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 10
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 12
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****..... 14
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 18
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 22

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: The Conflict of Interest (**Appendix N**) reporting form, and the State Agency resource requests and State Agency records request forms (**Appendix H & G**) will still be available on WSIRB's website under the 'Forms' link on the left side menu.

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 an @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)

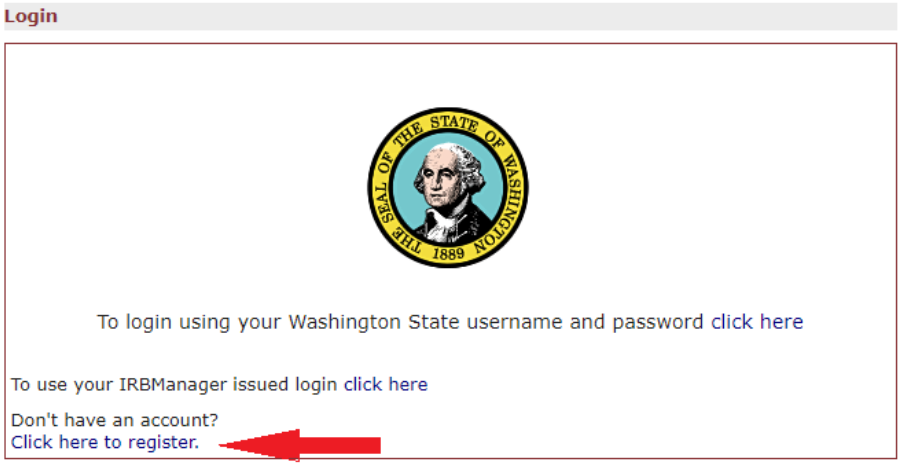
To log in as a Washington State Employee, use the "click here" link after "To login using your Washington State username and password" or simply click the Washington State logo.

The following screen will appear.

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.

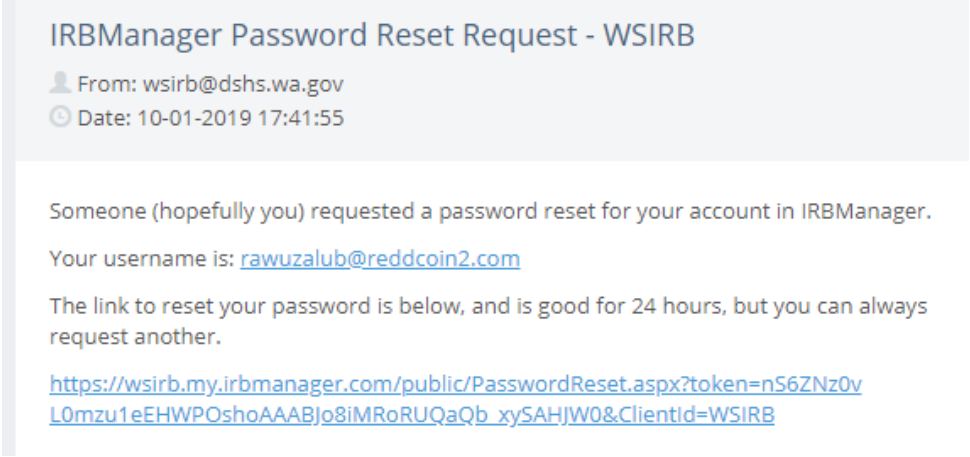
1.3.2 All Other Affiliated Users

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

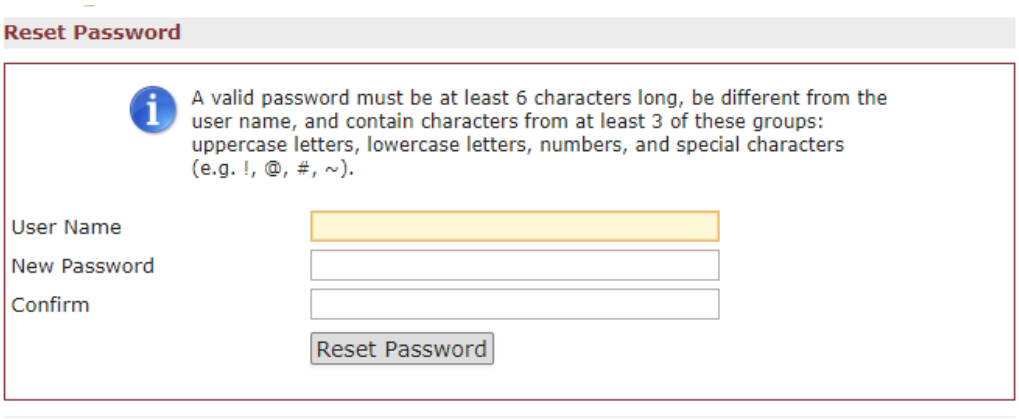


When prompted by the next screen, **enter the email you wish to use as your primary point of contact**

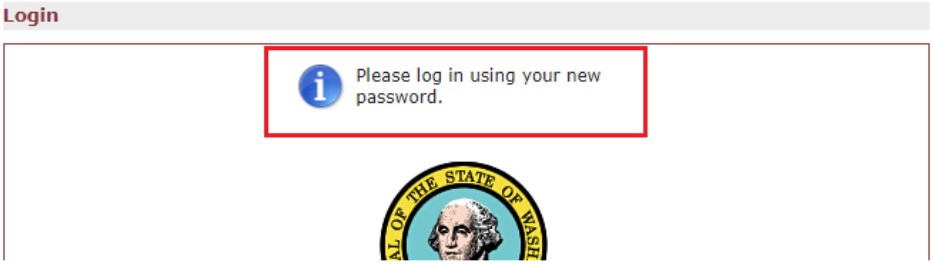
Clicking "Next" will generate an automated email from wsirb@dshs.wa.gov. The subject line will read "IRBManager Password Reset" even if you are registering for the first time.



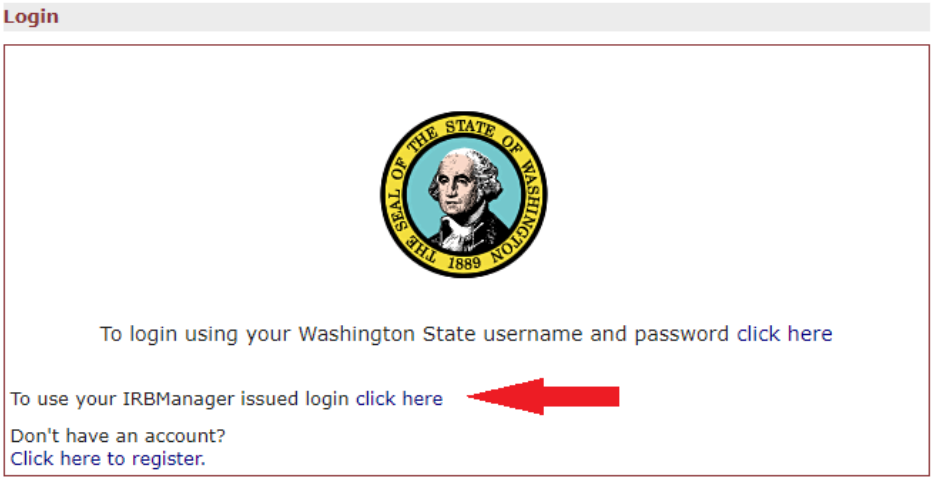
Follow the link. It will return you to the IRBManager login and prompt you to create a username and password. **NOTE: Your username must be the email you used to register**



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.



