IRB Training

Human Subjects Protection Program and Cayuse IRB

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Objectives

- What is the Institutional Review Board (IRB) responsible for? And why?
- What is Human subjects research?
- What do we look for when reviewing a protocol?
  - Document requirements for submission
  - Approval designations: Full, Expedited, Exempt
- Using Cayuse electronic system

So Why Bother…

- Primary objective is to protect human participants
- Bound by law (45 CFR Part 46) under our FWA Federal Wide assurance
- Thus, we report to U.S. Department of Health & Human Services; Office of Human Research Protection (OHRP)
- OHRP will take corrective actions for non-compliance
  - Including stopping all research projects related or un-related to the study in question

IRB Mission

- to support faculty, staff, students to complete their research in compliance with federal and state laws and MSU policy. As such, the IRB is charged to review, approve initiation of, and conduct periodic reviews of research projects that involve human participants.

IRB BOARD

- 12 Faculty /Staff and
  1 community member













Definition of human subjects research

- **Human subject** means a living individual about whom an investigator conducting research obtains
  (1) data through intervention or interaction with the individual, or
  (2) identifiable private information

- **Research** is defined as a systematic investigation that is hypothesis driven with the intent to develop knowledge that can be generalized.

Human Subjects research (HSR)?

- Student conducting an interview of a school counselor for a research paper in class only

NOT HSR! – Classroom experience

Student may still want to consider a consent form and privacy issues

- Student conducting interviews that are answering a research question. Interview includes pre-determined questions on counselor's personal opinions and this project will continue interviews with more subjects. The student thinks they might want to share this at the next student symposium.

YES HSR!

Human Subjects research (HSR)?

- An MSU Center is conducting surveys after their workshops. Workshops are a free service offered to clients. Purpose is solely to improve future programming.

NOT HSR! – Quality Improvement/Assurance

Center may still want to consider a consent form and privacy issues

- MSU Children's Center conducting surveys after workshops and would like to present program as a model to other Centers on how to provide a particular service to parents.

YES Program Evaluation can be HSR too!

IRB REVIEW PROCEDURES and categories

General themes involved in the IRB review

- how participants are recruited to be in the study
- how the privacy of participants will be protected
- the physical, psychological, and sociological risks to participants
- any discomfort and stress to participants
- benefits outweigh the risks
- consent process
  - Key summary
  - accurately reflect the study
  - Consent form written in simple lay language
  - appropriate to the participant pool(language)

Three categories (45 CFR 46.109)

- Exempt
- Expedited
- Full Board – MORE than minimal risk

Criteria for Exempt

- Research activities that

  present **no more than minimal risk** to human subjects
- Example: data analysis with existing data set
- Example: regular classroom activity where results are now intended for research

- ***Exempt*** Review- Goal: Two to three weeks

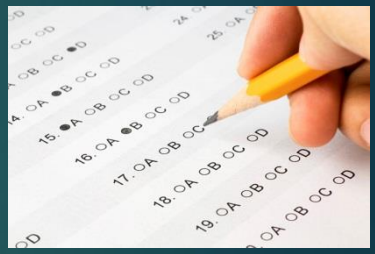
Criteria for Expedited

- Research activities that

  present **no more than minimal risk** to human subjects

At MSU:

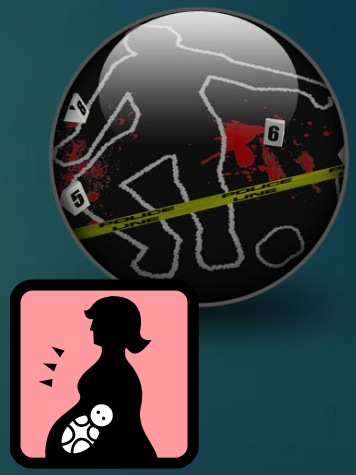
- Expedited: Collection of data through non-invasive procedures (e.g., weight)
- Most research on individual or group characteristics or behavior (including motivation, identity, social behavior, cultural beliefs) and research using survey, interview, focus group, program evaluation



- ***Expedited Review*** - Goal: Three to five weeks

Criteria for Full board

- Research activities that present **greater than minimal risk** to human subjects
- Triggers
  - Population involves persons with cognitive disabilities
  - Any disclosure of illegal activities, sexual attitudes, genetics, religious beliefs, mental health that could place participants at risk of criminal or civil liability, be damaging to the participants financial standing, employability, insurability, reputation, or be stigmatizing
    - Depression and mental health disorders
    - Violent crimes
    - Opinion about employer
  - Coercion; Deception or incomplete disclosure
  - Pregnant women
  - Medically invasive, e.g., clinical trial
- ***Full Review***- Goal: Four to six weeks (can be longer depending on IRB meeting schedule and PI response time)



