

# Cayuse IRB - Initial Training

Completing your initial submission

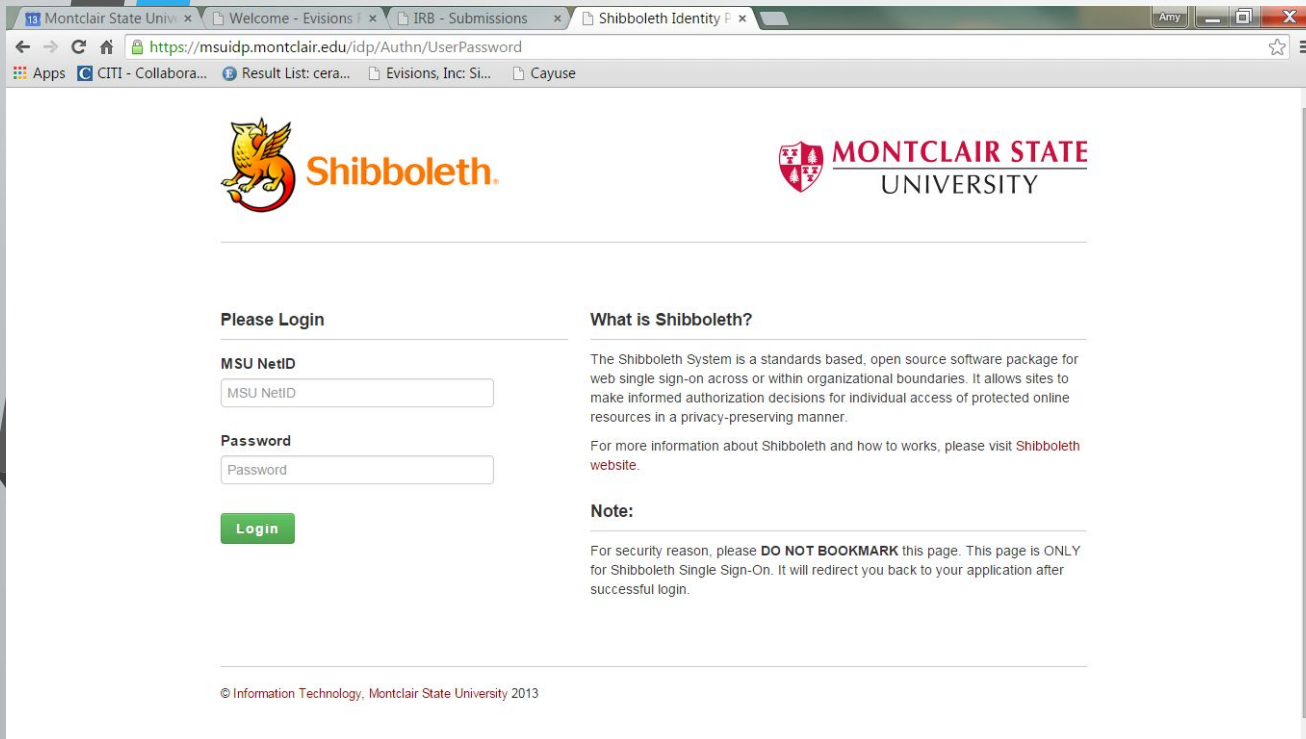
# Logging in to Cayuse IRB


## Active Faculty and Staff

- You will use your netID and regular Montclair password

## Students, New Staff and Faculty

- If you are a student or relatively new faculty or staff member, you will not be in our system
- You will request an account at our website, [www.montclair.edu/irb/cayuse](http://www.montclair.edu/irb/cayuse)
- **We will not ask you for your password or CWID**
- Your account will be activated in 1-2 business days





Before you begin...