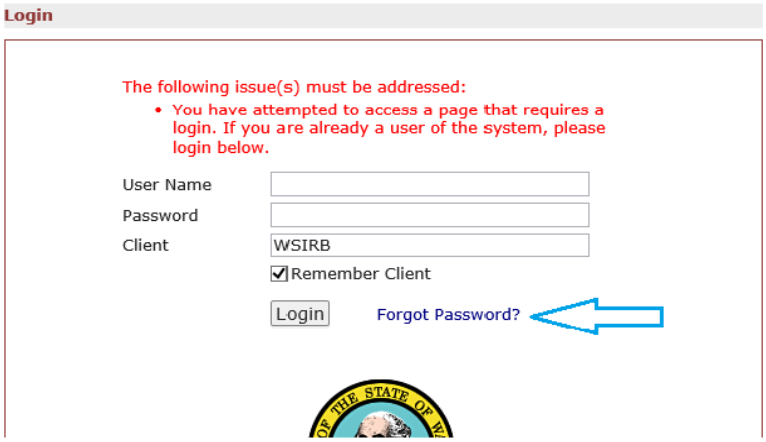
For all future logins, all users who are not Washington State employees will use their IRBManager issued login.



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.



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.

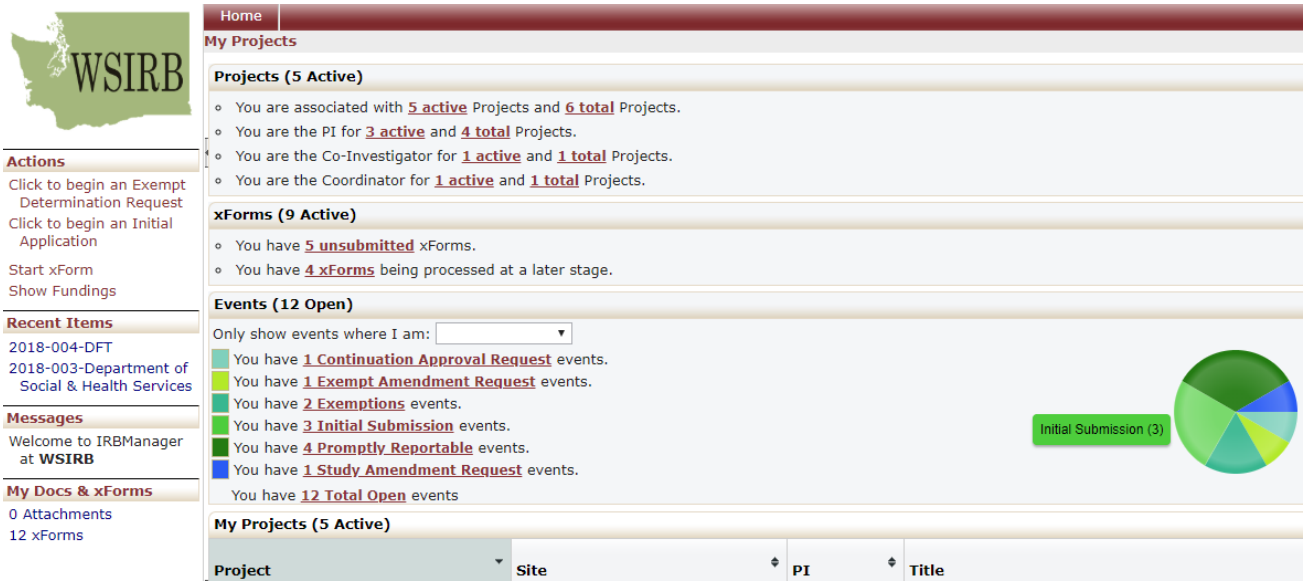
If you are a WA state agency employee who has attempted to log in using SSO and are routed to a separate login page that requests your SAW, or SSO login information, stop. This is an error. As a state employee, you should NEVER have to enter your information to login. In the event of difficulty logging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

1. Check your browser. IRBManager is not compatible with Microsoft Edge. If you are using Edge, please try another browser.
2. If you are still unable to login, click the “Tools” icon (looks like a small gear) in the top right corner of Internet Explorer. If you don’t use IE, you may need to search for the “Settings” option in the browser.
3. Click the “Internet Options” (should be near the bottom).
4. On the “General Tab”, click the “Settings” button.
5. Then click the “View Files” Button.
6. Find the cookie named “ADFS” (which should be near the top of the list as it is alphabetical), then right click, and delete.
7. Close out of the browser, and re-open the browser. Attempt to login to IRBManager again. If the problem persists, please consult with WSIRB staff.

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:



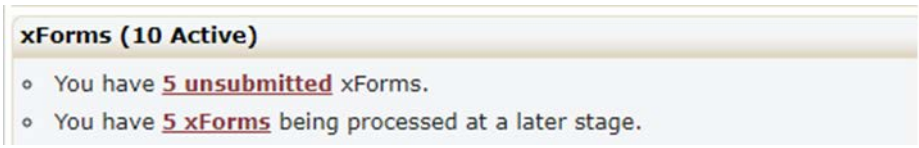
This is the **Dashboard**. The Dashboard displays information relevant to all projects you are associated with across the IRBManager system. The main Dashboard area displays **Projects, xForms,** and **Events** that are associated with your account. Clicking on the links under the Projects, xForms, or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

2.2. Dashboard Sections

2.2.1 Projects

The **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."