Proper Informed consent

- Template available online only to be used as outline
  - Remove any instructions including the audio and video request on consent form if you are not audio or video recording
  - Keep the tense the same throughout
    - Either "you" or "participant"
  - Do not use previous or outdated consent forms for your study
- The consent should clearly and succinctly tell people what your study is about; including any screening procedures
- Readability level
  - Adults – 6th-8th grade reading level for general public
- Informed consent translations if population is predominantly non-English speakers
- Ask for help!

Dealing with risk and disclosure

- TOPICS mental health, violent attacks
  - Counseling and Psychological Services (CAPS)
  - Other counseling services
- Referrals
  - Health Care Provider
  - Therapist

Clarify Recruitment

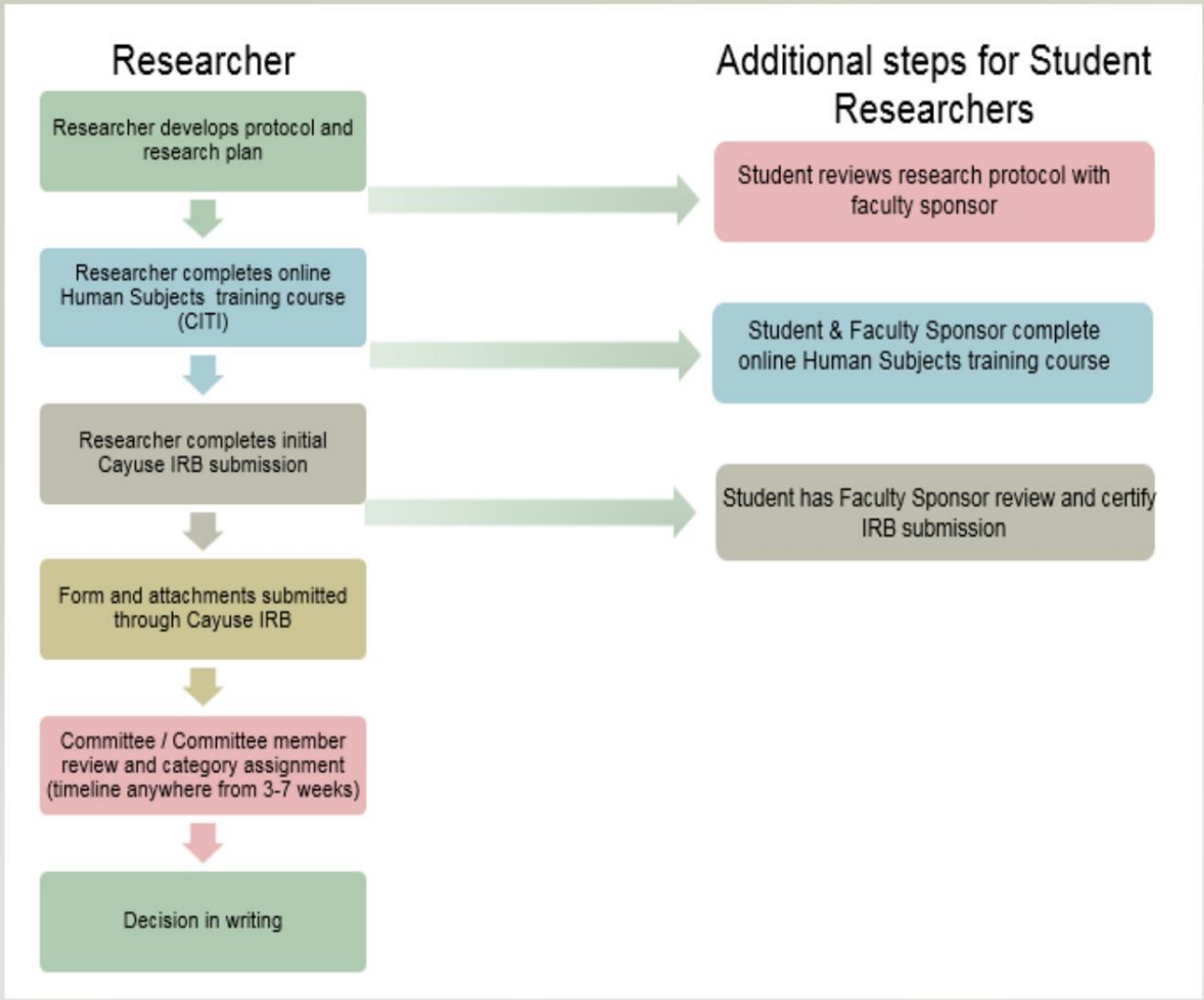
- Templates available on MSU website
  - MSU logo should be on all your recruitment material
  - Identify yourself on the flyer/recruitment "I am an MSU student in the Center for Audiology"
- Screening in recruitment
  - Justify inclusion or exclusion criteria in screening
  - Describe all screening procedures in application
  - Only minimal screening can be done at initial interaction
    - E.g. male under age 40
  - All other screening must be part of your consent process
    - E.g. mental health screening

