

Salus IRB

IRBManager User Guides

Getting Started, General Information, and Submitting

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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 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"

Salus IRB
Login

Email address

Password

Client SalusIRB

[Forgot Password?](#)

Don't have an account?
[Click here to register.](#)

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2025.2.8051.0/Release/e1e893f | GCWBWS1 | 2025-03-06 22:01:57Z | 0.005s

Powered By IRBManager

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

Salus IRB
Register

Email

Confirm Email

Copyright ©2000-2024 Tech Software. All Rights Reserved.
2024.10.7892.0/Release/aa104da | GCWBWS1 | 2024-11-13 20:05:19Z | 0.004s

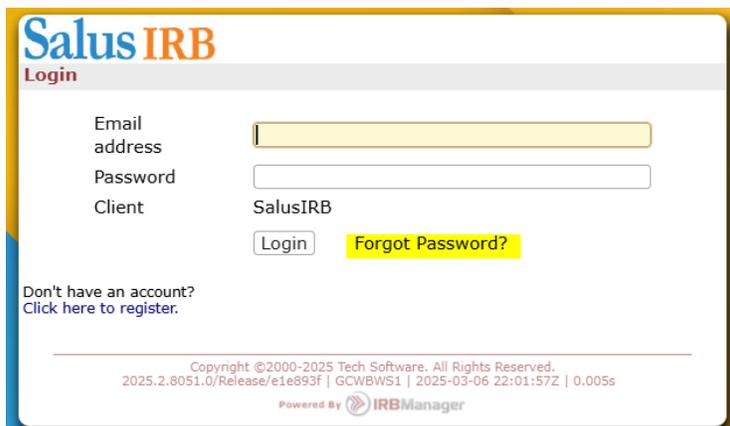
Powered By IRBManager

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 with study. See “Locating Reference Documents” or “Locating Event Attachments/Approval Documents” in this guide for more information.

IRBManager Dashboard

The screenshot shows the IRBManager dashboard interface. At the top, there are navigation tabs for 'Home' and 'My Studies'. Below this, there are summary statistics: 9 Studies and 19 xForms. A 'Sort by contact roll type' dropdown is set to 'PI/PM Name'. A 'News and Resources from Salus IRB' section is on the right. The main area displays a grid of study cards. One card, '24318-Test - Marvel Research Inc.', is highlighted in red, indicating it is 'Expiring Soon'. Other cards show study details like '24804-Fern Research (test)', '24808-GEHA', '24811-Anava (Test)', '24812-Site 5', '24819-Fern Research (test)', '24819-Test - Marvel Research Inc.', '24827-Site 3', and '25003-Fern Research (test)'. Each card includes the study name, status (Active), PI/PM name, and expiration date. An 'Inactive Studies' section at the bottom shows counts for 'PI' (2) and 'Research Staff' (1). A 'Messages & Links' section at the bottom right provides links to 'Guidance - Administering Informed Consent' and 'Guidance - Investigator Reporting Responsibilities'.

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

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 Stages & Meaning” for details

1	10	9	
Awaiting Your Attention	Unsubmitted	Being Processed At A Later Stage	
Continuing Review Data Entry 24819-Test - Marvel Research Inc. Emily Wilson Started on 22 hours ago	Continuing Review Data Entry 24819-Fern Research (test) Jane Doe (test) Started on 12/20/2024	Continuing Review Expedited Review Processing Sponsor: Continuing Review 24827-Site 3 As of 12/30/2024	Continuing Review Board Review Processing Sponsor: Continuing Review 24811-Ahava (Test) As of 12/19/2024
Continuing Review Teststudy105 Board Review Processing Sponsor: Continuing Review 24812-Site 5 As of 12/31/2024	Modification of Approved Research PM Review and Approval 24827-Site 3 Jane Doe (test) Started on moments ago	Modification of Approved Research QA Assignment Sponsor: Submitted Modification 24819-Fern Research (test) As of 01/20/2025	Modification of Approved Research Data Entry 24819-Fern Research (test) Jane Doe (test) Started on 12/20/2024
Modification of Approved Research Data Entry 24819-Fern Research (test) Jane Doe (test) Started on 02/17/2025 at 3:13 PM CT	Modification of Approved Research Data Entry 24819-Fern Research (test) Jane Doe (test) Started on 01/15/2025	Modification of Approved Research QC for Letters and Documents Sponsor: Submitted Modification 24819-Fern Research (test) As of 12/20/2024	Modification of Approved Research Board Letter Preparation Sponsor: Submitted Modification 24811-Ahava (test) As of 12/19/2024
Modification of Approved Research Board Letter Preparation Sponsor: Submitted Modification 24812-Site 5	Modification of Approved Research Teststudy105 QA/Screening Sponsor: Submitted Modification	New Contact Form New Contact Data Entry Jane Doe (test)	New Study Application Form Data Entry Jane Doe (test)