- You may have best results using Chrome (not necessary)
  - Must enable pop-ups

# Evisions Research Suite

3.2

## Research Administration Modules

[Cayuse SP \(Sponsored Projects\)](#)

[Cayuse 424](#)

[Cayuse IRB \(Human Studies Compliance\)](#)



## System Administration Applications

[Backbone](#)

[Research Contacts](#)

[Workflow](#)

## Application Help

[Research Suite Support Center](#)

[Browser Support & Configuration](#)



# Your Dashboard

When you sign in, every time you will come to this page!

cayuse IRB

Dashboard

Studies

Submissions

Tasks

Help

My Role: Researcher

Dashboard

Notifications will appear here. Click bell to view

23

Ida PI

Other ways to access the same things

Shows the statuses of your submissions

Shows all your studies

Shows all incomplete tasks

Shows you all your submissions

Shows you your approved studies

Shows soon-to-expire studies

Shows expired studies

2

In-Draft

0

Awaiting Approval

0

Pre-Review

9

Under Review

My Studies

IRB-FY15-16-27

Cayuse training

IRB-FY15-16-17

Veterans and their children: How they navigate the maze of Veteran Benefits

IRB-FY15-16-18

Focus Group with MSU Student's

View All

My Tasks

IRB-FY15-16-29

Complete Submission

IRB-FY2016-10

Complete Submission

View All

Submissions by Type

Initial

10

Withdrawal

1

Modification

3

Renewal

0

Incident

1

Closure

0

Legacy

0

Approved Studies

IRB-FY15-16-27

Cayuse training

Studies Expiring in 30 days

Shows soon-to-expire studies

Expired Studies

Shows expired studies

cayuse IRB

Dashboard

Studies

Submissions

Tasks

Help

My Role: Researcher

Dashboard

44

Harry Potter

0

In-Draft

1

Awaiting Approval

1

Pre-Review

6

Under Review

My Studies

IRB-FY15-16-  
37

A Sample Study

Open Help

Release Notes

View Dashboard Tutorial

View Visual Search Tutorial

another sample app with revisions

View All

My Tasks

IRB-FY15-16-25

View Submission

View All

Submissions by Type

Initial	8
Withdrawal	0
Modification	1
Renewal	0
Incident	0
Closure	0
Legacy	0

Approved Studies

Studies Expiring in 30 days

Expired Studies

Click the "open Help" option in the Help tab to launch Cayuse's web support page





Enter search string...

Contents

Index

- Navigating Cayuse IRB
- Dashboard
- Studies and Submissions
- Tasks
- Notifications
- IRB Users - Creating Studies**

- Completing Forms
- Submission Workflow
- Letters
- Addressing Comments
- Submission Types
- Viewing Submission History
- Working with Legacy Submissions
- Linking a Study to Cayuse SP
- Organizational Approvers - Approving Submissions
- IRB Analysts - Managing Submissions

*You are here: Creating a New Study*

## Creating a New Study

To create a new study, click the **New Study** button in the upper right of either the [Studies](#) page or your [Dashboard](#).

cayuse IRB

Dashboard

Studies

Submissions

Tasks

?

My Role: Researcher

Studies

+ New Study

Click to search

IRB#	Study	Status	PI	Exp Date	Last Activity
IRB-FY2016-3522	Extracurricular activities and perceived stress	Under Review	IRB User 2	N/A	06-18-2015
IRB-FY2016-3524	Internet use of adolescent Americans	Unsubmitted	IRB User 2	N/A	02-23-2015

Enter a title for your study (up to 600 characters). Then, click the **Save** button.



# What are notifications?

- Emails that will alert you that your submission requires attention  
i.e. revise submission to answer IRB questions, certification required
- Notifications will appear in-system **AND** be sent to your MSU email
- When you are required by the IRB to make corrections or revisions, it will also show up in your “Tasks” section of the dashboard


# Study vs. Submission


- Study refers to your entire research project
- Submission refers to specific applications- e.g. initial application, modification, renewal, closure, etc.


# Steps to creating an initial submission


1. Click on blue "+ New Study" button on top right hand side
2. Give your study a title. If it is a student led research project, preface your title with "SS" ex: "**SS Sample Study Title.**" Click on the blue checkmark on right-hand side to confirm study title.
3. You will see an IRB number such as "IRB-FY15-16-45" and you will see a pink banner on left side which states status "Unsubmitted".
4. Click on blue "+ New Submission" button on top right hand side.
5. A drop down will appear with the word "INITIAL" – click on it.
6. You are now able to "Edit" your new submission!