Instrument Design for Surveys

- Online
  - MSU IRB does not require use of one survey tool
  - Survey tools open to Faculty and Students
    - Qualtrics (NEW)
    - MSU limesurvey https://oit-app2.montclair.edu/msusurvey/admin/admin.php
      - Data stored in-house; similar features to survey monkey
  - Other survey tools:
    - The Survey Monkey, SoGoSurvey, SurveyGizmo, Google Forms
- Paper survey layout and design is up to the researcher

Be consistent

- Confidential vs. anonymous
  - Only anonymous if researcher and others cannot identify the participant (i.e. online survey)
- Participation time should be the same in application and in your consent form
- Use of data in the future
  - If you ask for permission to use data in future studies then include this on the consent
- Compensation
  - Compensation noted in the application should be noted in the consent form



The process overview

Checklist: Documents for IRB submission

- CITI training
- Request an Cayuse IRB account (students or new employees only)
- Following IRB TEMPLATES:
  - Consent form
    - Translated consent forms if applicable
  - Assent form with Parent/Guardian Consent if research is with minors
  - Site agreements
    - for any and all off-campus research sites
  - Recruitment material (flyer, ads, emails, brochures etc.)
- Scripts (e.g. in person pleas)
- Data collection instrument (survey, interview questions etc.)

