

**WASHINGTON STATE
INSTITUTIONAL REVIEW BOARD**

Guide to IRBManager for Researchers

Introduction and user manual for
researchers submitting
applications to WSIRB after
January 15, 2019.

Contents

1.0	IRBManager	2
1.1	What is IRB Manager.....	2
1.2	Definitions.....	2
1.3	Creating Your New Account with IRB Manager and Logging	3
1.3.1	Washington State Agency Users with Single Sign-On (SSO).....	3
1.3.2	All Other Affiliated Users.....	5
1.4	Resetting Passwords	7
1.5	Login Issues with SSO	7
2.0	Navigating the Home Page – Dashboard	8
2.1	Dashboard Overview.....	8
2.2.	Dashboard Sections.....	8
2.2.1	Projects.....	8
2.2.2	xForms.....	9
2.2.3	Events.....	9
2.2.4	My Projects (Active	9
2.2.5	Project Status (For Study Coordinators & Investigators).....	10
2.3	Left Side Menu	11
3.0	Creating a New Expedited or Full Board Research Application.....	11
4.0	Creating a new Exempt Determination Request.....	12
5.0	Creating a Continuation Approval Request (CAR),.....	13
	Study Amendment Request (SAR), & Exempt Amendment Request (EAR).....	13
5.1	Creating a CAR or SAR**	13
5.2	Submitting a CAR or SAR once it is completed	16
5.3	Creating an Exempt Amendment Request (EAR).....	17
5.4	Promptly Reportable: Reporting Unanticipated Problems, Adverse Events, and/or Protocol Deviations	17
5.5	Adding a New Contact to IRBManager – New Study Staff, or New PI.....	18
5.5.1	Adding new staff if those staff members have already been entered into IRBManager via the method described above.	20
6.0	Help and Support	21

1.0 IRBManager

1.1 What is IRB Manager

IRBManager is an online submission, workflow, and data management system for Washington State Institutional Review Board (WSIRB). IRBManager is a fully web based system, which means that users can log in anywhere they have internet access. The electronic forms provided within this system allow users to submit new full Board and expedited studies for review, upload attachments and documentation, as well as submit other forms for continuing review, study amendments, exempt determination requests, exempt amendment requests, promptly reportable, and study closures. These forms electronically route the study through the appropriate review process.

With the implementation of this system, **WSIRB will no longer accept submissions via email.**

Exceptions: Some individual *forms* are still required to complete the application process. These are the conflict of interest (**Appendix N**) reporting form, and the State Agency resource requests and State Agency records request forms (**Appendix H & G**). These forms are still available on WSIRB's website under the 'Forms' link on the left side menu and can be submitted in .docx or .pdf format. The Appendix N will need to be uploaded to IRBManager. All Appendix H and G forms need to be sent to the appropriate agency data manager for authorization. You can find the contact list for data managers alongside the download link to the Appendix G.

1.2 Definitions

[There are a number of definitions associated with IRBManager:](#)

Dashboard - Home page screen. Your Dashboard allows you to access and review all information relevant to the projects you have submitted.

Event - An action in IRBManager, such as a CAR, SAR, or Initial Research Application. *A project can have multiple "events" throughout its lifetime* (initial submission, CARS, an occasional SAR).

xForm – When you begin a new Event in IRBManager, you will start an xForm. xForms are the processes of the project, whether that is a new Exempt Determination Request, or a Continuation Approval Request for an ongoing research project.

[There are also definitions specific to WSIRB:](#)

CAR - Continuation Approval Request (considered an **Event** in IRBManager)

SAR - Study Amendment Request (considered an **Event** in IRBManager)

EDR - Exempt Determination Request (considered an **Event** in IRBManager)

EAR - Exempt Amendment Request (considered an **Event** in IRBManager)

PR - Promptly Reportable, includes protocol deviations, unanticipated problems, or adverse events (considered an **Event** in IRBManager)

SSO – Single Sign-On – Washington State Agency assigned log-in credentials given to all Washington State government employees. SSO is required for all State employees when using the WSIRBManager system whether they are acting as a researcher, or a reviewer.

1.3 Creating Your New Account with IRB Manager and Logging In

IRBManager can be accessed here: <https://wsirb.my.irbmanager.com/>.



If you have not used WSIRB’s IRBManager system before, and do not have an account, there are two routes available for registering: **Single Sign-On (SSO)** required for all Washington State employees with a @.wa.gov email address, and, **IRBManager issued** log-in for all other affiliated users.

SSO is required for all employees of Washington State in order to meet State security requirements. All other users **not** affiliated with Washington State will use the IRBManager issued log-in option.