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
collapse

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)
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 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)
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

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: None
 Site Approved Number of Participants: None
 Targeted Vulnerable Populations: None
 Reliance Completion Date: None

Project Manager/Lead: Jane Doe (test)
 Investigator: N
 Additional: N
 Expiration: December 29, 2025
 Other Expirations: None
 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	

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

Study-Site Emails (1)

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

Salus IRB Home

Event Details

Study-Site

Project Information

Event

Actions

Attachments (4)

Send EMail

Start xForm

xForms (0)

Done

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

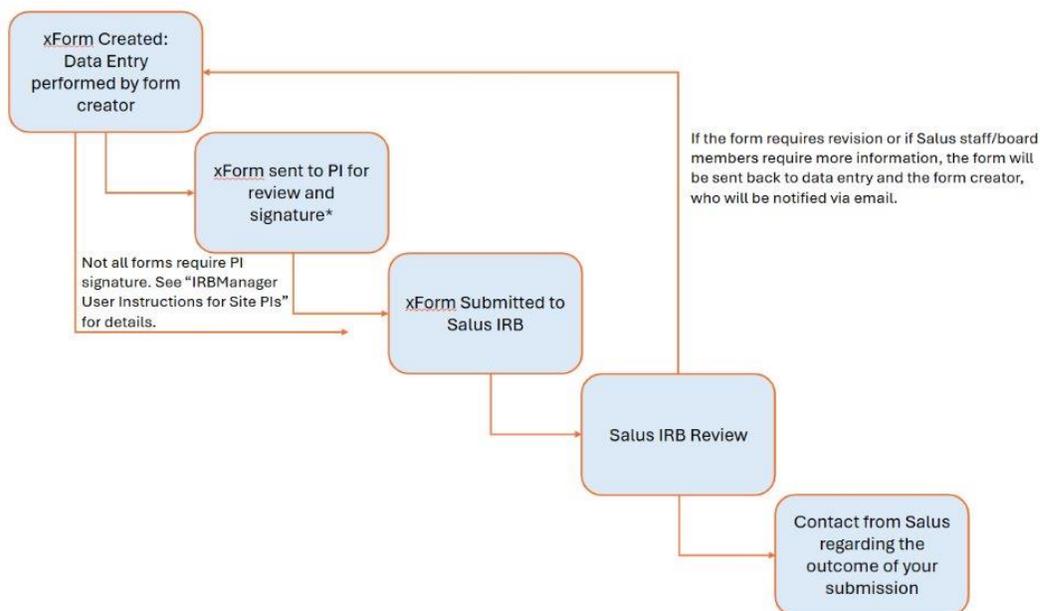
- Read all instructions on the xForm – Forms will provide detailed instruction regarding required attachments. By following xForm instructions and submitting all required documents, Salus is less likely to have to return the form with requests for additional information, confirmation, or clarification.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