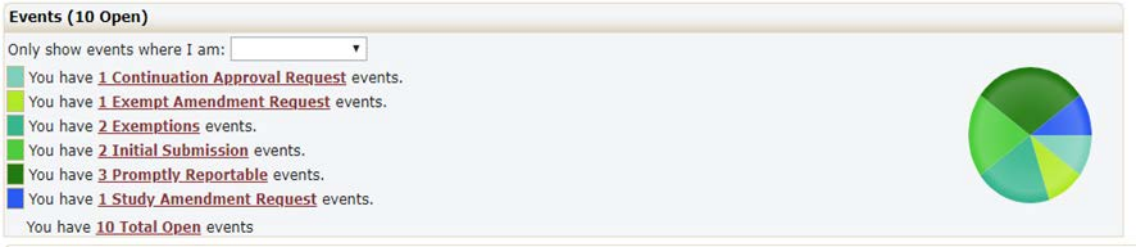
2.2.2 xForms



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

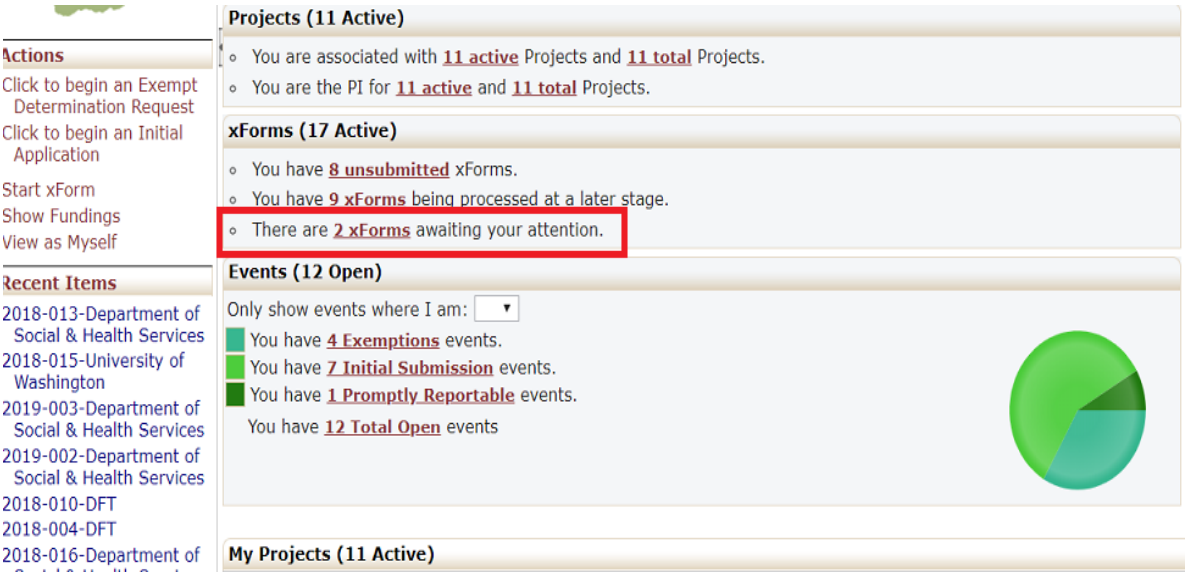
amendment requests, promptly reportable, etc. Clicking any of the links will take you directly to that form (i.e. it will open a new page with a link to all Continuation Approval Requests that are associated with you in the system)

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.

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.



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 Researc	PI Signature for Non PI Submission	Work in progress
Initial Research Application	Gena Researc	Data Entry *(2nd time)*	Work in progress

2.3 Left Side Menu

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

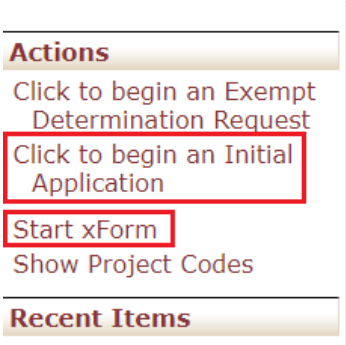
Note that this is for the IRBManager system only. **Communication about your projects will still take place via email, and WSIRB staff can be reached at wsirb@dshs.wa.gov.**

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.



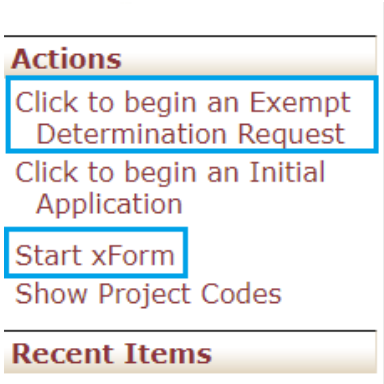
A **new tab** will open with the screen below. Click the link under the "Form (click to start)" column labeled "Initial Research Application." This will populate the new online application form. The Initial Submission xForm will guide you through the entire application, with certain requirements (such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

Select xForm to start

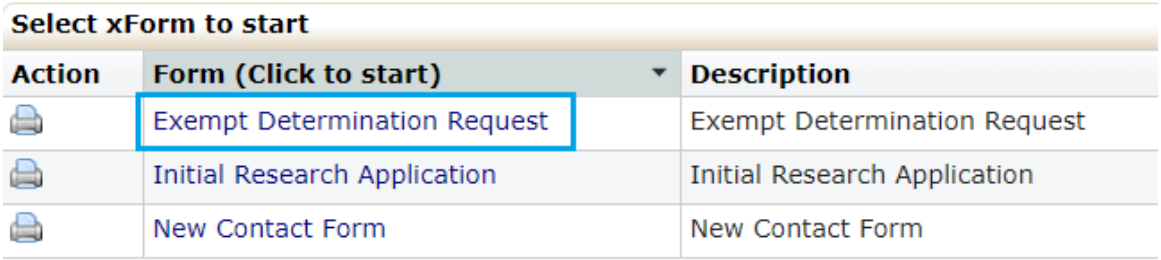
Action	Form (Click to start)	Description
	Exempt Determination Request	Exempt Determination Request
	Initial Research Application	Initial Research Application
	New Contact Form	New Contact Form

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.

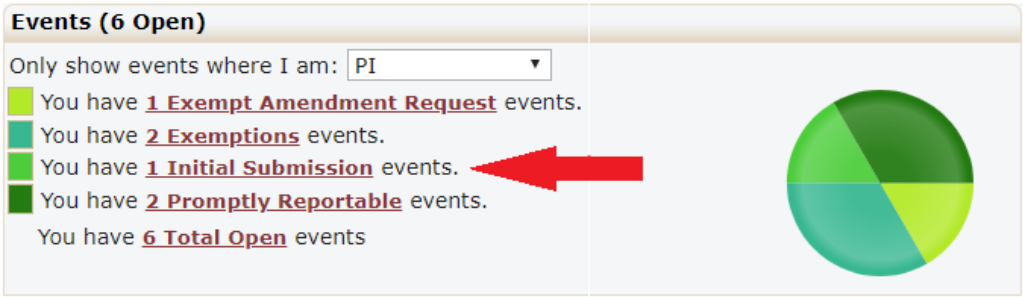


A **new tab** will open with the screen below. Click the link under the "Form (click to start)" column labeled "Exempt Determination Request." This will populate the new online EDR form. The EDR xForm will guide you through the entire application, with certain requirements (such as the Appendix G for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