1.3.1 Washington State Agency Users with Single Sign-On (SSO) in Active Directory

Washington State Employees who are in Active Directory, use the “click here” link after “To login using your Washington State username and password” or simply click the Washington State logo.



Login


To login using your Washington State username and password [click here](#)

To use your IRBManager issued login [click here](#)
Don't have an account?
[Click here to register.](#)

Copyright ©2000-2019 Tech Software. All Rights Reserved.
Steampunk (2017.11.833.0/Release/451b6f15c88957cc427342d420244f7c9b8f85e0)
TP-WEB01 at 2019-01-10 17:14:26Z
Page generated in 0.007 seconds.

The following screen will appear.



Sign in with one of these accounts

- Secure Access Washington
- Test-Secure Access Washington
- WA State Department of Transportat
- Washington State Legislature
- Test-Multi-Factor Secure Access Was
- Multi-Factor Secure Access Washing
- Test-DRS Multi-Factor Secure Access
- DRS Multi-Factor Secure Access Was
- Active Directory**


© 2016 Microsoft

Select **“Active Directory”** from the list as indicated with the arrow above. This should be the bottom most option. Once selected, the SSO will take over and log you in. You will enter IRBManager system for all actions using the Active Directory SSO. **Your SSO will update along with your State required passwords so you will never need to manually update your IRBManager password.** If you have any issues logging-in, please don't hesitate to reach out via email or phone at wsirb@dshs.wa.gov or 360-902-8075. Our office hours are 7:30am – 4:00pm, M-F, [excluding State holidays.](#)

1.3.2 All Other Affiliated Users

For users who are not Washington State employees in Active Directory, if you have not registered an account already, you will need to register. Click the highlighted link to begin the registration process.

Login



To login using your Washington State username and password [click here](#)

To use your IRBManager issued login [click here](#)

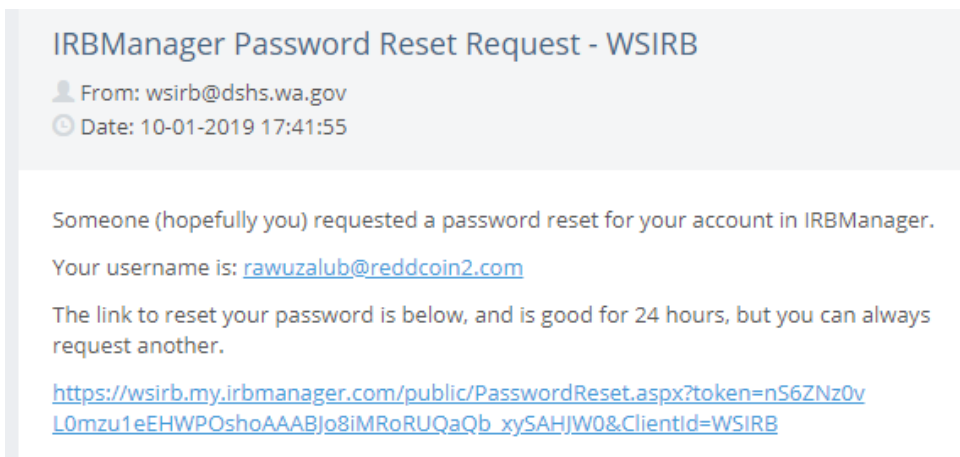
Don't have an account?
[Click here to register.](#)

When prompted by the next screen, **enter the email you wish to use as your primary point of contact**

Register


E-Mail	<input type="text"/>
Confirm E-Mail	<input type="text"/>
<input type="button" value="Next"/>	

Clicking “Next” will generate an automated email from wsirb@dshs.wa.gov. The subject line will read “IRBManager Password Reset” even if you are registering for the first time.



Follow the link. It will return you to the IRBManager login and prompt you to create a username and password. **NOTE: Your username must be the email you used to register**

Reset Password

 A valid password must be at least 6 characters long, be different from the user name, and contain characters from at least 3 of these groups: uppercase letters, lowercase letters, numbers, and special characters (e.g. !, @, #, ~).


User Name


New Password

Confirm

After choosing a password and confirming the password, click “Reset Password.” You will once again be returned to the login screen. IRBManager will prompt you to use your new login credentials you have just created.


Login

 Please log in using your new password.




For all future logins, all users who are not Washington State employees will use their IRBManager issued login.

