

WASHINGTON STATE INSTITUTIONAL REVIEW BOARD

Guide to IRBManager for WSIRB Board Members

Introduction and user manual for WSIRB Board Members for accessing and reviewing research in the IRBManager system.

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1.0 IRBManager

1.1 What is IRBManager

IRBManager is an online submission, workflow, and data management system for Washington State Institutional Review Board (WSIRB). The electronic forms provided within this system allow users to submit new 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.

Through IRBManager, Board members have access to review projects they are assigned and meeting materials. Events can be viewed as folders for the separate submissions required for each project site such as the initial submission, amendments, and continuing reviews. **Each Event will contain all associated forms, documents, and letters.**

IRBManager is a fully web-based system, which means that users can log in anywhere they have secure internet access or, for SSO users, the ability to remote connect to their desktop.

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)

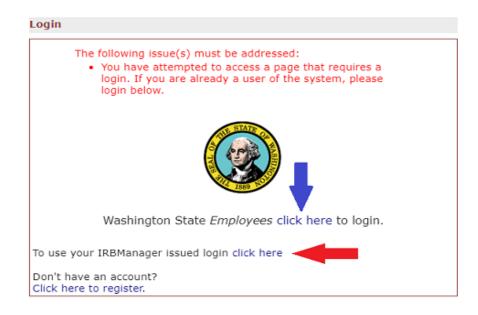
1.3 Creating Your New Account with IRB Manager and Logging In

As a member of the WSIRB you have been registered for IRBManager by WSIRB staff, please see below for details on logging in.

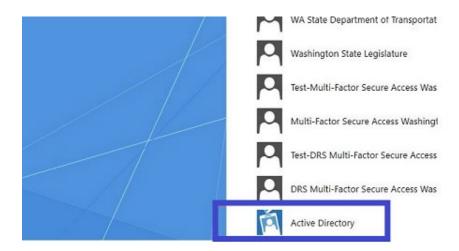
There are two routes available for registering, Single Sign-On and IRBManager Log-in. **Single Sign-On (SSO) may only be used for employees of a Washington State government agency** in order to meet state electronic security requirements. IRBManager-created Log-in will be used for all other reviewers. To log-in to either option, please use the following link: <u>https://wsirb.my.irbmanager.com/</u>

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

To log in as a Washington State Employee, use the blue highlighted "click here" link under the **blue arrow**, or simply click the Washington State logo.



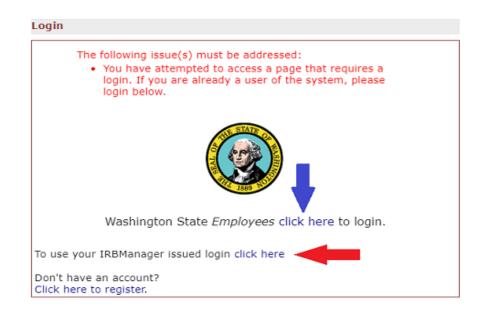
You may be directed to the following screen:



Select "Active Directory" from the list as indicated in **blue** above. 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 email WSIRB staff at wsirb@dshs.wa.gov. Our office hours are 7:30am – 4:00pm, M-F, excluding State holidays.

1.3.2 Sign-On for WSIRB Members who are **not State Employees**

For all users who do not have a .*wa.gov* email address, please use the blue highlighted "click here" link marked by the **red arrow.** As a Board Member, you will not need to create an account. If the system asks you to create an account, please email our staff.



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, select the "To user your IRBManager Issued login" option as described above. A second screen will open. Select the 'Forgot Password?' link as indicated by the **green 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, the link will expire.** You will need to repeat the 'forgot password' steps. If you have any issues receiving the email, please check the spam or junk folders within your email account. If issues persist, please contact WSIRB via email at <u>wsirb@dshs.wa.gov</u>. Our office hours are 7:30am – 4:00pm, M-F, excluding State holidays.

User Name		
Password		
Client	WSIRB	
	Login	Forgot Password?

1.5 Login Issues with SSO

One of the most common issues with logging into IRBManager for SSO is a problem with the autoauthenticating 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, contact WSIRB staff via email.

2.0 Navigating IRB Manager

2.1 Home Screen and the Dashboard

Upon login, you will be directed automatically to a landing screen. At the top you will see two tabs, "Home" and "Meetings." These tabs will allow you to view and traverse the documents required for your reviews. The tab **circled in blue** will always appear at the top of the screen and can be used to navigate to the Home age from anywhere within IRBManager. The **Red circled** link accesses the Dashboard.

	Home	gs
WSIRB	Fina Project	
WOIRD	Find Project	
	Project	
Actions	Committee	~
View Dashboard	Site	
Reviewer Open	Status	*All 🗸
Events Agendas and Minutes	Funding/CRO	
Recent Items	Funding	
2022-007-Health	PI	
Care Authority	Any Contact	
2019-003-TEST	Keyword(s)	
2019-009-TEST 2021-076-		Find Clear

The Dashboard is your landing screen and displays information relevant to all projects you are associated with across the IRBManager system.