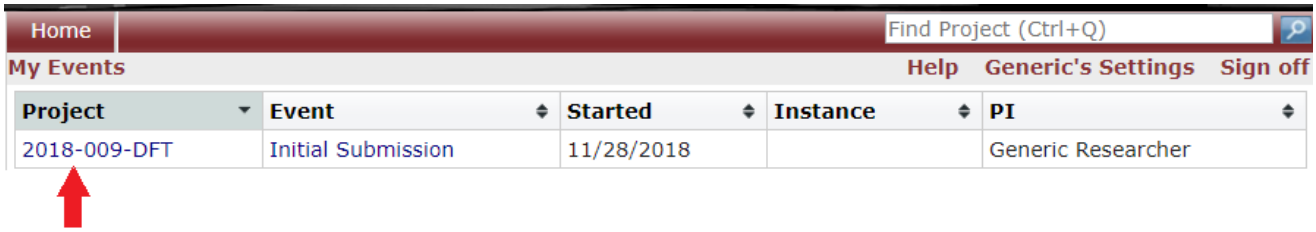


5.0 Creating a Continuation Approval Request (CAR), Study Amendment Request (SAR), & Exempt Amendment Request (EAR)

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.

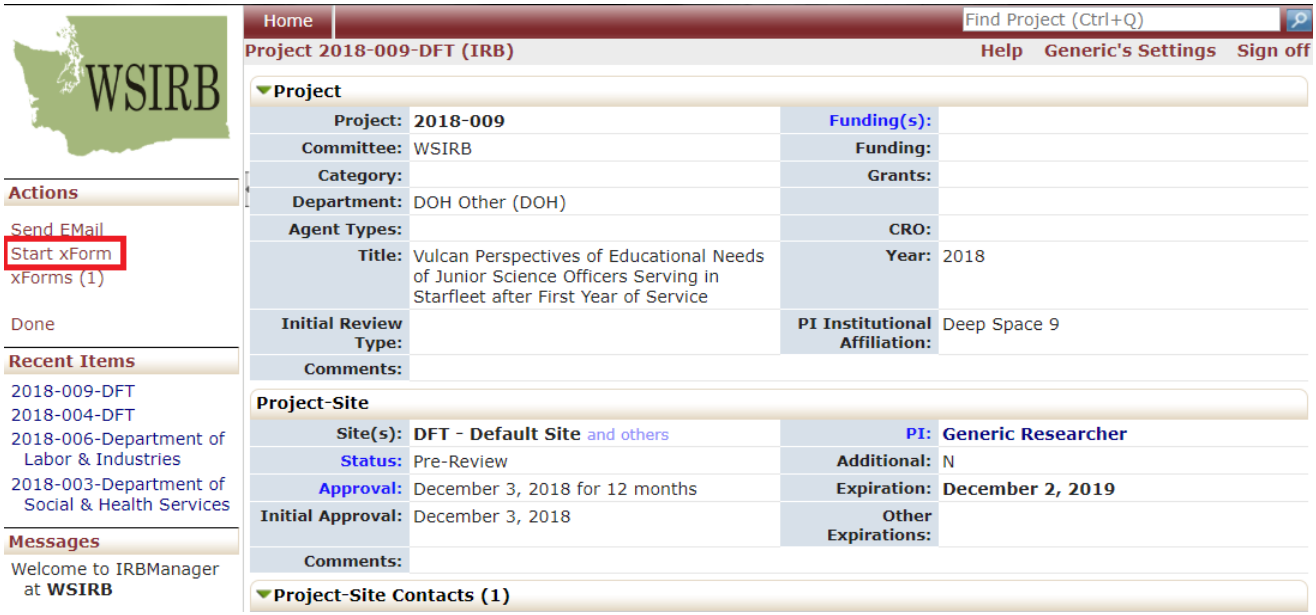


5.1 Creating a **CAR** or **SAR****

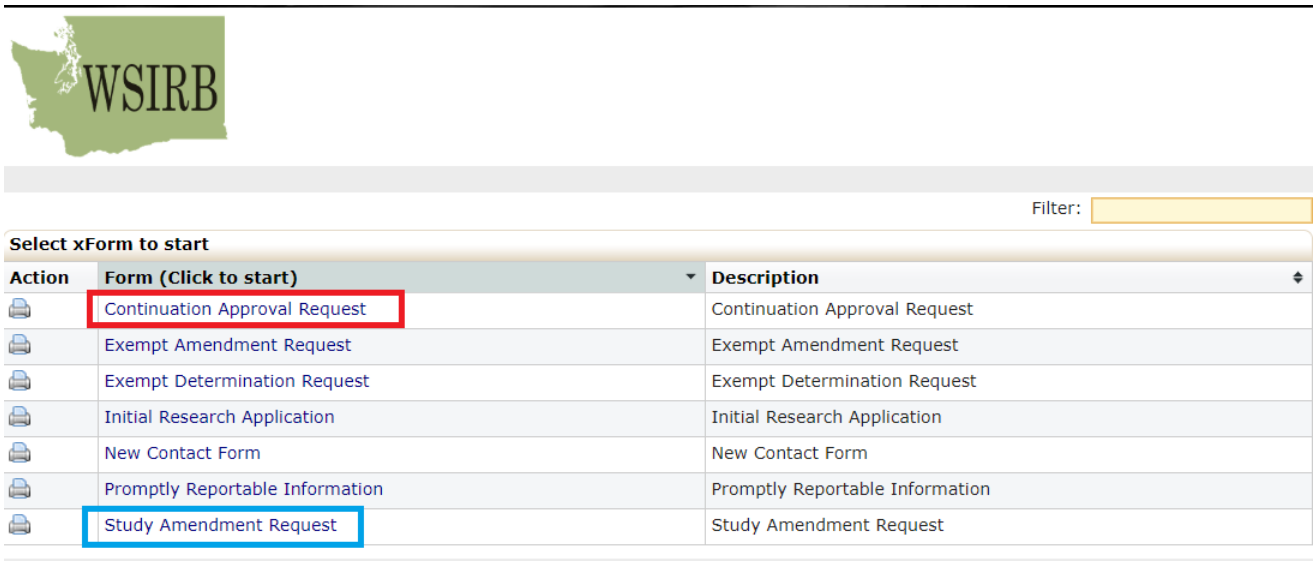
****If the study amendment is intended to add new study staff, please refer to section 5.5 before filling out the rest of the SAR.**