Click new study to begin [+ New Study](#)

 0  
In-Draft

 1  
Awaiting Approval

 0  
Pre-Review

 6  
Under Review

My Studies	
IRB-FY15-16-38	sample modification
IRB-FY15-16-36	sample app with revisions
IRB-FY15-16-37	another sample app with revisions
IRB-FY15-16-35	Sample initial application
View All	

My Tasks	
IRB-FY15-16-25	View Submission
View All	

Submissions by Type	
Initial	7
Withdrawal	0
Modification	1
Renewal	0
Incident	0
Closure	0
Legacy	0

Approved Studies
------------------

Studies Expiring in 30 days
-----------------------------

Expired Studies
-----------------



[Studies](#) / Study Details

[+ New Submission](#)

Study Details

Submissions

A Sample Study

Type the name of your study here

...and then click the check



PDF

Delete

Approval Date:

N/A

Expiration Date:

N/A

Organization:

N/A

Sponsors:

N/A

Active Submissions:

### Key Study Contacts

Team Member

Role

Number

Email

No Key Study Contacts.



Click “new submission” and  
select “Initial”

+ New Submission

Study Details

Submissions

Initial

Unsubmitted

IRB-FY15-16-41 A Sample Study

PDF

Delete

Approval Date:  
N/A

Expiration Date:  
N/A

Organization:  
N/A

Sponsors:  
N/A

Active Submissions:  
N/A

Key Study Contacts

Team Member	Role	Number	Email
No Key Study Contacts.			

Unsubmitted

Initial

IRB-FY15-16-41 - A Sample Study

Edit

PDF

Delete

Checklist

You can also select “Edit” to begin the submission too

PI:

Harry Potter

Current Analyst:

N/A

Decision:

N/A

Review Type:

Unassigned

Review Board:

N/A

Meeting Date:

N/A

Required Tasks:

✓ Assign PI

• Assign PC

• Complete Submission

Approvals

Task History

Research Team

Name

Role

Result

Date

No entries.

**Cayuse IRB will assume you are the PI when you create the study**

**However, if you are a student researcher you will need to assign your faculty sponsor as the PI. You can do this in the submission itself.**

**For now, assign yourself as the PC, or “primary contact.” The PC will be the IRB’s first point of contact in all communications about the submission. When you click this, you will be brought to the actual submission and can begin**



&lt; STUDY

IRB NUMBER: IRB-FY15-16-41

## A Sample Study - Initial

CREATE PDF

COMPARE

SAVE



Sections



Personnel

Activity

Attachments

## Personnel

## \* Applicant Status

*Please click one below.*

- ☒ Faculty
- ☐ Staff
- ☐ Adjunct
- ☐ Student

Applicant: Faculty or Staff or Adjunct Faculty

*Please provide the Principal Investigator and the Primary Contact of this study/activity.*

## Principal Investigator

- If you are the PI, your name should have already auto-filled.
- If another faculty or staff will be PI, delete your name and find the PI's name below.

## Primary Contact

- This can be the same individual as the listed PI.
- Select another individual as your primary contact if that individual will be managing the IRB submission process on your behalf.

This brings us to the submission. The PI and PC distinction is also explained here!



&lt; STUDY

IRB NUMBER: IRB-FY15-16-41

## A Sample Study - Initial

CREATE PDF

COMPARE

SAVE



Sections

Personnel

Activity

Attachments

## PRIMARY CONTACT

Search...



Name

Organization

Email

Phone

*Use the search box above to find records.*

You will be presented with this pop-up in which you will search for the designated person and click their name to select. Then click "Save"

Selected Records

\* Select a single record.

*No records selected. Select a record and click **Save** to apply.*

CANCEL

SAVE

Please describe the roles of each research team member.