Login



To login using your Washington State username and password [click here](#)

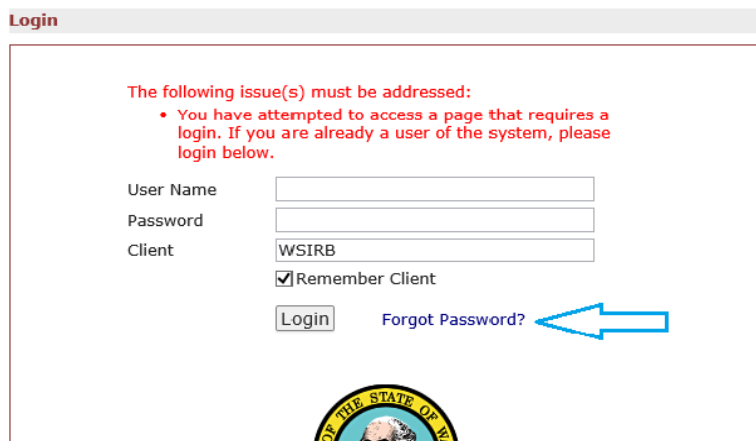
To use your IRBManager issued login [click here](#) 

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

1.4 Resetting Passwords

Washington State Agency employees using SSO **will not** need to reset their password manually.

For all other users, if you need to reset your password, click on the ‘Forgot Password?’ link as indicated by the arrow below, to reset your password. You will receive an email with a link to reset your password. **If you do not use the link within 24 hours, it will expire.** If you have any issues receiving the email, please check the ‘spam’ and ‘junk’ folders within your email account. If issues persist, please contact WSIRB via email at wsirb@dshs.wa.gov, or by phone at 360-902-8075. Our office hours are 7:30am – 4:00pm, M-F, excluding State holidays.



The screenshot shows a login page titled "Login". At the top, a red message states: "The following issue(s) must be addressed: • You have attempted to access a page that requires a login. If you are already a user of the system, please login below." Below this message are input fields for "User Name", "Password", and "Client" (with "WSIRB" entered). There is a checked checkbox for "Remember Client" and a "Login" button. A blue arrow points to the "Forgot Password?" link. At the bottom center is the seal of the State of Washington.

If on any future log-ins an incorrect password is entered three times, IRBManager will lock the account as a security precaution. If that happens, click the “Forgot Password” link from the login screen. After filling in the information requested, a new password will be emailed to you and your account will be unlocked.

1.5 Login Issues with SSO

One of the most common issues with logging into IRBManager for SSO is a problem with the auto-authenticating process in IRBManager. This is caused by conflicting cookies from a SAW login. “Realm Cookies” are used so a user doesn’t have to select their identity store every time they login. It is dynamic and will be there unless deleted or the user hasn’t logged in for 31 days.

If you are a WA state agency employee who has attempted to log in using SSO and are routed to a separate login page that requests your SAW, or SSO login information, stop. This is an error. As a state employee, you should NEVER have to enter your information to login. In the event of difficulty logging in, clear cookies from your browser.

2.0 Navigating the Home Page – Dashboard

2.1 Dashboard Overview

Once you have logged in, you will see a screen similar to the following:

The screenshot shows the WSIRB dashboard. On the left is a navigation menu with sections: **Actions** (Click to begin an Exempt Determination Request, Click to begin an Initial Application, Start xForm, Show Fundings), **Recent Items** (2018-004-DFT, 2018-003-Department of Social & Health Services), **Messages** (Welcome to IRBManager at WSIRB), and **My Docs & xForms** (0 Attachments, 12 xForms). The main area is titled 'My Projects' and contains three sections: **Projects (5 Active)** with a list of roles and counts (e.g., 'You are associated with 5 active Projects and 6 total Projects'), **xForms (9 Active)** with counts (e.g., 'You have 5 unsubmitted xForms'), and **Events (12 Open)** with a filter dropdown and a list of event types (e.g., 'You have 1 Continuation Approval Request events'). A pie chart on the right shows event distribution, with a callout for 'Initial Submission (3)'. At the bottom is a table header for 'My Projects (5 Active)' with columns: Project, Site, PI, Title.

This is the **Dashboard**. The Dashboard displays information relevant to all projects you are associated with across the IRBManager system. The main Dashboard area displays **Projects**, **xForms**, and **Events** that are associated with your account. Clicking on the links under the Projects, xForms, or Events tab will open more detailed summaries with links to each form.