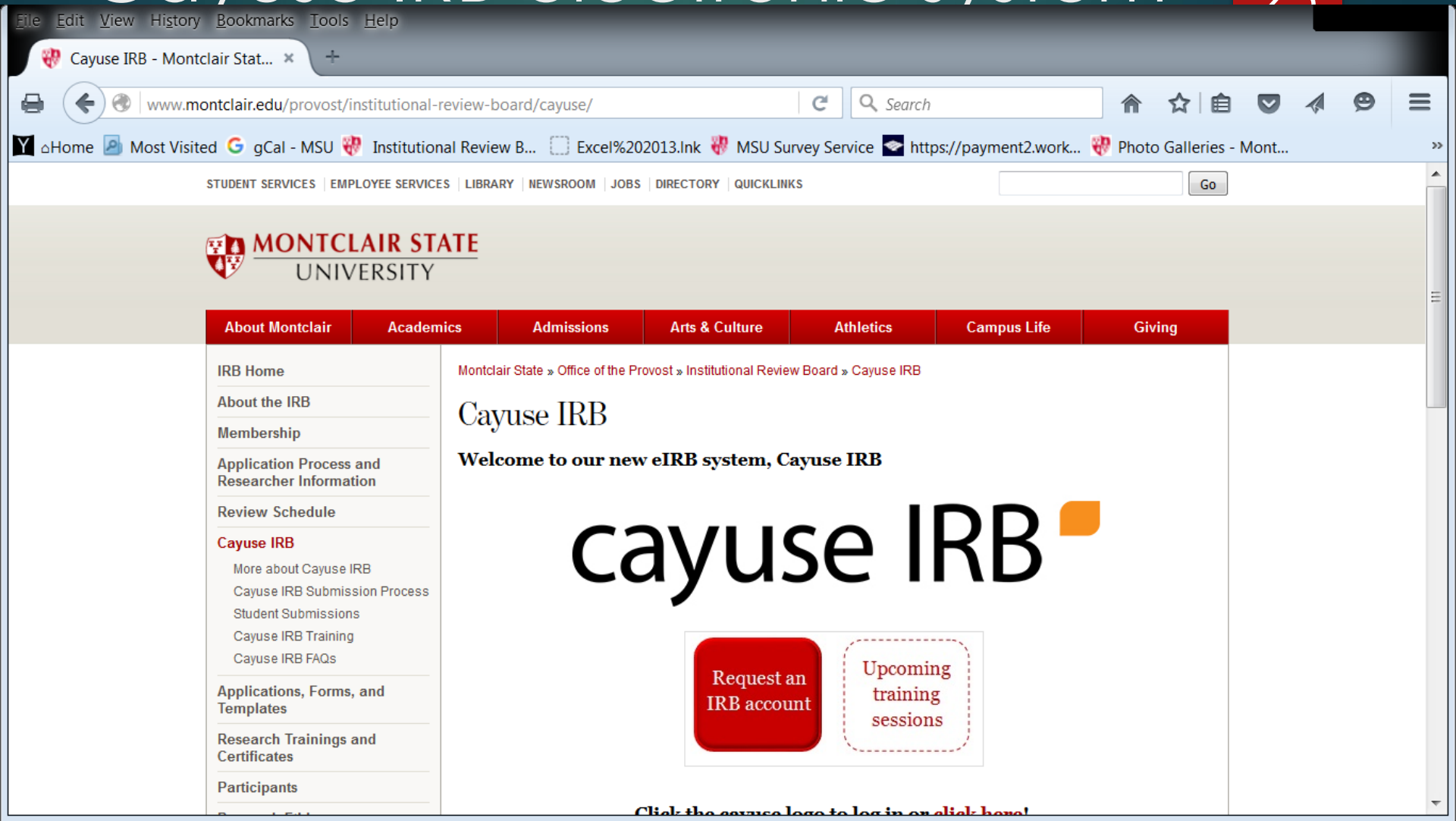
Understanding faculty sponsorship

- FS is affirming research design and implementation by serving as Principle Investigator
- FS should provide training and oversight of student in conducting research
- A faculty sponsor should be a permanent faculty member (adjunct faculty and faculty from other universities cannot serve as your sponsor)
- This may be your first time doing research, faculty sponsors must not only support your application but the entire implementation of your research activity.
- Assist your FS in accessing CAYUSE to either "Certify" or "Return to Investigators" your submission!

What's on the IRB webpages? montclair.edu/irb

- Templates
  - All consent documents including online consent
  - Recruitment Materials
  - Site Approval Letters
- Sample Applications
- Authorization Agreements
- Links to:
  - CITI Training
  - Requesting a Cayuse IRB account
  - Registering for a workshop

Cayuse IRB electronic system



Logged in as: *harrypotter*
Log out

Evisions Research Suite

3.2

Research Administration Modules

- Cayuse SP (Sponsored Projects)
- Cayuse 424
- Cayuse IRB (Human Studies Compliance)

