

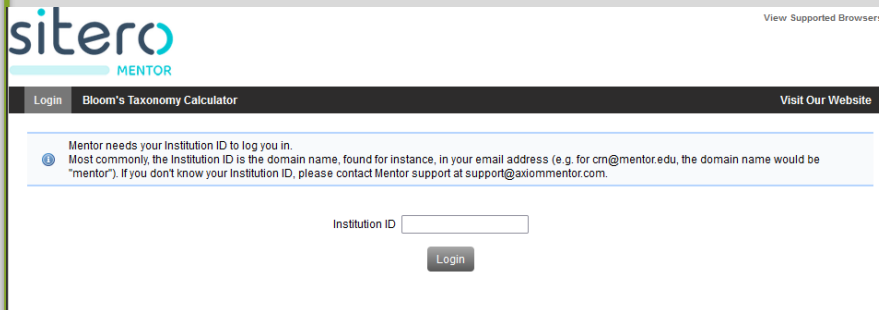
Sitero Mentor IRB

Getting Started for Study Teams

Logging in to Mentor IRB

For best results use Chrome, Edge, or Safari for your web browser!

- PNWU Employees and Students:
 - <https://shib.axiommentor.com/pages/irb/info.cfm>
- External Partners:
 - <https://www.axiommentor.com/pages/home.cfm>



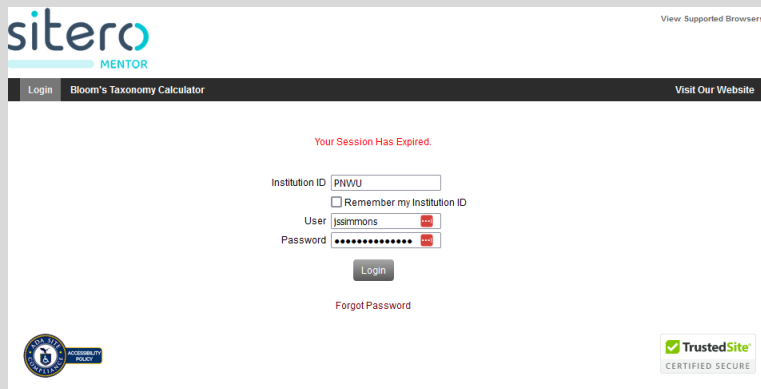
The screenshot shows the Mentor IRB login page. At the top left is the 'sitero MENTOR' logo. Below it is a navigation bar with 'Login' and 'Bloom's Taxonomy Calculator'. A message box states: 'Mentor needs your Institution ID to log you in. Most commonly, the Institution ID is the domain name, found for instance, in your email address (e.g. for cm@mentor.edu, the domain name would be "mentor"). If you don't know your Institution ID, please contact Mentor support at support@axiommentor.com.' Below this is a text input field labeled 'Institution ID' and a 'Login' button.

Institution ID: pnwu

PNWU Usernames: first part of email address (e.g., jssimmons). First time logging in will take you to the Institution ID box.

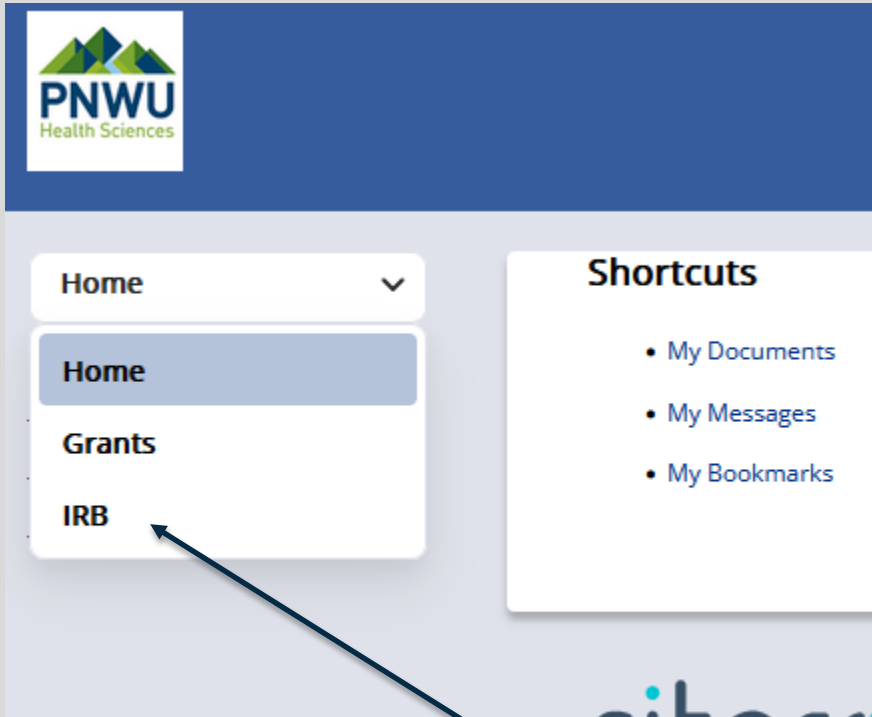
External Partners Usernames: first initial and last name