2.2. Dashboard Sections

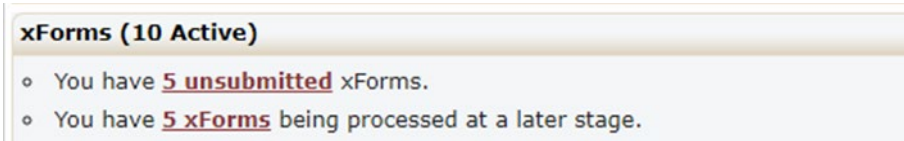
2.2.1 Projects

The screenshot shows the 'My Projects' section. It has a sub-section titled 'Projects (3 Active)' with a list of three items: 'You are associated with 3 active Projects and 4 total Projects.', 'You are the PI for 2 active and 3 total Projects.', and 'You are the Co-Investigator for 1 active and 1 total Projects.'

The **Projects** section shows the overall projects (research or exempt determination requests) that you are associated with whether as principal investigator, co-investigator, project coordinator, research assistant. Clicking on the underlined link will open the projects with which you are associated **in the same tab**. If you

wish to open projects in a new tab, right-click on the link and select “open in a new tab.”

2.2.2 xForms



The **xForms** tab shows the forms currently active at this time for the user. An **xForm** can also be referred to as a submission. In this view of the Dashboard: “You have [5 unsubmitted](#) xForms” means that the user has 5 xForms (submissions) started, but has not yet **completed the submission process**. (The user may have clicked “Save for Later” or just closed a form before pressing the “Submit” button at the end of the form.) By clicking the underlined link, “[5 unsubmitted](#),” the user can go straight to the unsubmitted **xForms**.

“You have [5 xForms](#) being processed at a later stage” means the user currently has 5 forms being processed. In this case, the user has successfully submitted the forms, and forms are currently under review by WSIRB staff, or in a later stage of the review process.

2.2.3 Events



The **events** section of the Dashboard shows the submissions open by submission type. This section shows all open events and the submission name, such as continuing review, initial review, study amendment requests, promptly reportable, etc. Clicking any of the links will take you directly to that form (i.e. it will open a new page with a link to all Continuation Approval Requests that are associated with you in the system)

2.2.4 My Projects (Active)

If you have active projects, they will be listed in the “My Projects (x Active)” tab. This tab will display the status of the project and when it expires.

My Projects (5 Active)				
Project	Site	Expires	Status	Reference Doc(s)
N/A	Default Site	10/29/2019	Pre-Review	
N/A	Department of Labor & Industries (LNI)		Pre-Review	

2.2.5 Project Status (For Study Coordinators & Investigators)

All submissions require the electronic signature of the PI. This is still applicable if someone **other** than the PI is filling out and submitting the xForm. To check the ‘stage’ of your project, go to your dashboard. If you see the highlighted text, you will need to click on it.

Actions

Click to begin an Exempt Determination Request

Click to begin an Initial Application

Start xForm

Show Fundings

View as Myself

Recent Items

2018-013-Department of Social & Health Services

2018-015-University of Washington

2019-003-Department of Social & Health Services

2019-002-Department of Social & Health Services

2018-010-DFT

2018-004-DFT

2018-016-Department of Social & Health Services

Projects (11 Active)

- You are associated with **11 active** Projects and **11 total** Projects.
- You are the PI for **11 active** and **11 total** Projects.

xForms (17 Active)


- You have **8 unsubmitted** xForms.
- You have **9 xForms** being processed at a later stage.
- There are 2 xForms awaiting your attention.**

Events (12 Open)

Only show events where I am:

- You have **4 Exemptions** events.
- You have **7 Initial Submission** events.
- You have **1 Promptly Reportable** events.

You have **12 Total Open** events




My Projects (11 Active)

Select the link to the project you wish to check on. Another page will open and IRBManager will display a table with the following columns: Form, Identifier, Owner, Stage, Status, and Started. The **Form** indicates the type of submission (CAR, SAR, Initial Submission etc.) The **Identifier** indicates the PI associated with the project. The **Owner** indicates the relevant agency or organization. The **Stage** indicates where in the process the submission is. If – as highlighted – the stage says “PI Signature for Non PI Submission” the PI associated with the project needs to electronically sign the xForm before WSIRB staff will be notified that the project is ready for review. **Without that signature, the xForm will not be submitted to WSIRB staff.**

Form	Identifier	Stage	Status
Continuation Approval Request	Gena Research	PI Signature for Non PI Submission	Work in progress
Initial Research Application	Gena Research	Data Entry (2nd time)	Work in progress

2.3 Left Side Menu



Actions

Click to begin an Exempt Determination Request

Click to begin an Initial Application

Start xForm

Show Project Codes

Recent Items

2018-004-DFT

2018-006-Department of Labor & Industries

2018-003-Department of Social & Health Services

Messages

Welcome to IRBManager at **WSIRB**

My Docs & xForms

0 Attachments

14 xForms

Actions

To start a new research application or a new exempt determination request, click the desired link under the “Actions” menu. **Note that certain forms** (e.g., Continuation Approval Request) **can only be completed for a protocol already active in IRBManager**. These forms are not available from the Dashboard and must be accessed through the project itself.