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

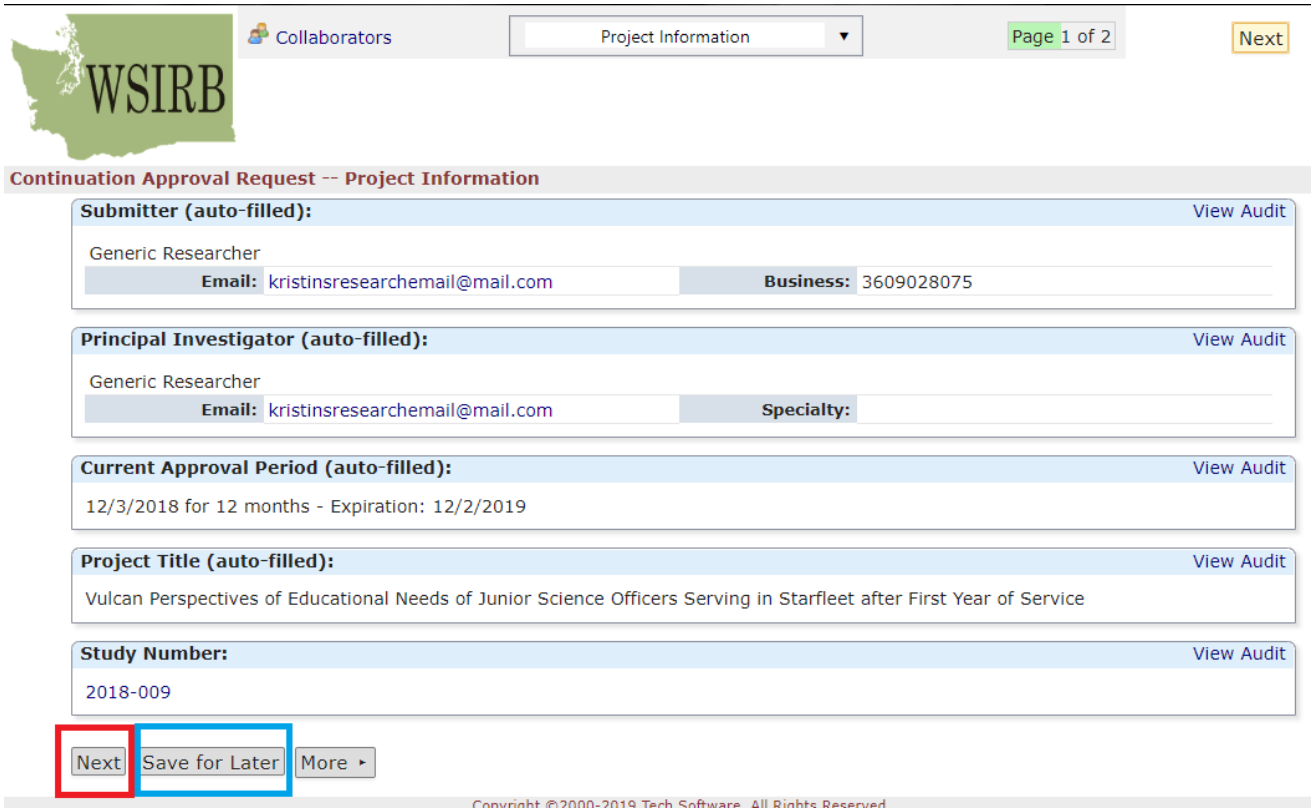
Once in the project home screen, click "Start xForm" on the left hand side menu. (Circled)
Only click "Start xForm" once you are inside the project. Otherwise, the xForm will not be attached to your project.

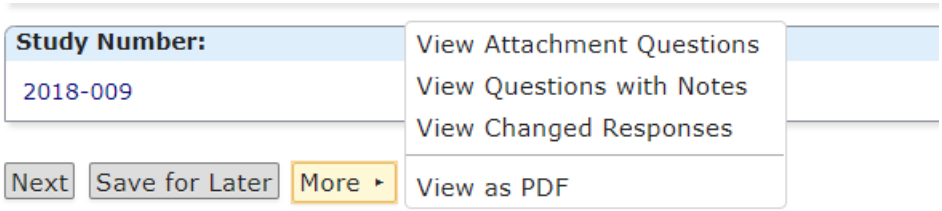


Clicking "Start xForm" will open a new **tab.** The new tab will present you with all the possible xForms that IRBManager allows for the selected project. Choose the desired Form and click the link (circled).

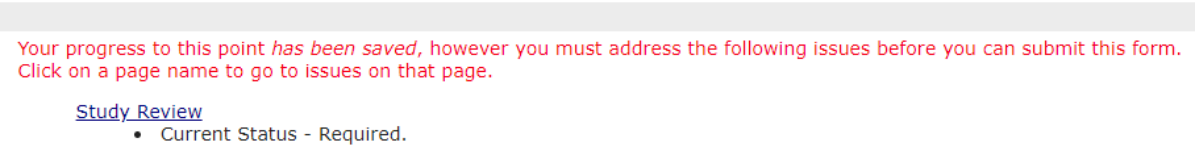


Choosing the Continuation Approval Request link will open the CAR document to fill out. Navigate the form via the “Next” “Save for Later” and “More” buttons at the bottom as pictured below. “Next” will move you to the next part of the CAR form. “Save for Later” allows you to save your form and return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

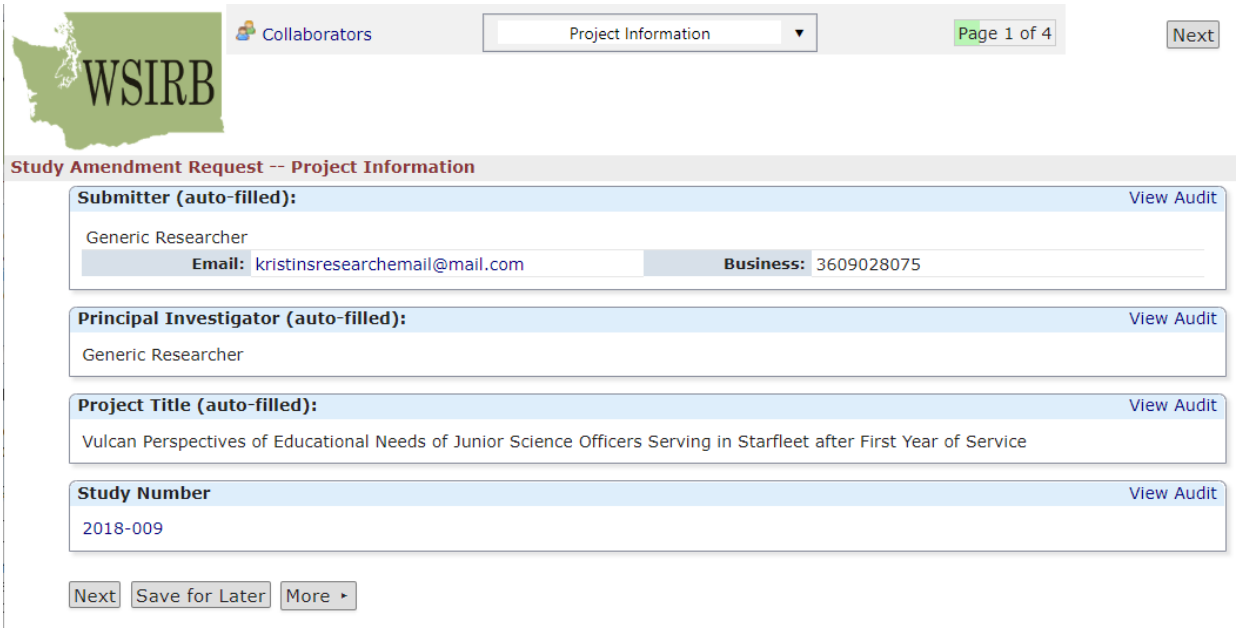




IRBManager will not allow you to submit an incomplete form. Attempt to submit an incomplete form will produce the following screen.