System Administration Applications

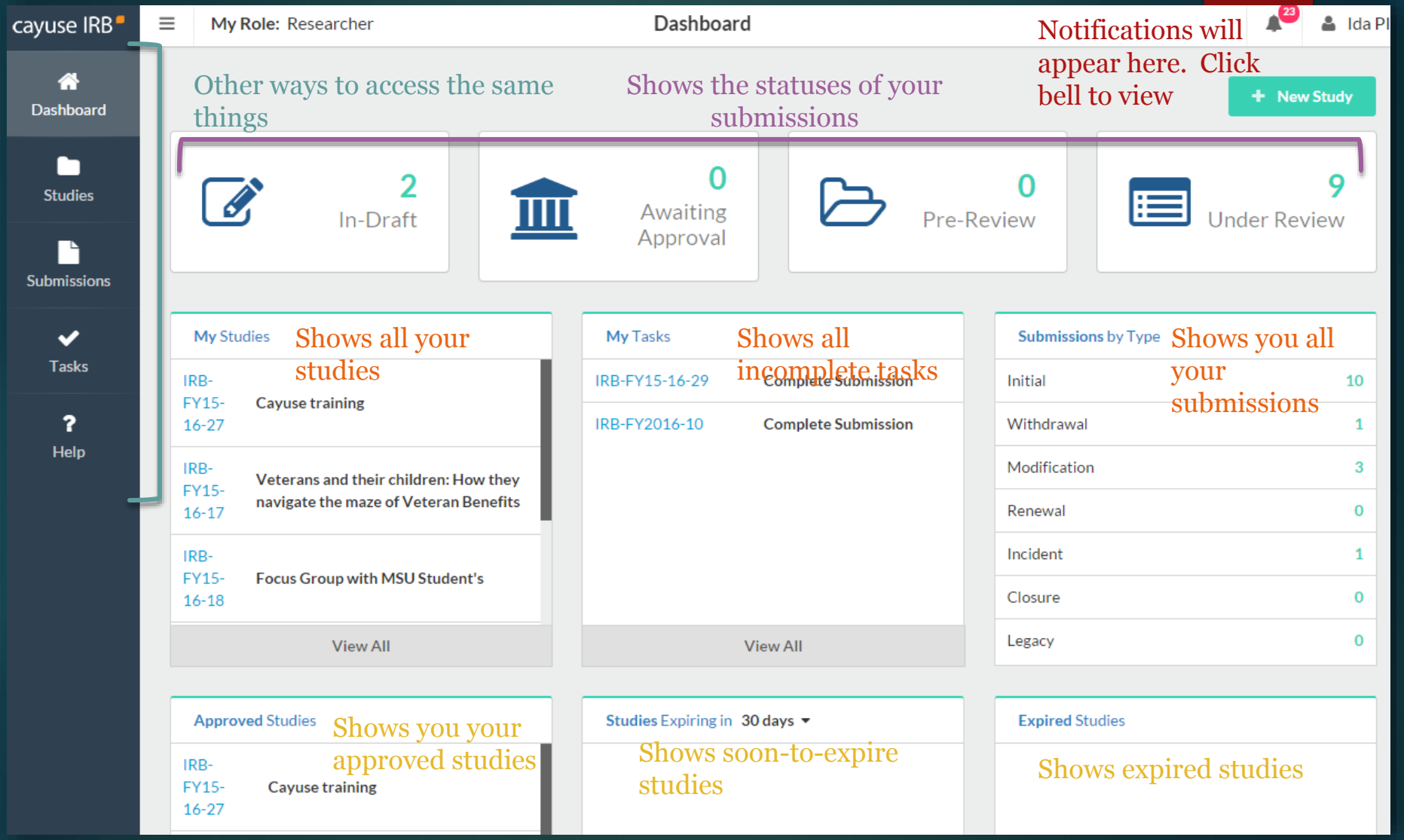
- Backbone
- Research Contacts
- Workflow