Recent Items

The links under this heading will show the most recent items you have viewed or modified in IRBManager. Click on any link under “Recent Items” to go directly to that project.

Messages

Note that this is for the IRBManager system only. **Communication about your projects will still take place via email, and WSIRB staff can be reached at wsirb@dshs.wa.gov.**

My Documents and Forms

This heading shows how many attachments and xForms you have submitted. Note if you click the “xForms” link, it will take you to a new **tab** showing all xForms.

3.0 Creating a New Expedited or Full Board Research Application

To start a **new expedited or full Board research project**, from the Home Dashboard screen, click the “Click to begin an Initial Application” link in the left side action menu under the **Actions** tab. You may also click the “Start an xForm” link from the same page.

Actions

Click to begin an Exempt Determination Request




Click to begin an Initial Application

Start xForm

Show Project Codes

Recent Items

A **new tab** will open with the screen below. Click the link under the “Form (click to start)” column labeled “Initial Research Application.” This will populate the new online application form. The Initial Submission xForm will guide you through the entire application, with certain requirements (such as the request for a waiver of elements of consent/assent– previously Appendix I) populating automatically based on your responses.

Select xForm to start		
Action	Form (Click to start)	Description
	Exempt Determination Request	Exempt Determination Request
	Initial Research Application	Initial Research Application
	New Contact Form	New Contact Form

4.0 Creating a new Exempt Determination Request

To start a new Exempt Determination Request from the Home Dashboard screen, click the “Click to begin an Exempt Determination Request” link in the left side action menu under the Actions tab. You may also click the “Start an xForm” link from the same page.

Actions

Click to begin an Exempt Determination Request




Click to begin an Initial Application

Start xForm

Show Project Codes

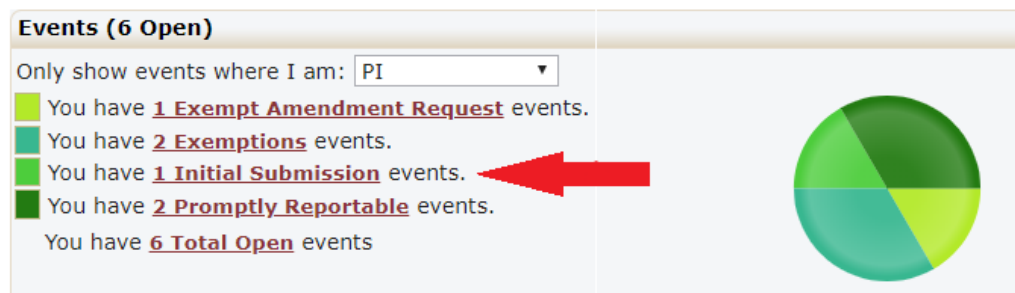
Recent Items

A **new tab** will open with the screen below. Click the link under the “Form (click to start)” column labeled “Exempt Determination Request.” This will populate the new online EDR form. The EDR xForm will guide you through the entire application, with certain requirements (such as the Appendix G for State Agency data requests) populating automatically based on your responses.

Select xForm to start		
Action	Form (Click to start)	Description
	Exempt Determination Request	Exempt Determination Request
	Initial Research Application	Initial Research Application
	New Contact Form	New Contact Form

5.0 Creating a Continuation Approval Request (CAR), Study Amendment Request (SAR), & Exempt Amendment Request (EAR)

To submit a Continuation Approval Request (CAR) or Study Amendment Request (SAR), start at your Home Screen. Under the “Events” tab, you can use the drop down menu to select for events where you are the PI, Co-PI, or Coordinator. Click the link marked **Initial Submission**. You may also click the Total Open events link at the bottom.



The link will redirect to a new screen that looks like the picture below. Choose the project that you wish to submit a CAR or SAR for.

Home					Find Project (Ctrl+Q)		
My Events					Help	Generic's Settings	Sign off
Project	Event	Started	Instance	PI			
2018-009-DFT	Initial Submission	11/28/2018		Generic Researcher			



5.1 Creating a CAR or SAR**

****If the study amendment is intended to add new study staff, please refer to section 5.5 before filling out the rest of the SAR.**

IRBManager will open the project Home screen. It should appear similar to what is pictured below.

Once in the project home screen, click “Start xForm” on the left hand side menu. (Circled)
Only click “Start xForm” once you are inside the project. Otherwise, the xForm will not be attached to your project.