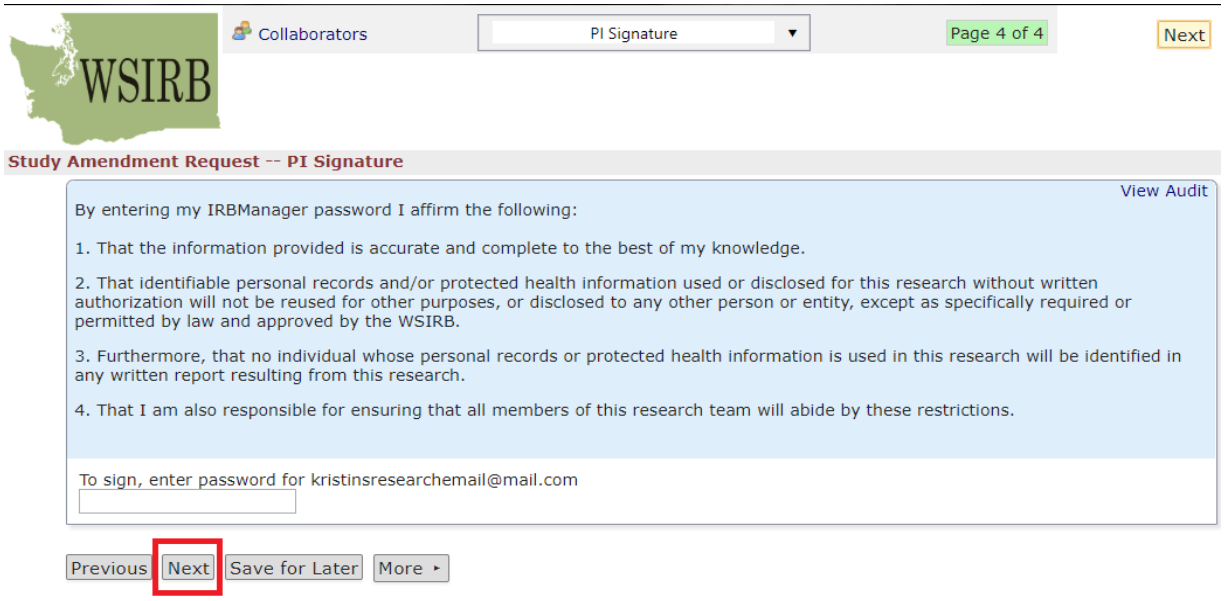


Choosing the Study Amendment Request link in the "Select xForm to Start" page will open a similar screen to the CAR, but it will say "Study Amendment Request—Project Information" at the top, as pictured below. The navigation features are the same as the CAR.

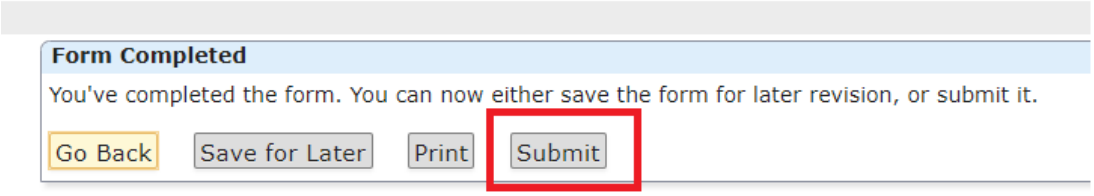


5.2 Submitting a CAR or SAR once it is completed.

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.



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

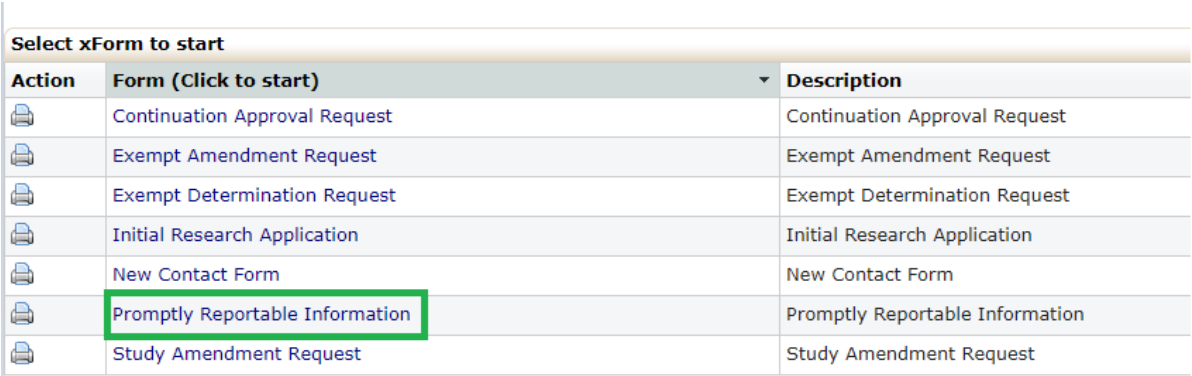
Action	Form (Click to start)	Description
	Continuation Approval Request	Continuation Approval Request
	Exempt Amendment Request	Exempt Amendment Request
	Exempt Determination Request	Exempt Determination Request
	Initial Research Application	Initial Research Application
	New Contact Form	New Contact 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.