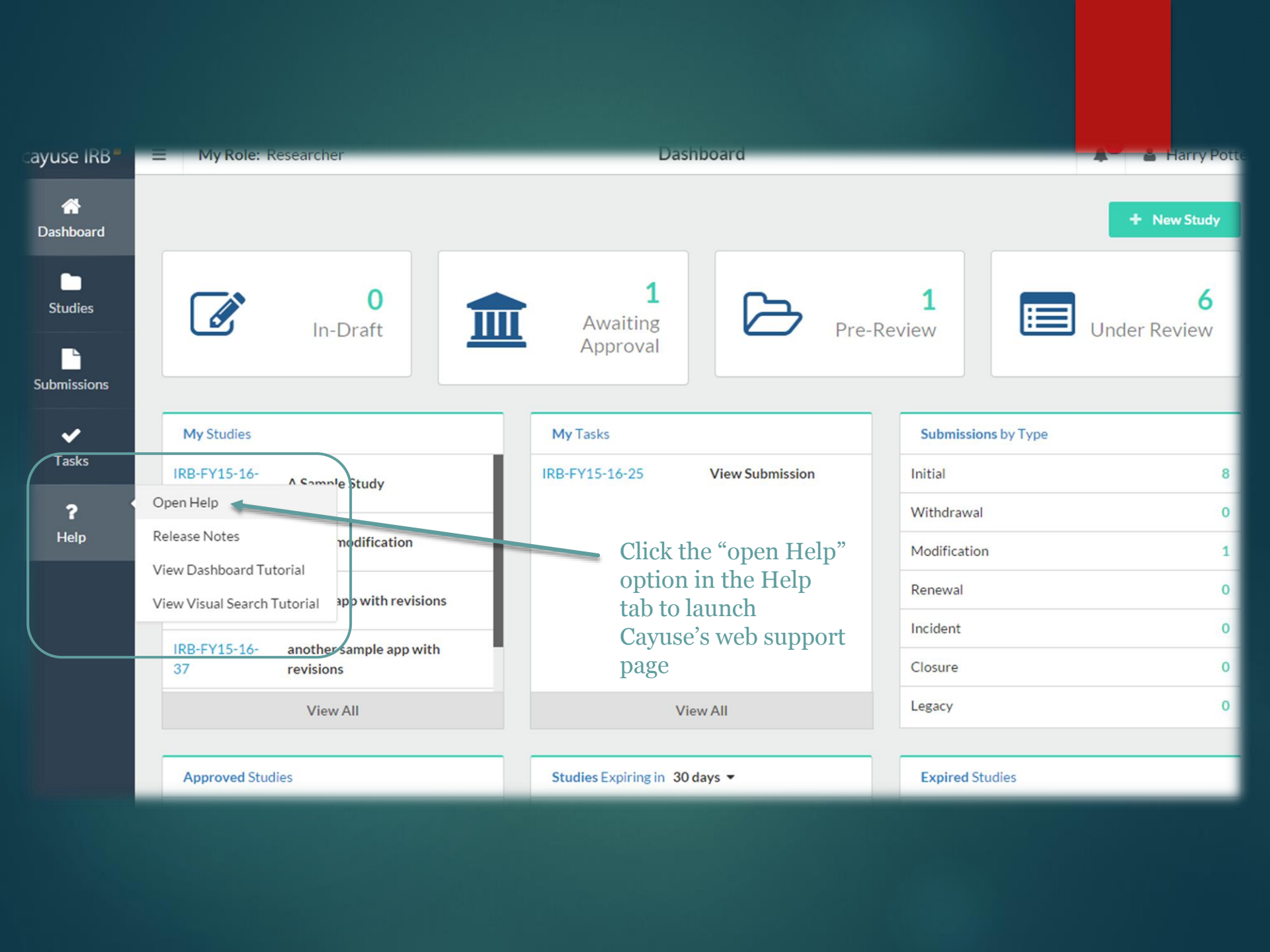
Application Help

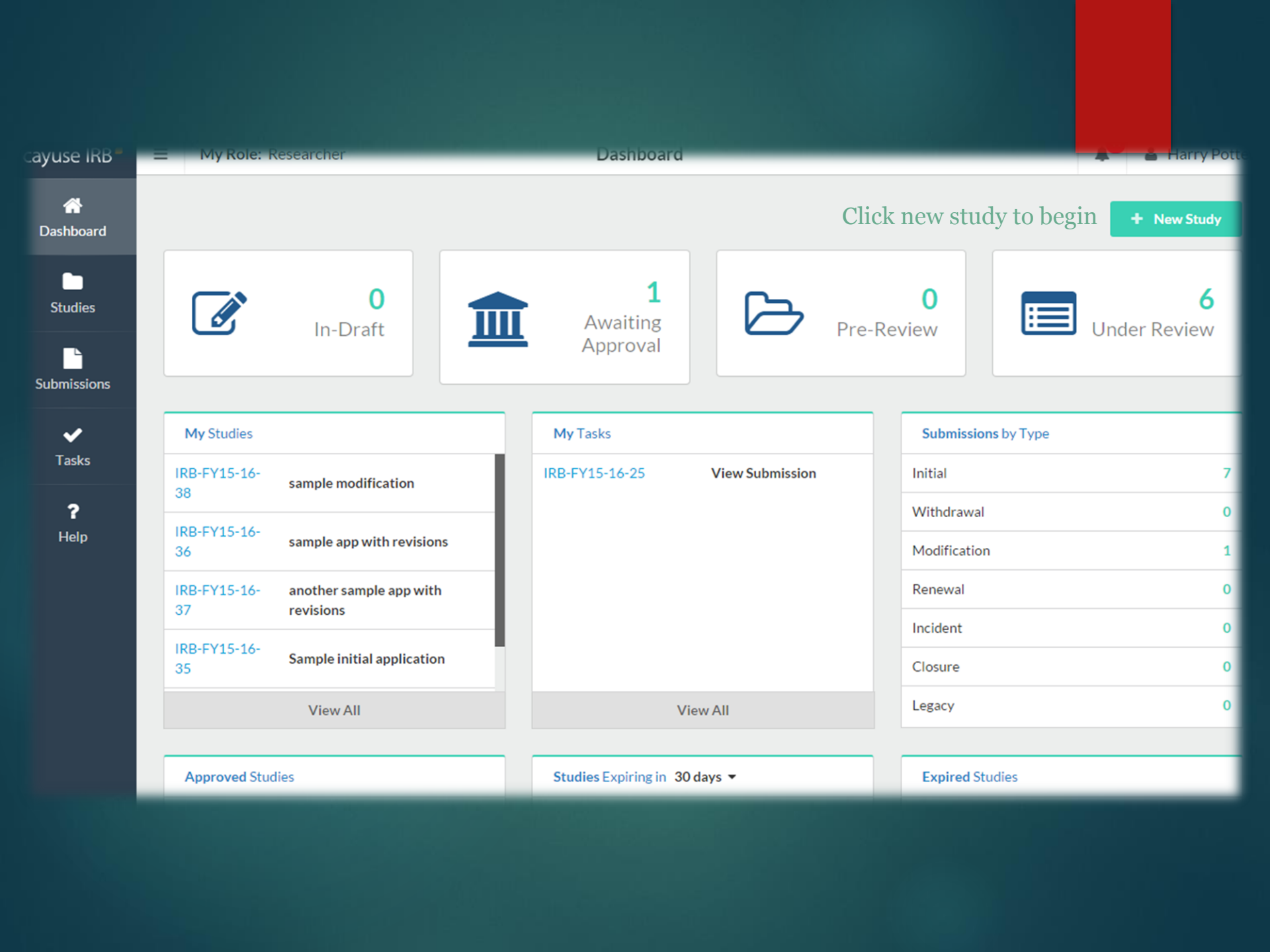
- Research Suite Support Center
- Browser Support & Configuration