The screenshot shows the IRBManager interface. On the left, there is a sidebar with a 'WSIRB' logo and a menu under 'Actions' where 'Start xForm' is circled in red. The main area displays project information for 'Project 2018-009-DFT (IRB)'. The project details are as follows:

Project:	2018-009	Funding(s):	
Committee:	WSIRB	Funding:	
Category:		Grants:	
Department:	DOH Other (DOH)		
Agent Types:		CRO:	
Title:	Vulcan Perspectives of Educational Needs of Junior Science Officers Serving in Starfleet after First Year of Service		Year: 2018
Initial Review Type:		PI Institutional Affiliation:	Deep Space 9
Comments:			

Below the project details is the 'Project-Site' section:

Site(s):	DFT - Default Site and others	PI:	Generic Researcher
Status:	Pre-Review	Additional:	N
Approval:	December 3, 2018 for 12 months	Expiration:	December 2, 2019
Initial Approval:	December 3, 2018	Other Expirations:	
Comments:			

At the bottom, there is a section for 'Project-Site Contacts (1)'.

Clicking “Start xForm” will open a new **tab**. The new tab will present you with all the possible xForms that IRBManager allows for the selected project. Choose the desired Form and click the link (circled).

The screenshot shows the 'Select xForm to start' dialog box. It features a search filter at the top right and a table of available forms. The 'Continuation Approval Request' form is circled in red.

Action	Form (Click to start)	Description
	Continuation Approval Request	Continuation Approval Request
	Exempt Amendment Request	Exempt Amendment Request
	Exempt Determination Request	Exempt Determination Request
	Initial Research Application	Initial Research Application
	New Contact Form	New Contact Form
	Promptly Reportable Information	Promptly Reportable Information
	Study Amendment Request	Study Amendment Request

Choosing the Continuation Approval Request link will open the CAR document to fill out. Navigate the form via the “Next” “Save for Later” and “More” buttons at the bottom as pictured below. “Next” will move you to the next part of the CAR form. “Save for Later” allows you to save your form and return to it at a later date. “More” presents more options such as viewing the form as a PDF.

WSIRB

Collaborators Project Information Page 1 of 2 Next

Continuation Approval Request -- Project Information

Submitter (auto-filled): View Audit
 Generic Researcher
 Email: kristinsresearchemail@mail.com Business: 3609028075

Principal Investigator (auto-filled): View Audit
 Generic Researcher
 Email: kristinsresearchemail@mail.com Specialty:

Current Approval Period (auto-filled): View Audit
 12/3/2018 for 12 months - Expiration: 12/2/2019

Project Title (auto-filled): View Audit
 Vulcan Perspectives of Educational Needs of Junior Science Officers Serving in Starfleet after First Year of Service

Study Number: View Audit
 2018-009

Next Save for Later More ▾

Copyright ©2000-2019 Tech Software. All Rights Reserved.

Study Number:
2018-009

View Attachment Questions
 View Questions with Notes
 View Changed Responses
 View as PDF

Next Save for Later More ▾

IRBManager will not allow you to submit an incomplete form. Attempt to submit an incomplete form will produce the following screen.

Your progress to this point *has been saved*, however you must address the following issues before you can submit this form. Click on a page name to go to issues on that page.

[Study Review](#)

- Current Status - Required.

Choosing the Study Amendment Request link in the “Select xForm to Start” page will open a similar screen to the CAR, but it will say “Study Amendment Request—Project Information” at the top, as pictured below. The navigation features are the same as the CAR.

The screenshot shows the WSIRB logo on the left. The top navigation bar includes a 'Collaborators' icon, a dropdown menu set to 'Project Information', 'Page 1 of 4', and a 'Next' button. The main content area is titled 'Study Amendment Request -- Project Information' and contains four sections, each with a 'View Audit' link:

- Submitter (auto-filled):** Generic Researcher. Email: kristinsresearchemail@mail.com. Business: 3609028075.
- Principal Investigator (auto-filled):** Generic Researcher.
- Project Title (auto-filled):** Vulcan Perspectives of Educational Needs of Junior Science Officers Serving in Starfleet after First Year of Service.
- Study Number:** 2018-009.

At the bottom, there are buttons for 'Next', 'Save for Later', and 'More >'.

5.2 Submitting a CAR or SAR once it is completed.

Make sure to sign and submit the CAR or SAR once you have completed entering the required information in the xForm. For external researchers only: you will be required to enter your IRBManager password before you can submit your xForm. The screen should look similar to this.