External Partners - First time logging in: Click on Forgot Password and Mentor IRB will send you an email with a link to set your password



The screenshot shows the Mentor IRB login page after a session has expired. A red message says 'Your Session Has Expired.' Below it is the login form with fields for 'Institution ID' (containing 'PNWU'), 'User' (containing 'jssimmons'), and 'Password' (masked with dots). There is a 'Remember my Institution ID' checkbox, a 'Login' button, and a 'Forgot Password' link. At the bottom left is a 'TRUSTED SITE' logo and at the bottom right is a 'TrustedSite CERTIFIED SECURE' logo.

Home Screen



Select IRB from the dropdown menu in the top left of the page.

Information Page

PNWU Health Sciences

IRB

IRB

Info Page

Resources

My Studies

(1) Pending Signatures

Study Reports

Student Studies

Research Coordinators

Reviewer

Training Certificates

IRB Members

Welcome to Mentor IRB!

Navigating the Mentor IRB system:

When you see this icon: click it. We call this the "Context Menu" and when you click on it, the following menu is displayed:

If you need additional information about the specific questions, hover over the button.

To view the slide deck for study teams getting started with Mentor, [click here](#). To review [For Assistance Contact](#): PNWU IRB Administrator: Jeremy Simmons (jssimmons@pnwu.edu)

The Information page has links to some resources such as protocol templates and consent form templates as well as basic information about research requirements.

IRB Page Menu. When you click on a menu item button it will be highlighted in gray to indicate what menu page you are on.

Resources Page

The screenshot shows the PNW Health Sciences IRB Resources page. The left sidebar has a dropdown menu for 'IRB' and a list of navigation options. The main content area shows a folder named 'Institutional Review Board' with a list of sub-folders:

- Calendars
- Historical Documents
- Investigator Toolbox
- OSA Policies and Procedures
- PNWU Consent Templates
- Protocol Templates

The resources page has folders that contain many resources such as the standard operating procedures, links to the regulations, links to historical documents such as the Belmont Report and links to CITI Program training site.

My Studies Page

The screenshot shows the 'My Studies' page in the IRB system. The page has a blue header with the PNWU Health Sciences logo on the left and a user profile 'Jeremy' on the right. A left sidebar contains navigation links: IRB, Info Page, Resources, My Studies (highlighted), Study Reports, Student Studies, Research Coordinators, Reviewer, Training Certificates, and IRB Members. The main content area features a 'Create New Study +' button, the title 'My Studies', and two key dates: 'Next Meeting: 02/08/2024' and 'Deadline for Submission: 02/01/2024'. Below these are search filters for IRB ID, Status, Submitted, Study Title, and Role. A 'Search' button and a 'Clear' button are also present. At the bottom, a table lists studies with columns for IRB #, Title, PI, Approved, C.R. Due, and Tracking Status.

IRB #	Title	PI	Approved	C.R. Due	Tracking Status
23-006	Test Study	Lizzie Lamb			
24-004	Testing	Jeremy Simmons			Submitted to the IRB

The My Studies page is where you will access your current studies or create a new study.

To access your study, click on the study title. The link will take you to the study page where you can access your study documents and the forms for ongoing submissions such as amendments and continuing review.

Study Reports Page

PNW Health Sciences

IRB

IRB

Info Page

Resources

My Studies

Study Reports

Student Studies

Research Coordinators

Reviewer

Training Certificates

IRB Members

Study Reports

Select Report: Cont Reviews

Status: All

To submit new Cont Reviews, please navigate to the view protocol page and...