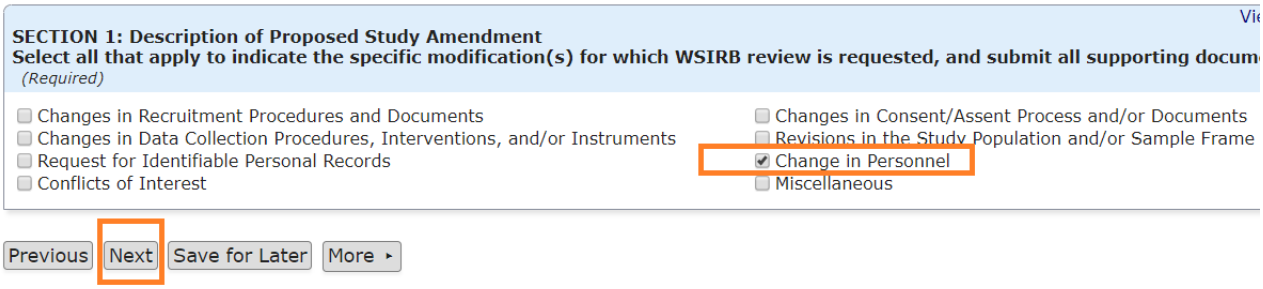
Select xForm to start

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

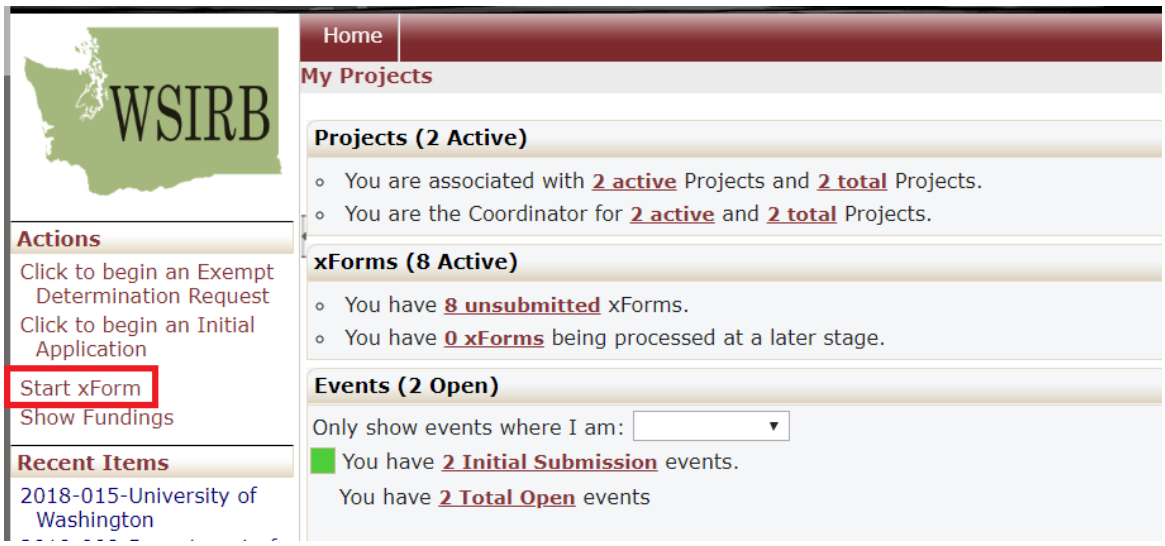
When submitting a Study Amendment Request to add new study staff, a new coordinator, research assistant, Co-PI, or PI, if that person is not *already* in IRBManager, they will need to be added to the system before the SAR can be completed. **A contact can be added to IRBManager two ways.**

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).



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

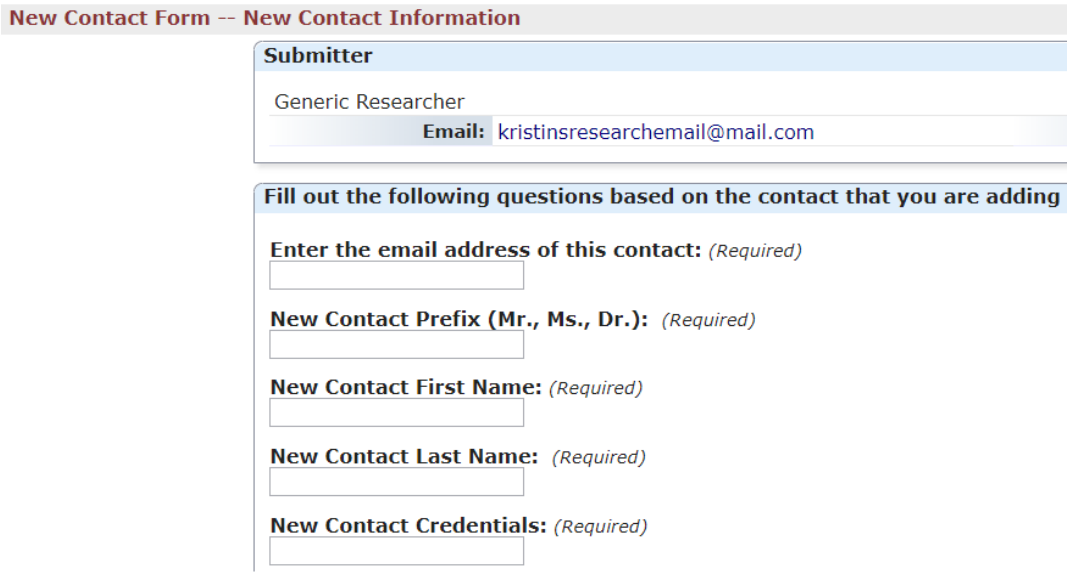
To add a new contact directly from the Dashboard prior to creating a new Study Amendment, select "Start xForm" under the left hand Actions menu.



A new tab will open with the following options.

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

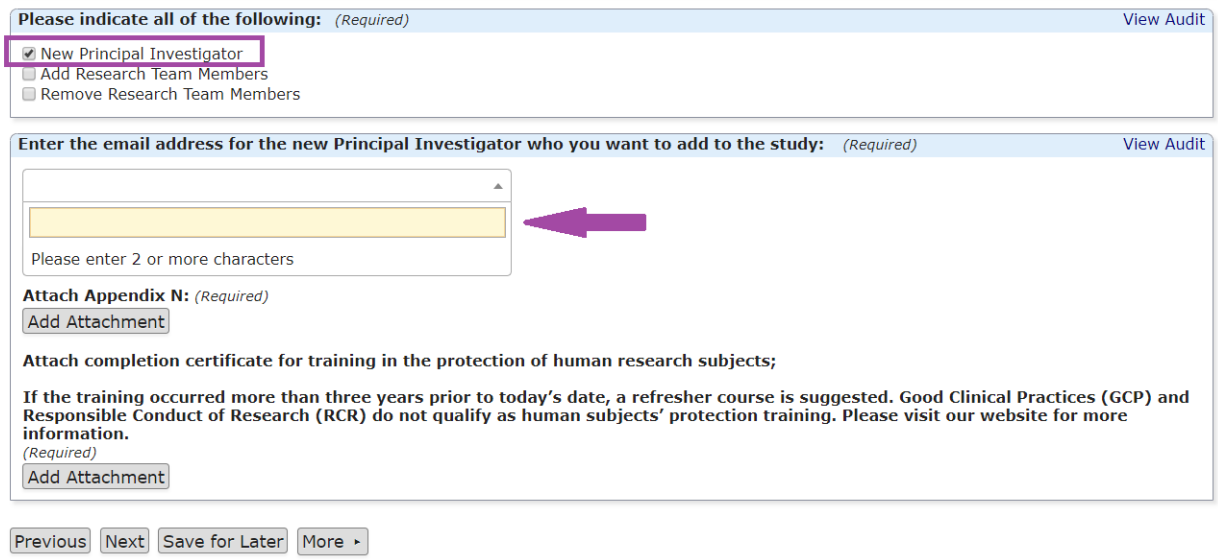
(University, Hospital, Agency, etc) mailing address.