The screenshot shows the WSIRB logo on the left. The top navigation bar includes a 'Collaborators' icon, a dropdown menu set to 'PI Signature', 'Page 4 of 4', and a 'Next' button. The main content area is titled 'Study Amendment Request -- PI Signature' and contains a blue box with the following text:

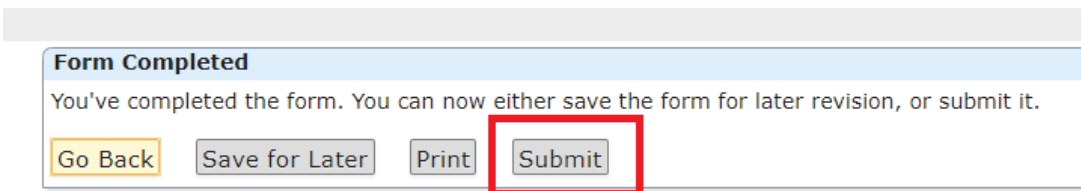
By entering my IRBManager password I affirm the following:

1. That the information provided is accurate and complete to the best of my knowledge.
2. That identifiable personal records and/or protected health information used or disclosed for this research without written authorization will not be reused for other purposes, or disclosed to any other person or entity, except as specifically required or permitted by law and approved by the WSIRB.
3. Furthermore, that no individual whose personal records or protected health information is used in this research will be identified in any written report resulting from this research.
4. That I am also responsible for ensuring that all members of this research team will abide by these restrictions.

To sign, enter password for kristinsresearchemail@mail.com

Below the text is a password input field. At the bottom, there are buttons for 'Previous', 'Next' (highlighted with a red box), 'Save for Later', and 'More >'.

For Washington State Agency employees using SSO with a @wa.gov email address, you will not be asked to enter your password. Once you have completed the CAR or SAR, you will see a “Form Completed” page. Click the “Submit” link to submit the form.



5.3 Creating an Exempt Amendment Request (EAR)

If your project is an Exemption (EDR), once you navigate to the “Select xForm to Start” page, ONLY choose the Exempt Amendment Request xForm.



Select xForm to start		
Action	Form (Click to start)	Description
	Continuation Approval Request	Continuation Approval Request
	Exempt Amendment Request	Exempt Amendment Request
	Exempt Determination Request	Exempt Determination Request
	Initial Research Application	Initial Research Application
	New Contact Form	New Contact Form
	Promptly Reportable Information	Promptly Reportable Information
	Study Amendment Request	Study Amendment Request

Copyright ©2000-2019 Tech Software. All Rights Reserved.

The navigation process will be similar to the CAR and SAR, but tailored to projects determined to be Exempt.

5.4 Promptly Reportable: Reporting Unanticipated Problems, Adverse Events, and/or Protocol Deviations

To submit a Promptly Reportable action, follow the same steps as if submitting a CAR or SAR for a specific project. When presented with the “Select xForm to Start” tab, select the link labeled “Promptly Reportable Information” (circled). Follow the steps in the xForm and submit as detailed above in the CAR & SAR section.

Select xForm to start		
Action	Form (Click to start)	Description
	Continuation Approval Request	Continuation Approval Request
	Exempt Amendment Request	Exempt Amendment Request
	Exempt Determination Request	Exempt Determination Request
	Initial Research Application	Initial Research Application
	New Contact Form	New Contact Form
	Promptly Reportable Information	Promptly Reportable Information
	Study Amendment Request	Study Amendment Request

5.5 Adding a New Contact to IRBManager – New Study Staff, or New PI

When submitting a Study Amendment Request to add new study staff, a new coordinator, research assistant, Co-PI, or PI, if that person is not *already* in IRBManager, they will need to be added to the system before the SAR can be completed. [A contact can be added to IRBManager two ways.](#)

The first way to add a contact is [during the process of creating the study amendment](#). Once the “Change in Personnel” box is checked in the SAR xForm, the system will automatically generate the step to add new contacts. (See below for examples of what information will be required).

SECTION 1: Description of Proposed Study Amendment View
 Select all that apply to indicate the specific modification(s) for which WSIRB review is requested, and submit all supporting documents. (Required)

<input type="checkbox"/> Changes in Recruitment Procedures and Documents <input type="checkbox"/> Changes in Data Collection Procedures, Interventions, and/or Instruments <input type="checkbox"/> Request for Identifiable Personal Records <input type="checkbox"/> Conflicts of Interest	<input type="checkbox"/> Changes in Consent/Assent Process and/or Documents <input type="checkbox"/> Revisions in the Study Population and/or Sample Frame <input checked="" type="checkbox"/> Change in Personnel <input type="checkbox"/> Miscellaneous
---	---

The second way to add a new contact is independent of any other study action.