IRB #	Title	Due	Received	Appr
No Cont Reviews Found				

The study reports page allows you to run basic reports on your studies such as upcoming continuing reviews and the due dates . Click the select report drop down to see the reports you can run. Click status to set the status such as due.

Student Studies Page



IRB



IRB



Info Page

Resources

My Studies

Study Reports

Student Studies

Research Coordinators

Reviewer

Training Certificates

IRB Members

Student Studies

Study Status

- Show all statuses -

Acceptance Status

Not Yet Accepted

IRB #	Title	PI	Approved
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No Studies Found

The student studies page allows the Principal Investigator, to search and/or review student studies under their direction.



Research Coordinator Page



The screenshot shows the IRB system interface. At the top left is the PNWU Health Sciences logo. Below it is a navigation menu with options: Info Page, Resources, My Studies, Study Reports, Student Studies, Research Coordinators (highlighted), Reviewer, Training Certificates, and IRB Members. The main content area has a button 'Designate A New Research Coordinator +' and a heading 'Research Coordinators'. Below this is a table with columns 'Name', 'Designated by', and 'On'. The table is currently empty, displaying the message 'No Research Coordinators found.'

The research coordinator page allows you to designate a research coordinator for all of your studies. **This will not allow you to designate a research coordinator to one of your studies.** By designating a research coordinator, you are giving the coordinator access to perform tasks for all studies such as adding documents to the study.

Training Certificates Page

PNWU Health Sciences

Jeremy Simmons

IRB

IRB

- Info Page
- Resources
- My Studies
- Study Reports
- Student Studies
- Research Coordinators
- Reviewer
- Training Certificates**
- IRB Members

Training Certificates

CITI Completions

Curriculum/Group/Stage	Date of Completion	Date Expires
Information Privacy & Security / IPS for IRB Members /	01/16/2024	01/16/2028
Revised Common Rule / IRB Administrators and Staff - Revised Common Rule /	01/16/2024	01/16/2027