Unless you are an investigator and submitting projects for WSIRB review, you will access reviewer worksheets through your email, not through the home screen. The home screen will give you information if you are a PI as well as a Board member.

2.2. Navigating Review Assignments

2.2.1 Accessing Reviews that have been assigned to you

The easiest way to access your review assignment is to follow the hyperlink in the automated email you receive when you are assigned a review.

Mon 10/28/2019 6:24 PM Wsirb@dshs.wa.gov Initial Full Board Application for Your Review
Study Title: Using SMART Design to Identify an Effective and Cost-Beneficial Approach to Preventing OUD in Justice-Involved Youth Principal Investigator: Kym Ahrens, M.D.
Dear Board Member,
WSIRB would appreciate your help reviewing an Application. We know life can get busy, so we really appreciate you considering this review.
If you choose to accept, please use the link below to review this application. The staff reviewer can access your checklist from the system. The for document your review of this submission and importantly, to prepare the review letters provided to the PL.
If you are agreeable to help with this review, please email the compliance specialist within the next 24 hours to set up a phone call/in-person meetir reviewer. You can access the materials for your review on your IRB Manager Account. We understand your time is valuable, so if you are unable to please let us know as soon as possible.
We look forward to hearing from you.
To complete your review click: https://wsirb.my.irbmanager.com/Admin/ReviewAssignment.aspx?TargetGuid=90/202f6-11ae-457e-87b0- 76639652ea+4:R-asonGuid=af37aa3e-2a00-4101-8988-405289b4d41c

This link in the email accesses the Reviewer Checklist - Initial Application - Board Member.

Now that you have linked to the IRBManager system, open the **Application xForm** by scrolling up in the Reviewer checklist and selecting the **green circled** link (see below). Selecting the Initial Submission link will take you another screen to access the Application.

	Review Type: Initial Review - Board Member Reviewer: Cons Researcher	
	Reviewer: Const Researcher	
	Nevrenet. Land Nesear Cher	
	Review Item: Initial Submission 2021-076-Department of Corre	ections
Review xF	Form	
	🖨 Collabo	rators
R	Reviewer Checklist - Initial Application - Board I	Member ·

When you click on the green circled link (above) you will be taken to an information screen about this submission. This screen is called the "Event Details". Remember, an event is a subfolder within the research project. *A project can have multiple "events" throughout its lifetime* (initial submission, CARS, an occasional SAR).

Home Meetings			Find Project (C	(trl+Q)	٩
vent Details: Initia	Submission on 2021-100-Department of Child	ren, Youth, and Fami	lies Help	Gena's Settings	Sign of
Project-Site					
Project:	2021-100-Department of Children, Youth, and Families	Site:	Department of Children, Department of Children, (DCYF)		
Title:	iKinnect2.0 for Juvenile Justice Involved Youth at Risk for Suicide	Committee:	WSIRB		
PI:	Linda Dimeff	Funding			
Event					
Туре:	Initial Submission	Started:	09/23/2021		
Instance:		Completed:			
Committee:	Inherited from Study	Assigned:			
Review Type:	Full Board				
Board Member Response to Review:		Expedited Category:			
Full Board Review Level:			The initial research appl for Juvenile Justice Invo Suicide"; The qualification research; The FCOI mar in the revised application approved as modified:	lved Youth at Risk f ons of the PI to con nagement plan as s	for iduct the ubmitte

Select **"xForms(x)"** under the left hand "Actions" menu.

WSIRB			I Submission on 2
	Project	-Site	
		Project	2021-100-Depart Families
Actions	Į –		
Attachments (62) Send EMail	1	Title	iKinnect2.0 for Ju Risk for Suicide
Start xForm		PI	: Linda Dimeff
xForms (2)			
Recent Items	Event		
Ketent ftems		-	A STATE OF A STATE

This will open a page with all the xForms for this project. If it is a project being presented at Board, there may be multiple Board member reviewer checklists. Otherwise, the page should look like this:

Forms on Event Details: Initial Submission on 2021-100-Department of Children, Youth, and Families					
Action	Form	• Identifier	• Stage/Status •	Started *	S
×	Reviewer Checklist - Initial Application - Board Member	Gena Researcher	Data Entry	17 hours ago)
<	Initial Research Application	Linda Dimeff	Complete	09/16/2021	04

Select the **Initial Research Application** from the xForm list. This will open a new tab with the application xForm.

You are now ready to begin your review. You are not required to complete a review in one session. At the bottom of each page of the reviewer checklist is a 'Save for Later' option which will ensure your progress is saved.

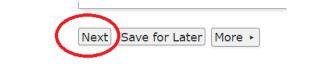
Next	Save for Later	More 🕨

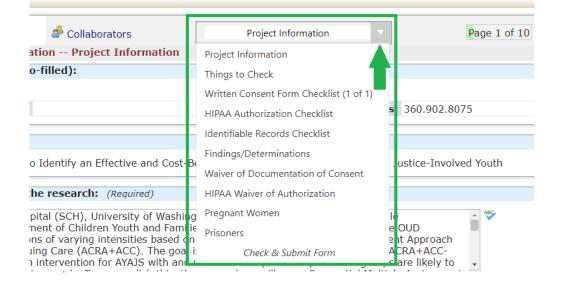
2.2.2. Completing Reviews

Please note that WSIRB policy now requires acknowledgement of the invitation to review **within 24 hours**. Reviews should also be completed **within 5 business days of agreeing to review the application**.