To add a new contact directly from the Dashboard prior to creating a new Study Amendment, select “Start xForm” under the left hand Actions menu.

A new tab will open with the following options.

Action	Form (Click to start)	Description
	Exempt Determination Request	Exempt Determination Request
	Initial Research Application	Initial Research Application version 2 07/12/2019
	New Contact Form	New Contact Form

Select the New Contact Form option. A page will open that will provide required fields for the new staffer’s name, credentials, and contact information. The address requested should be the organization (University, Hospital, Agency, etc) mailing address.

New Contact Form -- New Contact Information

Submitter

Generic Researcher
Email: kristinsresearchemail@mail.com

Fill out the following questions based on the contact that you are adding

Enter the email address of this contact: (Required)

New Contact Prefix (Mr., Ms., Dr.): (Required)

New Contact First Name: (Required)

New Contact Last Name: (Required)

New Contact Credentials: (Required)

Once the new contact form has been filled out, click “Next” if ready to submit. After all new contacts have been entered, return to the Dashboard to begin the Study Amendment Request process.

5.5.1 Adding new staff if those staff members have already been entered into IRBManager via the method described above.

Check change in personnel

Check “Add Research Team Members” (or new PI, as applicable). Clicking Add New PI will generate a PI specific box.

Please indicate all of the following: (Required) [View Audit](#)

- New Principal Investigator
- Add Research Team Members
- Remove Research Team Members

Enter the email address for the new Principal Investigator who you want to add to the study: (Required) [View Audit](#)

Please enter 2 or more characters

Attach Appendix N: (Required)

[Add Attachment](#)

Attach completion certificate for training in the protection of human research subjects;

If the training occurred more than three years prior to today's date, a refresher course is suggested. Good Clinical Practices (GCP) and Responsible Conduct of Research (RCR) do not qualify as human subjects' protection training. Please visit our website for more information.

(Required)

[Add Attachment](#)

[Previous](#) [Next](#) [Save for Later](#) [More ▾](#)

Use the text box to select the correct staff member from the options. This function **only** works if the contact has previously been entered into IRBManager. If you have not yet added the staff member (whether staff or new PI) stop here, and click the hyperlink to “Start New Contact Form” in the appropriate row.

If you attempt to enter a contact that is not found in the system, click the link below to add a new contact.

[Start New Contact Form](#)

Please indicate all of the following: (Required)

- New Principal Investigator
- Add Research Team Members
- Remove Research Team Members

Selecting “Add New Principal Investigator” will generate a new form below that looks like this:

Please indicate all of the following: (Required) View Audit

New Principal Investigator
 Add Research Team Members
 Remove Research Team Members

Enter the email address for the new Principal Investigator who you want to add to the study: (Required) View Audit

Please enter 2 or more characters

Attach Appendix N: (Required)

Attach completion certificate for training in the protection of human research subjects;

If the training occurred more than three years prior to today's date, a refresher course is suggested. Good Clinical Practices (GCP) and Responsible Conduct of Research (RCR) do not qualify as human subjects' protection training. Please visit our website for more information.
 (Required)



If “Add Research Team Members” is checked, the system will generate a form to add new staff members.

Do not include information for a new Principal Investigator. Enter email address of new research team member, attach CV/resume and certificate of completion for human subject protections training for each new team member. Click ADD at the end of each row for additional research team members. View Audit

New Study Personnel (Required)

Enter the email address of the new research team member: * <input type="text"/>	Choose the role of the new study staff: * <input type="text"/>	Attach CV here: * <input type="button" value="Add Attachment"/>	Attach human subject protection certificate of completion: * <input type="button" value="Add Attachment"/>	If there is a Confidentiality Agreement for this project, attach a PDF of Additional Signature Page(s) for new staff. That form is available: Additional Signature Page - Confidentiality Agreement <input type="button" value="Add Attachment"/>	<div style="border: 2px solid red; padding: 2px; display: inline-block;"> Action <input type="button" value="Add"/> </div>
--	---	--	---	---	--

Attach Appendix N here. (Required)



Once the sections have been completed, **you must click “Add” (red box)** before moving on to the next part of the xForm. If “Add” is not selected, the information will not be entered into the system. Clicking “Add” will also generate another line to add more staff. Repeat the process until you have added all necessary staff members, then click “Next” and continue with the Study Amendment Request.

6.0 Help and Support

If you have any questions or problems using IRBManager, please contact the WSIRB staff at 360-902-8075 or wsirb@dshs.wa.gov. Our office hours are 7:30am – 4:00pm, M-F, excluding State holidays.