IRB Human Subjects Training Certification Upload

File	Date of Completion	Renewal	File Size	Date Posted
No items found				

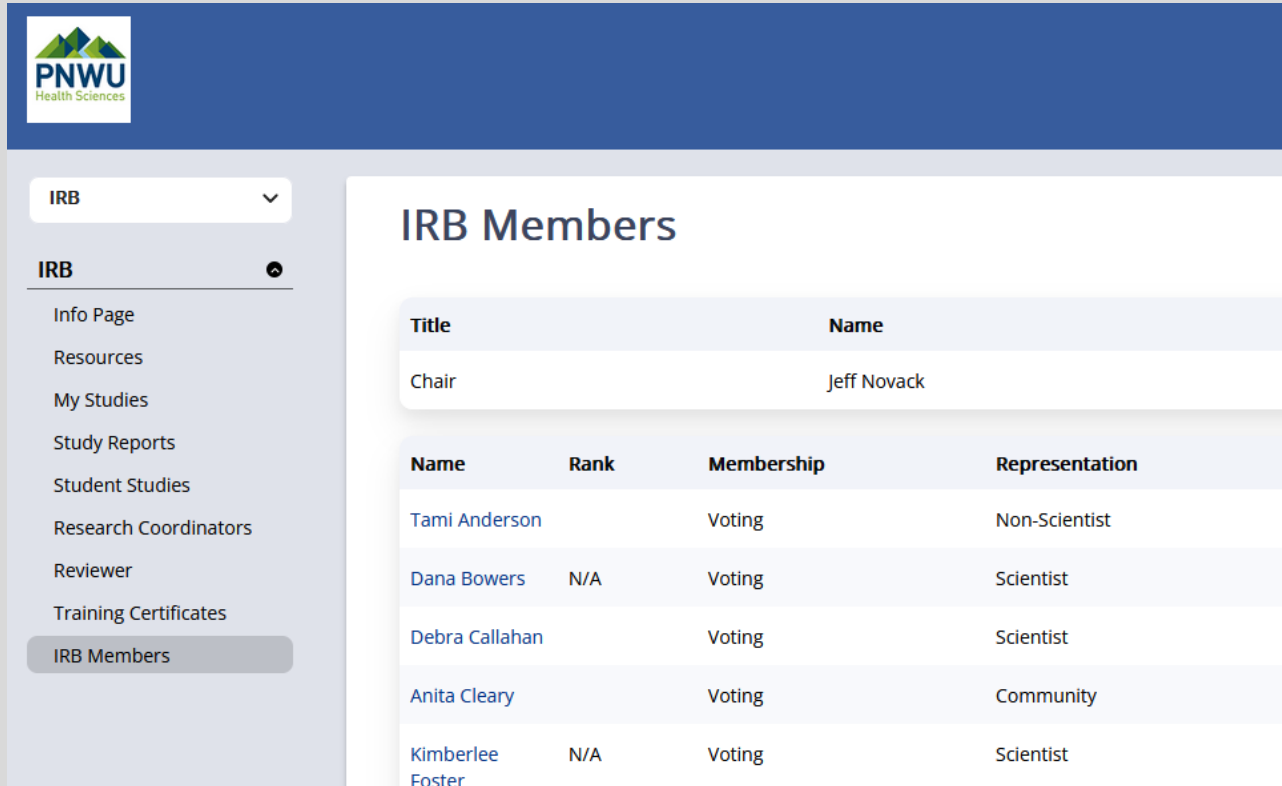
CV Upload

File	Date of Completion	Renewal	File Size	Date Posted
Testing CV.docx	01/16/2024	01/12/2027	12 K	01/16/2024

Healthcare Provider License Upload

The training certificates page is where all your trainings, such as CITI, and your current CV can be found. You can also upload a new CV to this page.

IRB Member Page



PNW
Health Sciences

IRB

IRB

- Info Page
- Resources
- My Studies
- Study Reports
- Student Studies
- Research Coordinators
- Reviewer
- Training Certificates
- IRB Members**

IRB Members

Title	Name
Chair	Jeff Novack

Name	Rank	Membership	Representation
Tami Anderson		Voting	Non-Scientist
Dana Bowers	N/A	Voting	Scientist
Debra Callahan		Voting	Scientist
Anita Cleary		Voting	Community
Kimberlee Foster	N/A	Voting	Scientist

The IRB Member page lists the current members of the IRB, their voting status and representation.

Creating a New Study

PNWU Health Sciences

Jeremy

IRB

IRB

- Info Page
- Resources
- My Studies
- Study Reports
- Student Studies
- Research Coordinators
- Reviewer
- Training Certificates
- IRB Members

Create New Study +

My Studies

Next Meeting: 02/08/2024

Deadline for Submission: 02/01/2024

IRB ID: Status: Submitted:

Study Title: Role:

Search Clear

IRB #	Title	PI	Approved	C.R. Due	Tracking Status
23-006	Test Study	Lizzie Lamb			
24-004	Testing	Jeremy Simmons			Submitted to the IRB

Click on Create New Study



Fill out the Information Page

Create IRB Study Cancel X

Next Meeting: 02/08/2024 Add User
Deadline for Submission: 02/01/2024

Please answer the questions on the facesheet below. After answering the questions click on the "Save" button at the bottom of the page, the initial study record will be created.

* PI
Jeremy Simmons

* Study Title

Study Short Title

* Proposed Start Date

Proposed End Date

① * Risk Level
-Select-

Funding Source

Grant Number

* Review Type

Answer the questions in the information page.

The Study Page

IRB

IRB

- Info Page
- Resources
- My Studies
- Study Reports
- Student Studies
- Research Coordinators
- Reviewer
- Training Certificates
- IRB Members

More

Testing 24-004

Unapproved study. Please see the information below

All Electronic Signatures Recorded

Tracking Status: Submitted to the IRB

PI	Approval Status	Created	01/16/2024	Approved	Set Date
Jeremy Simmons	Exempt Review	Received	01/22/2024	Date Closed	Set Date
Staff , Staff - Staff	Exempt Review Requested	Date of Completion	Set Date		
Scholarly Activity	(2) Tests, Surveys, Interviews				
	Withdraw Study from Review				

Application Sections

Personnel

Add/Edit personnel

PI

Name

Jeremy Simmons

Study Fields

Submitted By

Jeremy Simmons

Risk Level

Total Number of Sub

The study page contains information about the study (e.g., review level, waivers of consent have been requested, total number of subjects to be enrolled etc.).

Approved documents will have a green checkmark and a blue checkmark for acknowledged documents. The most current consent form and recruitment material will be in the approved consent form/approved recruitment materials folders.