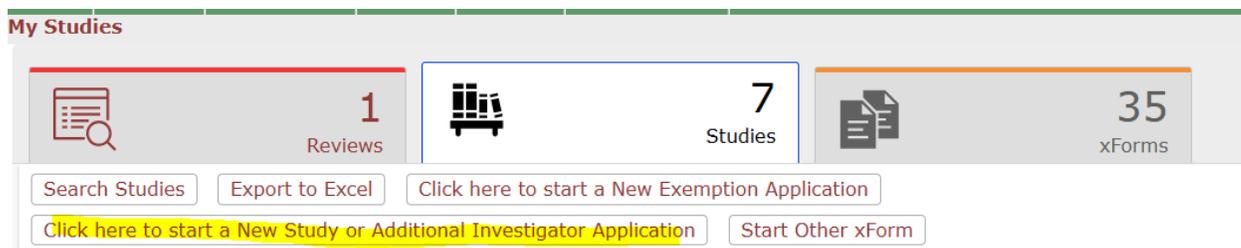
Form Stage	Stage Meaning
Application Form Data Entry	The application form is with the research team and you are able to make edits or enter in new data/ information.
PI Signature for Coordinator Submission	The application form was completed by somebody other than the PI. The form is waiting for the PI 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, see next section on “Submitting an Exempt/HSR Determination Form”.

To submit a new study:

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



My Studies

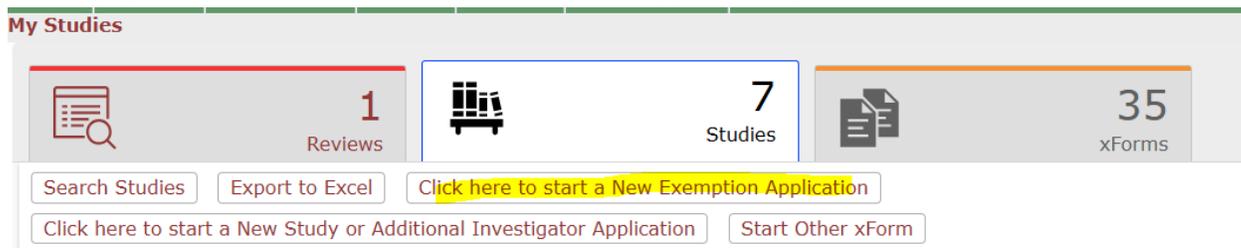
 1 Reviews	 7 Studies	 35 xForms
---	---	---

[Search Studies](#) [Export to Excel](#) [Click here to start a New Exemption Application](#)
[Click here to start a New Study or Additional Investigator Application](#) [Start Other xForm](#)

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 an Exempt/HSR Determination Form

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



My Studies

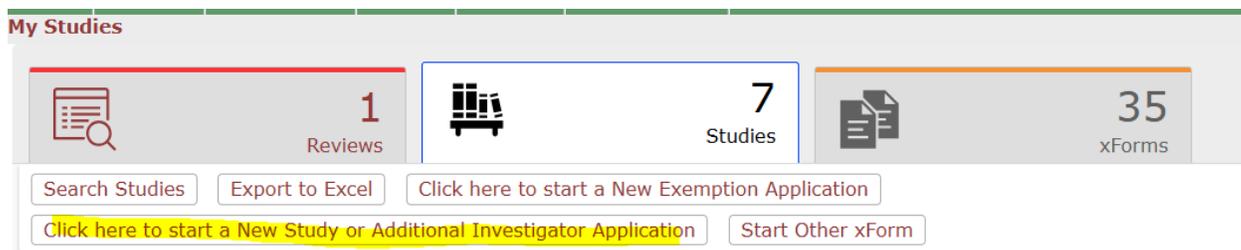
 1 Reviews	 7 Studies	 35 xForms
---	---	---

[Search Studies](#) [Export to Excel](#) [Click here to start a New Exemption Application](#)
[Click here to start a New Study or Additional Investigator Application](#) [Start Other xForm](#)

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 an Additional Investigator to a Currently Approved Multi-Site Study

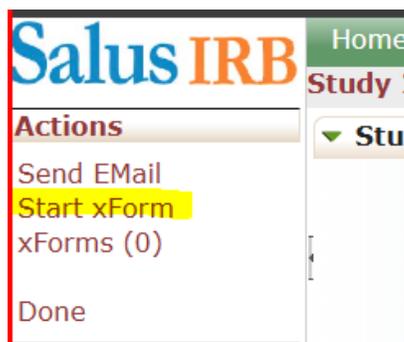
1. Log into IRBManager
2. Click on [Click Here to Start a New Study or Additional Investigator Application]