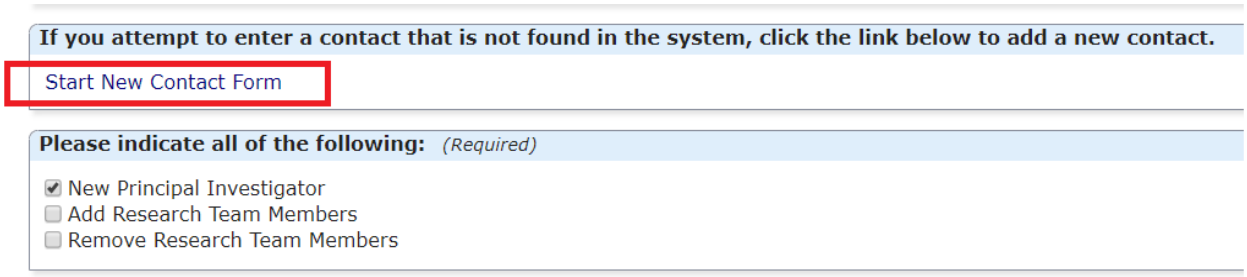
Once the new contact form has been filled out, click "Next" if ready to submit. After all new contacts have been entered, return to the Dashboard to begin the Study Amendment Request process.

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

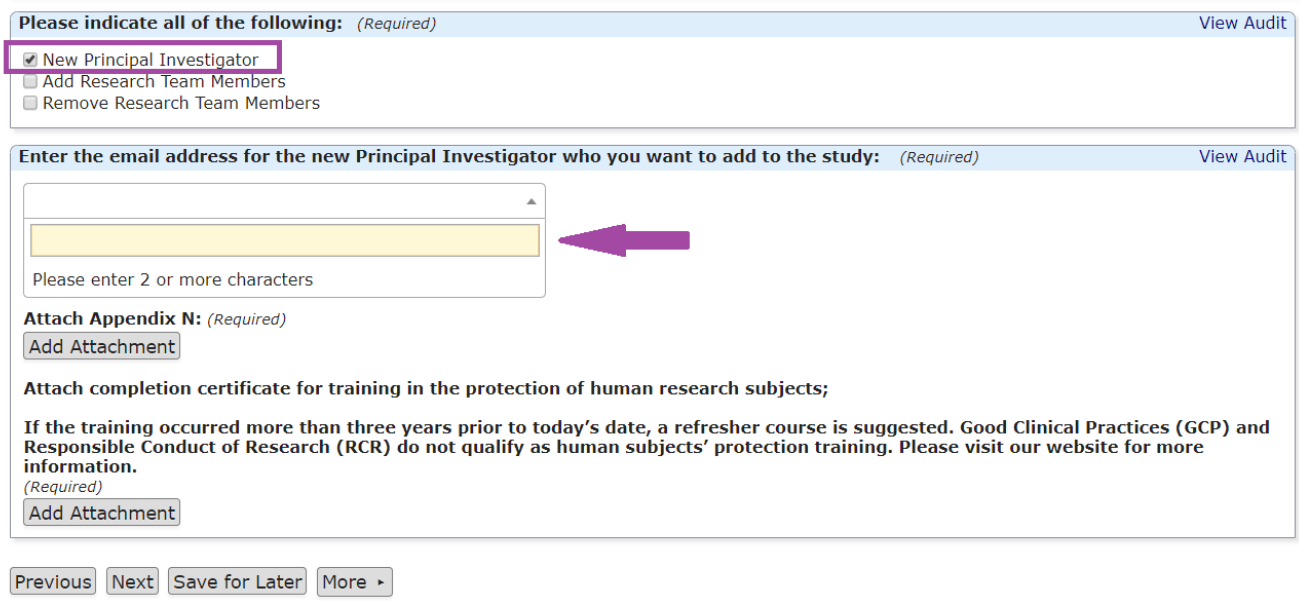
Check change in personnel
Check "Add Research Team Members" (or new PI, as applicable). Clicking Add New PI will generate a PI specific box.



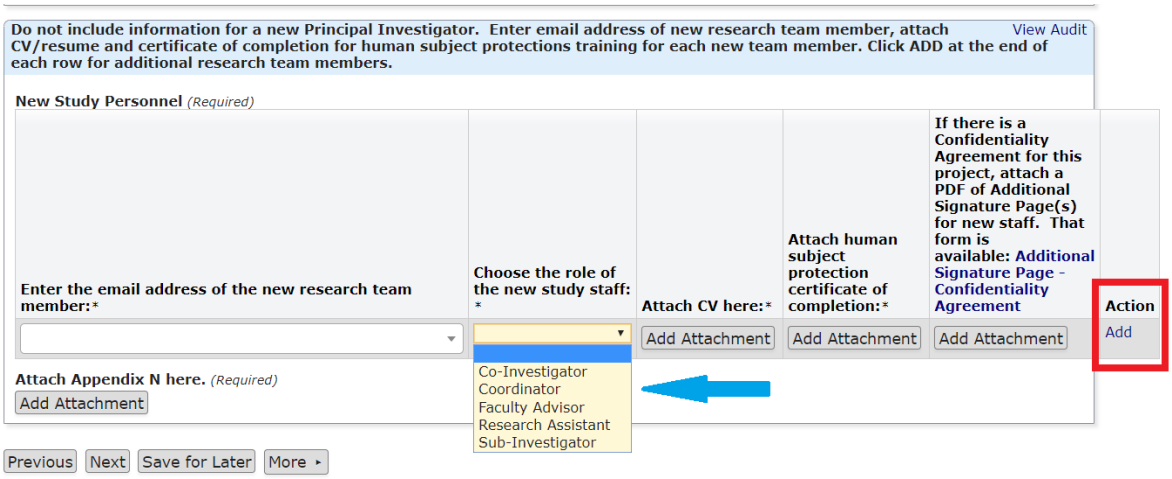
Use the text box to select the correct staff member from the options. This function **only** works if the contact has previously been entered into IRBManager. If you have not yet added the staff member (whether staff or new PI) stop here, and click the hyperlink to "Start New Contact Form" in the appropriate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



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



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



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.