The Study Page

PI





Name	CITI Status	FCOI Status	Signed Date	Date Added
Jeremy Simmons	Docs ✓	No COI Reported ✓	01/22/2024 4:13 PM PST	01/16/2024

Study Fields

Submitted By Jeremy Simmons	Proposed Start Date 01/31/2024	Grant Number	Consent Waived Not Requested
Risk Level	Proposed End Date	Funding Source	Waiver of Documentation of Informed Consent Not Requested
Total Number of Subjects 15	Vulnerable Subjects	Regulatory Agency None	Legacy Import

(2) Tests, Surveys, Interviews Questions Last Updated : 01/16/2024 3:44 PM PST

Files

Date	File name	Status	Amendment
Consent Form 01/16/2024			
Consent Script 01/16/2024			
Recruitment Materials 01/16/2024			
Survey Instruments 01/16/2024			

Amendments | Adverse Events | Reportable Events

No Amendments yet.

Enrollment Number (points to Total Number of Subjects)

IRB Application Attachments (points to File name column)

Filling out the IRB Application

IRB

- Info Page
- Resources
- My Studies
- Study Reports
- Student Studies
- Research Coordinators
- Reviewer
- Training Certificates
- IRB Members

Testing 24-004

Unapproved study. Please see the information below.

All Electronic Signatures Recorded

PI	Approval Status	Created/Received	Approved/Date Closed	Set Date
Jeremy Simmons Staff - Staff - Staff Scholarly Activity	Exempt Review Requested (2) Tests, Surveys, Interviews Withdraw Study from Review	01/16/2024 01/22/2024	Set Date Set Date	

Application Sections

Personnel

Add/Edit personnel

Name	CITI Status	FCOI Status	Signed Date	Date Added
Jeremy Simmons	Docs	No COI Reported	01/22/2024 4:13 PM PST	01/16/2024

Study Fields

Submitted By	Proposed Start Date	Grant Number	Consent Waived
Jeremy Simmons	01/31/2024		Not Requested

Risk Level	Proposed End Date	Funding Source	Waiver of Documentation of Informed Consent

The application sections are accessed via the study page.

Application Sections 24-004. Testing

View Study Page

PI: Jeremy Simmons

To begin answering questions click on the section title. Once the section opens you will see the questions and buttons to begin answering the questions. Buttons are labeled Start Answering, Answer (single question sections), Add/Edit Answers (sections with multiple questions or when your return to continue answering/editing a question/section or Continue Answering.

Show Hidden Sections

Expand All Sections

Personnel 01/16/2024 3:46 PM PST

Study Information and Research Setting 01/16/2024 3:47 PM PST

Expand the sections by clicking on the arrows.

Answering the Questions on the Application

▼ Data Collection, Protection, and Records Retention

Required Questions Unanswered: 5 01/22/2024 4:53 PM PST

📘 You have answered all questions in this Survey.

Answer ✎

* Will direct participant identifiers be recorded or obtained?

(Names, dates of birth; procedure dates; email address; social security numbers; patient, hospital, laboratory or claim numbers; medical record numbers; addresses; telephone numbers; locator information; images, etc.)

- Yes
 No

Comments

Answer ✎

* Mark the option that applies to the identifiable data:

- HIPAA (PHI) Does Not Apply to this Study.
- HIPAA applies and will Seek Authorization for the Use and Disclosure of PHI.
- Requesting a Waiver of HIPAA Authorization (elimination of HIPAA authorization form).
- FERPA applies and will Seek Authorization for use from the Office of Institutional Effectiveness or the student (when appropriate).
- FERPA does not apply to this study.
- Requesting a waiver of FERPA Authorization (elimination of HIPAA authorization form).
- Secondary analysis of a Limited HIPAA Data Set

Answer Required

After opening a section of the checklist, click on the Answer button to answer the questions on the checklist.

Click save answer at the bottom of each of the question sections as you answer the questions.



Reviewing CV's, License, & Training

24-004. Testing

PI: Jeremy Simmons

To begin answering questions click on the section title. Once the section opens you will see the questions and buttons to begin answering the questions. Buttons are labeled Start Answering, Answer (single question sections), Add/Edit Answers (sections with multiple questions or when your return to continue answering/editing a question/section or Continue Answering.