For example; study lead, data collector, recruiter, consenting, data analyst

My Role: Researcher

44

Harry Potter

STUDY

IRB NUMBER: IRB-FY15-16-41

A Sample Study - Initial

CREATE PDF

COMPARE

SAVE

<

>

Sections

Personnel

Activity

Study Information

Assurances

Study Population

Study Procedures

Study Design

Funding

Conflict of Interest (COI)

Attachments

Activity

\* What type of activity is this submission for?

☒ Research Study

\* Is this a multi-institutional study?

☐ Yes

☐ No

☐ Activities Without a Plan to Conduct Research (Case Study, Secondary Data Analysis of publicly available data-sets, or Quality Improvement project) requiring Human Subjects Research determination.

Click the save button at any time. You can leave Cayuse IRB and complete your submission at a later time.

These arrows are used to tab through the submission

Sidebar lists all the subsections of the submission. The green bar is a status bar. When the section is complete, the green check mark will show.





&lt; STUDY

IRB NUMBER: IRB-FY15-16-41

## A Sample Study - Initial

CREATE PDF

COMPARE

SAVE



## Sections &lt;

Personnel



Activity



Study Information



Assurances

Study Population



\* Study Procedures

Study Design

Funding

Conflict of Interest (COI)

Attachments

## \* Adult Consent

Check any and all that apply.

☒ Adult Consent FormLink to the MSU IRB [Adult Consent Form Templates](#)

Readability for consent documents must follow:

- General public - 6th to 8th grade reading ability
- College Students - 10th to 12 grade reading ability
- Professionals -12+ reading ability

## \* Adult Consent Form (s)

Please attach your adult consent form(s)

ATTACH

- ☐ Online Consent
- ☐ Requesting waiver or alteration of standard informed consent procedures
- ☐ Consent form non-English speaking participants
- ☐ Debriefing form (for use in deception studies only)
- ☐ Cognitively impaired or differently abled population consent

\* Will you offer compensation to your participants?

You will likely have to attach several things to your submission. You'll click the "Attach" button and follow the instructions of the pop-up. You can now attach a link OR a document

STUDY

IRB NUMBER: IRB-FY15-16-41

A Sample Study - Initial

CREATE PDF

COMPARE

SAVE

Sections

Personnel

Activity

Study Information

Assurances

Study Population

Study Procedures

Study Design

Funding

Conflict of Interest ...

Attachments

Routing

Send to PI for certification?

COMPLETE SUBMISSION

Translated Material(s)

Attach any translated recruitment, consent or instrument(s).

ATTACH

Grant Proposal

Please attach the sponsor notification that states the intention to award the study.

ATTACH

Outside IRB of Record

Please make sure all of the documents below have been uploaded.

Study Protocol

Attach the protocol for this study that was reviewed by the outside IRB.

ATTACH

Outside IRB Approval

Attach the IRB Approval from the outside IRB.

ATTACH

\*If you are not the PI, you will have to select the “Send to PI for certification” option for the PI to sign off on the submission

When you are finished with your submission, click “complete submission”





### In-Draft

Submission is with researchers



### Awaiting Approvals

Submission is awaiting certification or approval

3

### Pre-Review

Submission is being prepared for review

4


### Under-Review


Submission is with reviewers

Under Pre-Review

## Initial

IRB-FY15-16-41 - A Sample Study

 View

 PDF

 Delete

 Checklist

PI:

Harry Potter

Current Analyst:

N/A

Decision:

N/A

Required Tasks:

N/A

Review Type:

Unassigned

Review Board:

N/A

Meeting Date:

N/A

Approvals

Task History

Research Team

The submission has been sent to the IRB Staff and is now in pre-review!

# Making revisions and replying to IRB requests

- In most cases, you will be required to make some revisions to your submission before receiving IRB approval
- In Cayuse IRB, this takes the form of both making changes to your submission and replying directly to comments
- You will receive an email notification for revisions, and you will find your “tasks” on the dashboard



☰

My Role: Researcher

< STUDY

IRB NUMBER: IRB-FY15-16-41

A Sample Study - Initial

CREATE PDF

COMPARE

Sections

Personnel 1

Activity ✓

Study Information ✓

Assurances ✓

Study Population ✓

Study Procedures ✓

Study Design ✓

Funding ✓

Conflict of Interest ... ✓

Attachments ✓

Personnel

\* Applicant Status

Please click one below.