3. Follow the instructions to complete the *New Study* xForm
 - a. Select “Additional Investigator” when prompted
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



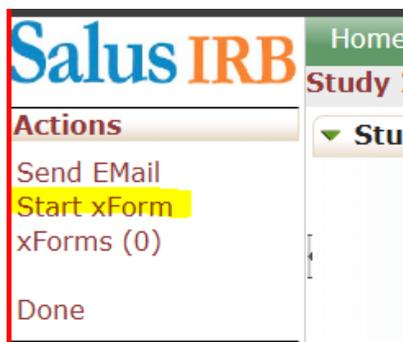
4. Select *Continuing Review* (IRBManager will automatically select the correct continuing review form for you to complete)

Select xForm to start	
Action	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



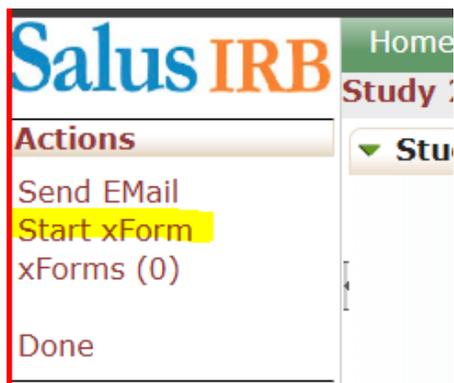
4. Select *Annual Check In*

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



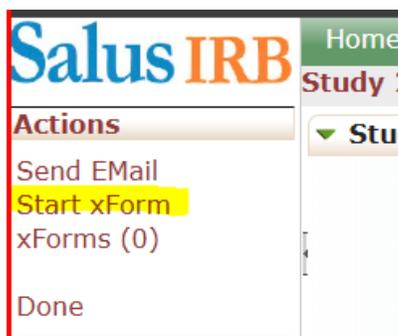
4. Select *Final Report*

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*

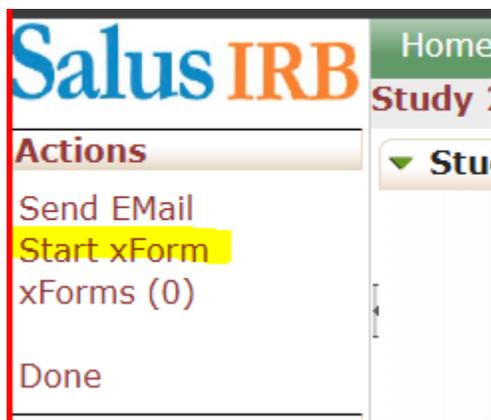
Select xForm to start		
Action	Form (Click to start)	Description
	Annual Check In	Annual Check In for Exempt and Minimal Risk Research
	Continuing Review	Application for Continuing Review
	Final Report	Final Report Form
	Modification of Approved Research	Request for Review of Modification
	New Contact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

Filter:

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. 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”

My Studies



9

Studies



21

xForms

Export to Excel
Click here to start a New Study Application
Start Other xForm

2. Select *Training Certification Submission*

Select xForm to start		
Action	Form (Click to start)	Description
	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	Form (Click to start)	Description
	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.

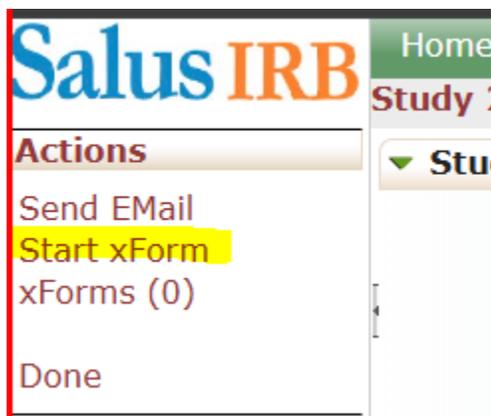
This form is only to be used for *Study-Site* personnel changes. If you need to update your study level personnel, please contact Salus.

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”)