- Show Hidden Sections
- Expand All Sections

Personnel

01/16/2024 3:46 PM PST

PI

Jeremy Simmons (01/16/2024)

[Docs](#)

CITI Completions

Curriculum/Group/Stage	Date of Completion	Date Expires
Information Privacy & Security / IPS for IRB Members /	01/16/2024	01/16/2028
Revised Common Rule / IRB Administrators and Staff - Revised Common Rule /	01/16/2024	01/16/2027

CV

File	Date of Completion	Renewal	File Size	Date Posted
<input type="checkbox"/> Testing CV.docx	01/16/2024	01/12/2027	12 K	01/16/2024

Expand the personnel section of the application and scroll down to see training, CVs, and license for the study team members.



Signing your Application

ⓘ Electronic Signature(s) Required of Jeremy Simmons:
New Study Signature Required as PI

ⓘ Unapproved study. Please see the information below.

⚠ 1 Signature Missing

PI Jeremy Simmons Staff , Staff - Staff Scholarly Activity	Approval Status ⓘ Exempt Review Exempt Review Requested (2) Tests, Surveys, Interviews Revisions Required Withdraw Study from Review	Created 01/16/2024 Received 01/22/2024 Date of Completion Set Date	Approved Set Date Date Closed Set Date
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🔗 Application Sections

▼ **Personnel**

Add/Edit personnel ✎

PI

Name	CITI Status	FCOI Status	Signed Date	Date Added
Jeremy Simmons	Docs 📄		Sign Electronically	01/22/2024

▼ **Study Fields**

Submitted By Jeremy Simmons	Proposed Start Date 01/31/2024	Grant Number	Consent Waived Not Requested
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The sign electronically button is used to sign the submission. Note: you will be asked if you have conflicts of interest to disclose as part of the signature process.

A submission confirmation will be emailed to you.



Submissions/Reporting for Open Studies

Study Fields			
Submitted By Jeremy Simmons	Proposed Start Date 01/31/2024	Grant Number	Consent Waived Not Requested
Risk Level	Proposed End Date	Funding Source	Waiver of Documentation of Informed Consent Not Requested
Total Number of Subjects 15	Vulnerable Subjects	Regulatory Agency None	Legacy Import

> (2) Tests, Surveys, Interviews Questions Date Last Updated : 01/16/2024 3:44 PM PST

> Files

- Annual Check-Ins
- Amendments
- Adverse Events
- Reportable Events

Use this tab to submit study changes to the IRB for review and approval. When submitting revised documents you must submit one copy with the revisions clearly marked and one clean copy will all of the revisions accepted. The redline feature in Microsoft Word is recommended.

New Amendment +

No Amendments yet.

Forms for submissions such as Amendments are found at the bottom of the study page.

Continuing Review/Annual Review Status

Annual Check-Ins Amendments Adverse Events Reportable Events

Year	Due Date	Date Received	Date Approved	Status	Submitted By
▼ ⋮ 1	12/10/2024			Due	

[Continuation Form](#) [Submit](#) (0) Tracking Status: No Status Recorded

You can find due dates for continuing review or annual check-in at the bottom of the page in the appropriate tab.



Submitting Amendments or Reports

Annual Check-Ins Amendments Adverse Events Reportable Events

i Use this tab to submit study changes to the IRB for review and approval. When submitting revised documents you must submit one copy with the revisions clearly marked and one clean copy with all of the revisions accepted. The redline feature in Microsoft Word is recommended.

New Amendment +

No Amendments yet.

Annual Check-Ins Amendments Adverse Events Reportable Events

i Use this tab to report any deviations from the protocol or unanticipated events that are not adverse events in the conduct of the research.

New Reportable Event +

No Reportable Event Found.

Amendments & reports are created and submitted via the tabs at the bottom of the page.



Closing a study

Close Study More :

Tracking Status: Review Completed

Testing

24-004

To submit post-approval continuing reviews, amendments, additional documents and other required reports, please use the sub-tabs found at the bottom of this page.

PI Jeremy Simmons Staff , Staff - Staff Scholarly Activity	Approval Status Exempt Review Exempt Determination (2) Tests, Surveys, Interviews	Created 01/16/2024	Approved 01/22/2024	Approval Expires 01/21/2025	Date Closed Set Date
Received 01/22/2024		Date of Completion 01/22/2024			

Application Sections

Personnel

Add/Edit personnel

PI

A button to close the study is provided at the top of the page. Click the button, fill out the questions and submit the form.



Please contact the IRB Administrator
at research@pnwu.edu if you have
any questions or need assistance
with the software!