After accessing the reviewer checklist and opening the initial application xForm, (see Section 2.2.1 if you need assistance walking through these steps) proceed with the review and answer the questions in the Reviewer Checklist.

Naturally you can move to the next page by clicking "Next" at the bottom of the page, however if you **have** <u>not</u> completed all text boxes on a page, but want to navigate to another part of the reviewer checklist, use the drop-down menu at the top of the page.





A note: some sections of the smart form will only populate once specific answers have been provided. For example, it is not possible to navigate to the Prisoners checklist section unless the vulnerable populations section has already been filled out.

2.2.3. Submitting a Reviewer Checklist

If you are assigned a review (primary reviewer), please remember that a **Reviewer Checklist - Initial Application - Board Member** must be submitted, either before the review conference with a WSIRB staff member, or before a Board meeting. To submit a Reviewer Checklist - Initial Application - Board Member, ensure that all sections have been completed, and click "Next" at the bottom of the page until the following screen populates. Click Submit. Now the form has been sent to the next stage in the system and is complete.

Form Completed					
You've completed the form. You can now either save the form fo					
Go Back	Save for Later	Print	Submit)	

If you are not the assigned primary reviewer, you may use the **Reviewer Checklist - Initial Application -Board Member** as a guide during review prior to a convened Board meeting.

2.3 Board Meetings

2.3.1 Accessing the Meeting Agenda

All relevant Board Meeting information can be found under the **Meetings** tab at the top of the screen, or via the **hyperlink** in the left hand menu.

	Home	Meeting	s		
UUUUDD	Find Pro	ject 🛕			
WSIKB	Find Pr	oject			
		Proje			
Actions	Cor	nmittee		~	
View Dashboard	[Site			
Reviewer Open		Status	*Al		
Events	Fundi	ng/CRO			
Agendas and Minutes		unding			

The Meetings tab opens a new screen with columns containing all the previous Meeting Agendas sorted by year.

Meeting Maintenance						
Last 12	Months 2022	2021 2020 2019				
Meetings						
Action	Date	 Committee 				
e 1	03/17/2022	WSIRB				
\bigcirc	02/17/2022	WSIRB				
e 1	01/20/2022	WSIRB				
1	12/16/2021	WSIRB				
e 1	11/18/2021	WSIRB				
7 🗋	10/21/2021	WSIRB				
e 1	08/19/2021	WSIRB				

The three pieces of paper icon circled in **red** will open the meeting Agenda. From there, all materials that will be presented and/or reviewed at Board can be accessed. The Agenda should appear like this:

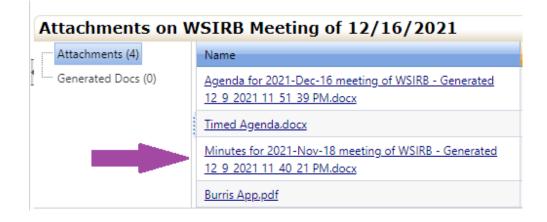
4	Home Meetings		
WOIDD	Member Agenda		
WSIRB	Report to Board - Ongoing Status Nothing to report		
Actions	Expedited and Other Review	Reporting	
Hide Empty Sections			
Attachments (13)	In-Service Training		
Done	Applications (2)		
Recent Iter	Initial Submissions		
2021-100-	Project		Title
Department of Children, Youth, and Famili 2022-007-Health	2021-100-Department of Ch	ildren, Youth, and Families	iKinnect2.0 for Juvenile Justice Youth at Risk for Suicide
Care Authority 2019-003-TEST	2021- Event Attachments	rections	Women's Pathways
2019-009-TEST	Generated Docs		
2021-076-	Previous Review	ions (1)	
Department of Corrections	Full Boa	d Submission of Initial	Submission

Each project being presented at the Board meeting will have its own hyperlink for members to access the project. Next to the name of each project will be a down arrow the opens a drop down menu with the options: xForms, Attachments, Generated Docs, and Review. Selecting 'Review' will create a *new* reviewer checklist xForm. Only select this option if you wish to fill out a reviewer checklist for the study. Once you have opened the Reviewer Checklist you can go to Section 2.2.1 and follow the directions to open the initial submission as well.

2.3.2 Accessing Attachments

The Attachments (#) link will open a page with the option to download any documents that WSIRB staff

have deemed important for the Board to view in regard to the studies being presented at the meeting. You may access the previous meeting's minutes via the attachments section.



2.3.3 Accessing Minutes

A link to the previous meeting's minutes will also be available on the main page of the agenda:

Executive Secretary's Report
Review of Minutes
Please Review February Minutes
https://wsirb.my.irbmanager.com/Attachments/ad7eb9fc-40b1-4a43-9efb-8838a9921399/12c0db89-523c-43c8-b378-c1e336e02a81

3.0 Help and Support

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