event
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3. Event Attachments + Approval Documents can be opened or saved onto your computer

Attachments on Event Site Modification Submission Started 03/03/2025 on 24827-Site 3			
Attachments (4)	Name	Attached	Type
Approval Documents (2)	2025.02.20 Protocol Version 3 Revised ICD.docx	03/03/2025 12:32 PM CT	IRB Approval Letter
	2025Jan31 ICD.docx	03/03/2025 12:33 PM CT	Consent Form

Submitting an xForm

Tips for xForms

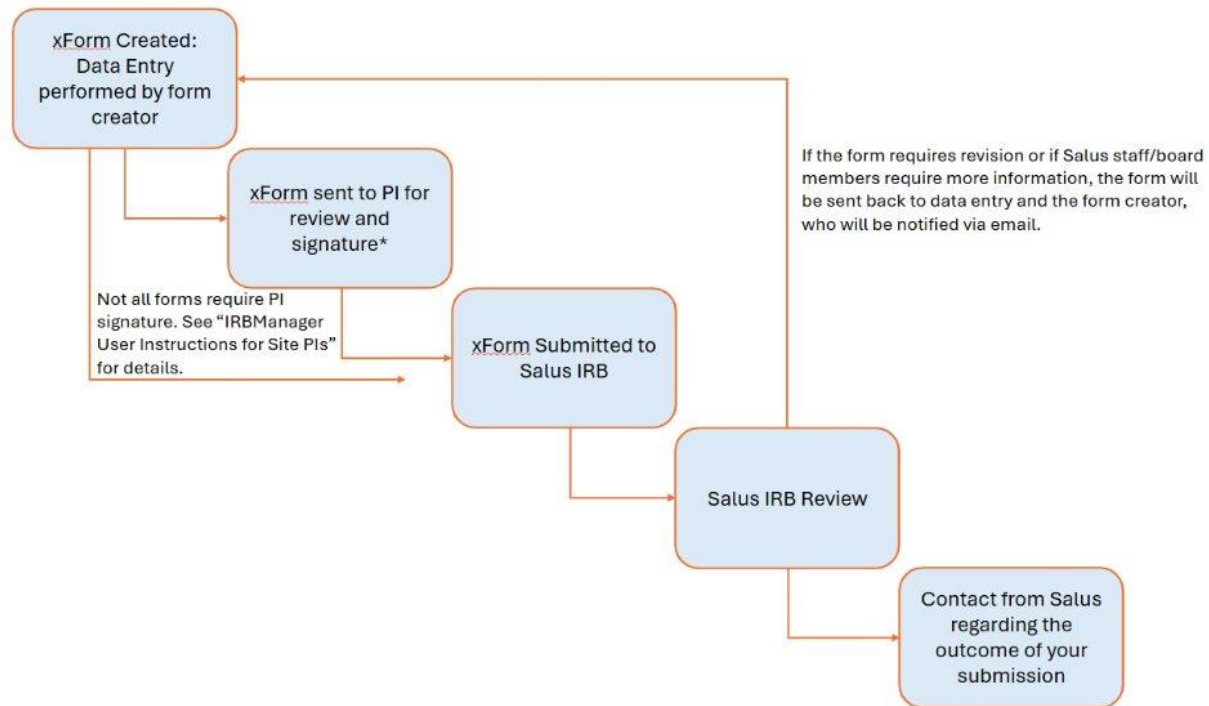
- Read all instructions on the xForm – Forms will provide detailed instruction regarding required attachments. By following xForm instructions and submitting all required documents, Salus is less likely to have to return the form with requests for additional information, confirmation, or clarification.
- 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.

Be certain to click 'Save' after each entry.

#	Is the document new or revised? *	Is this a clean or tracked document? *	Document	Action
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="Add Attachment"/> <input type="button" value="Save"/>

- 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:

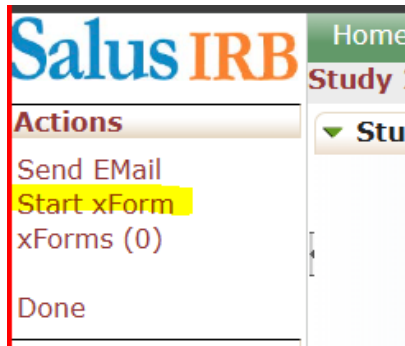
1. Log into IRBManager
2. Click on [Click Here to Start a New Study Application]

The screenshot shows the IRBManager dashboard. At the top, there's a 'Home' link and a 'My Studies' section. Under 'My Studies', there are two boxes: 'Studies' with a count of 9 and 'xForms' with a count of 21. Below these boxes are three buttons: 'Export to Excel', 'Click here to start a New Study Application' (highlighted in yellow), and 'Start Other xForm'. At the bottom, there are five status bars: '1 Expiring Soon!' (red), '6 PI' (grey), '1 Coordinator (Site Level)' (grey), '3 Coordinator (Study Level)' (grey), and '1 Research Staff' (grey).