☒ Faculty

☐ Staff

☐ Adjunct

☐ Student

1 Collapse Comments

Albus Dumbledore Today at 10:21 AM

Are you sure about this?

Reply

B I U ↺ ☰ ☷ 🔗

yes!

REPLY CANCEL

Not Addressed ▾

There is a comment that needs our attention

It is important to both make the requested changes and reply to all the comments!

You'll click "Expand comments" here to view

Type your response and click "reply"

Change the status to "Addressed"

Sections



Personnel



Activity



Study Information



Assurances



Study Population



Study Procedures



Study Design



Funding



Conflict of Interest ...



Attachments



## Study Population

### \* Study Population

Please describe the characteristics of your participant population(s).

This will be a great study!

### \* Vulnerable Populations

You can click “compare” to view a revised submission against its original

◀ VIEW SUBMISSION

## Comparison: IRB-FY15-16-41 (Initial)

◀ ▶

PREVIOUS SUBMISSION

CURRENT SUBMISSION

Sections

◀

◀ PREVIOUS DIFF

NEXT DIFF ▶ 1

Personnel

0

Study Population

Activity

0

Study Information

0

Assurances

0

Study Population

1

Study Procedures

0

Study Design

0

Funding

0

Conflict of Interest ...

0

Attachments

0

\* Study Population

Please describe the characteristics of your participant population(s).

test

\* Study Population

Please describe the characteristics of your participant population(s).

This will be a great study!

\* Vulnerable Populations

\* Vulnerable Populations

Revisions will be noted in the sidebar and highlighted

# How will I know my study has been approved?

- You will be notified via email!
- Study will appear on your dashboard under “Approved Studies”.
- All approved documents will appear under your approved study – those are the documents you need to use for your active research.

# So do I still need to...?

- Complete CITI Training?

Yes, all research team members will still have to complete CITI training every 3 years

- Pick up my approval documents?

No, you will also not be sent physical approval documents

- Use the Montclair templates for consent forms/site approval letters?

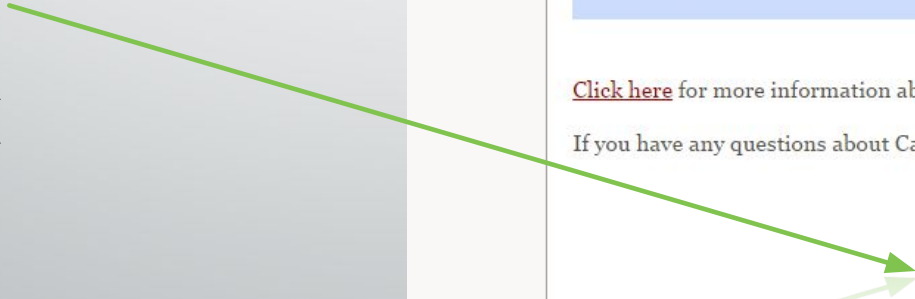
Yes, these templates will continue to be available on our website

- Apply for continuing review?

Yes, you will eventually have to fill out a renewal submission if your study is not exempt



Please give  
us your  
feedback



October 12th-November 15th

PILOT USERS ONLY (see below to sign up to be a pilot user)

November 16th, 2015 - January 31st, 2016

All new applications accepted in Cayuse IRB; We encourage you to use Cayuse IRB for new studies!

February 1st, 2016

All new study applications require Cayuse IRB

Spring 2016

We will be rolling out the Continuing Review (renewal) application on the system sometime in late Spring 2016. Check back, more information will be posted as available.

[Click here](#) for more information about Cayuse IRB.

If you have any questions about Cayuse IRB, please contact [cayuseIRB@mail.montclair.edu](mailto:cayuseIRB@mail.montclair.edu)

Give us your feedback