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



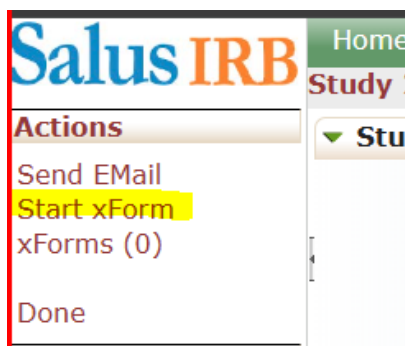
4. Select *Continuing Review*

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
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



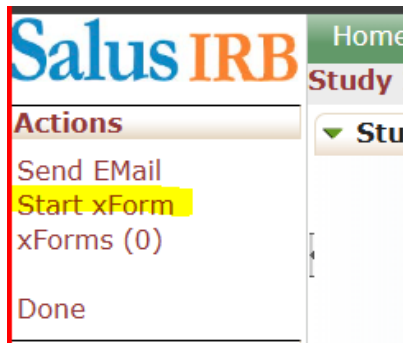
4. Select *Continuing Review* (IRBManager will automatically select the correct continuing review form for you to complete)

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
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*

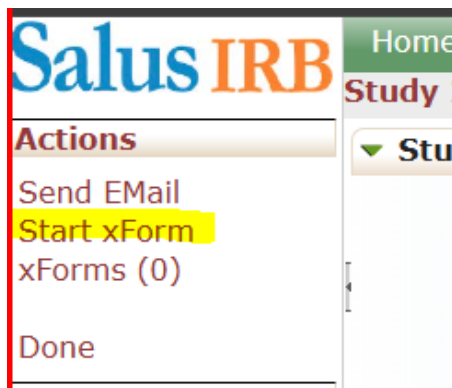
Select xForm to start		
Action	Form (Click to start)	Description
	Annual Check In	Annual Check In for Exempt and Minimal Risk Research
	Continuing Review	Application for Continuing Review
	Final Report	Final Report Form
	Modification of Approved Research	Request for Review of Modification
	New Contact 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 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



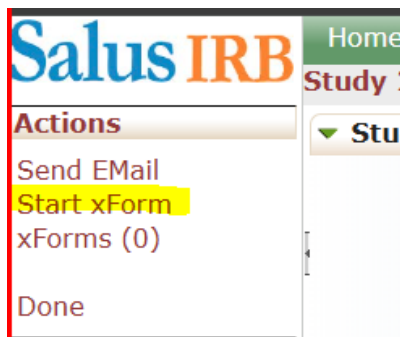
4. Select *Final Report*

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*

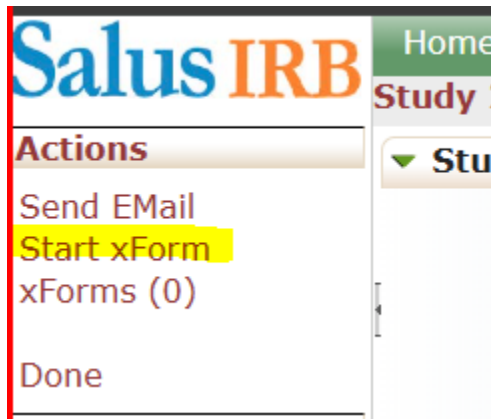
Select xForm to start		
Action	Form (Click to start)	Description
	Annual Check In	Annual Check In for Exempt and Minimal Risk Research
	Continuing Review	Application for Continuing Review
	Final Report	Final Report Form
	Modification of Approved Research	Request for Review of Modification
	New Contact 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*

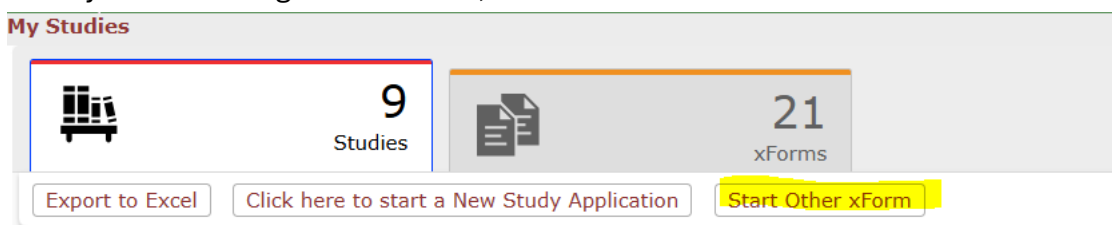
Select xForm to start Filter:

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
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*


Select xForm to start	
Action	Description
Form (Click to start)	
 New Contact Form	Registering a New User
 New Study	New Study Application for Initial Review
 Training Certification Submission	Use this form to update HSP Training Submission for a contact

3. Complete and submit the form


Registering a New User in IRBManager on their Behalf

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

My Studies





9
Studies



21
xForms

[Export to Excel](#)
[Click here to start a New Study Application](#)
[Start Other xForm](#)

2. Select *New Contact Form*

Select xForm to start	
Action	Description
Form (Click to start)	
 New Contact Form	Registering a New User
 New Study	New Study Application for Initial Review
 Training Certification Submission	Use this form to update HSP Training Submission for a contact

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.

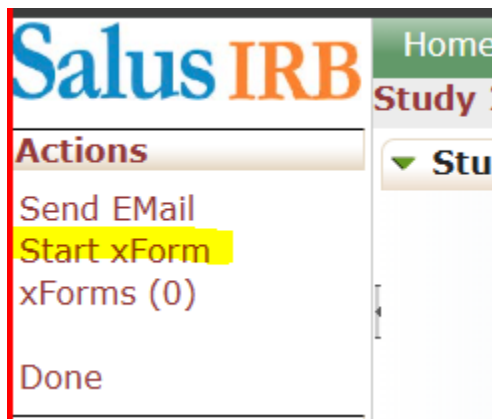
This form is only to be used for *Study-Site* personnel changes. If you need to update your study level personnel, please contact Salus.

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”)