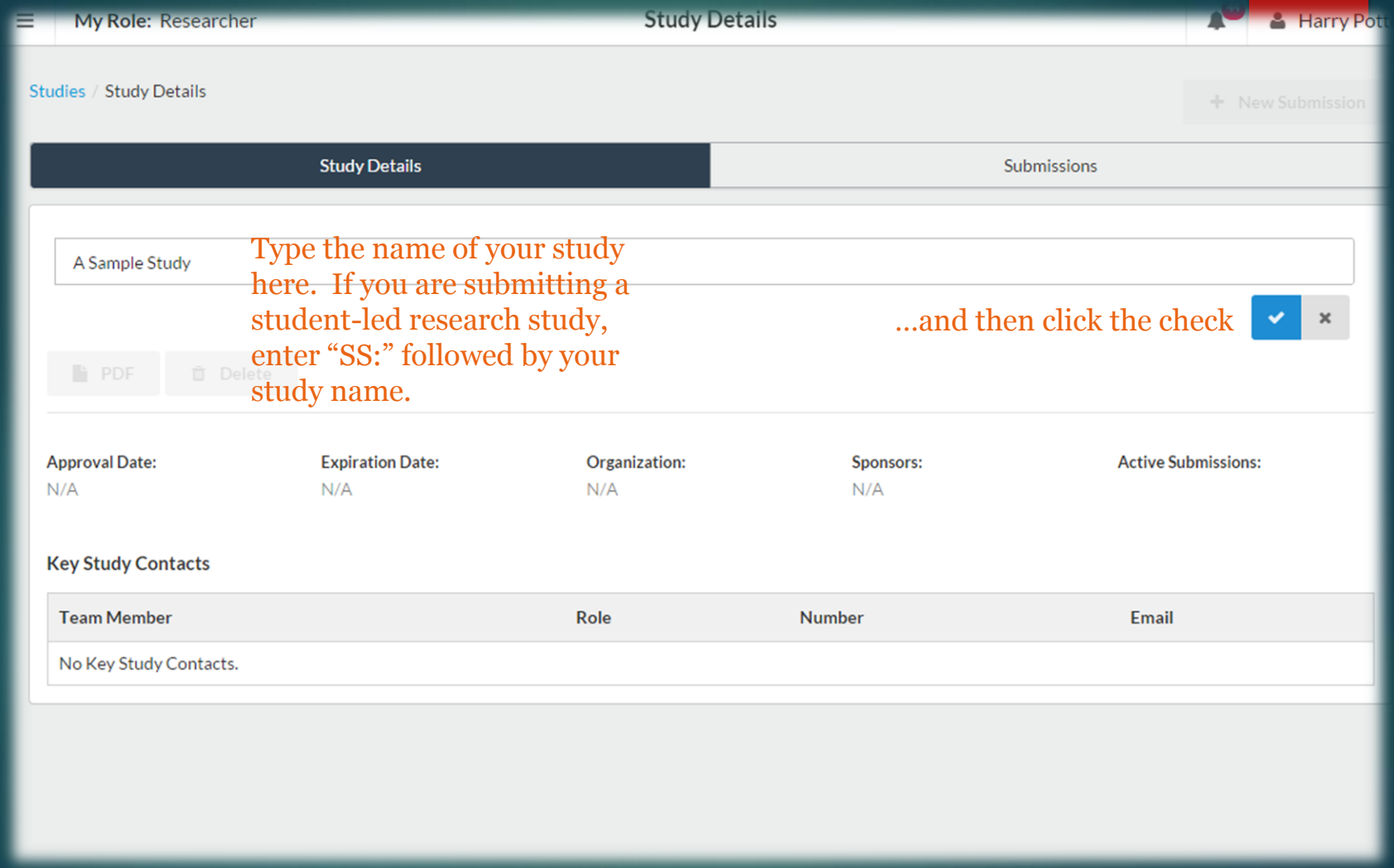
Research Administration Modules

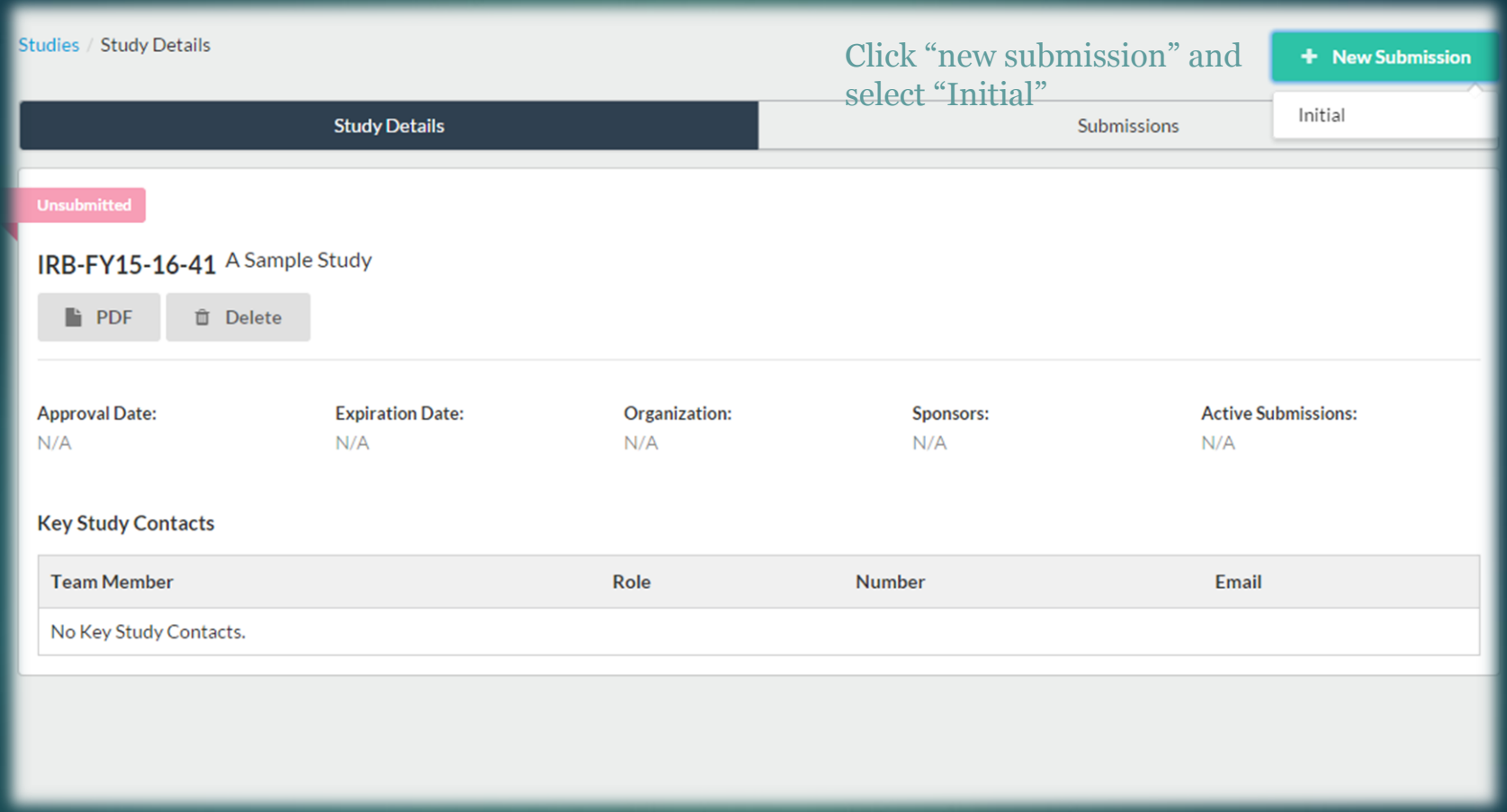
- Cayuse SP (Sponsored Projects)
- Cayuse 424
- Cayuse IRB (Human Studies Compliance)

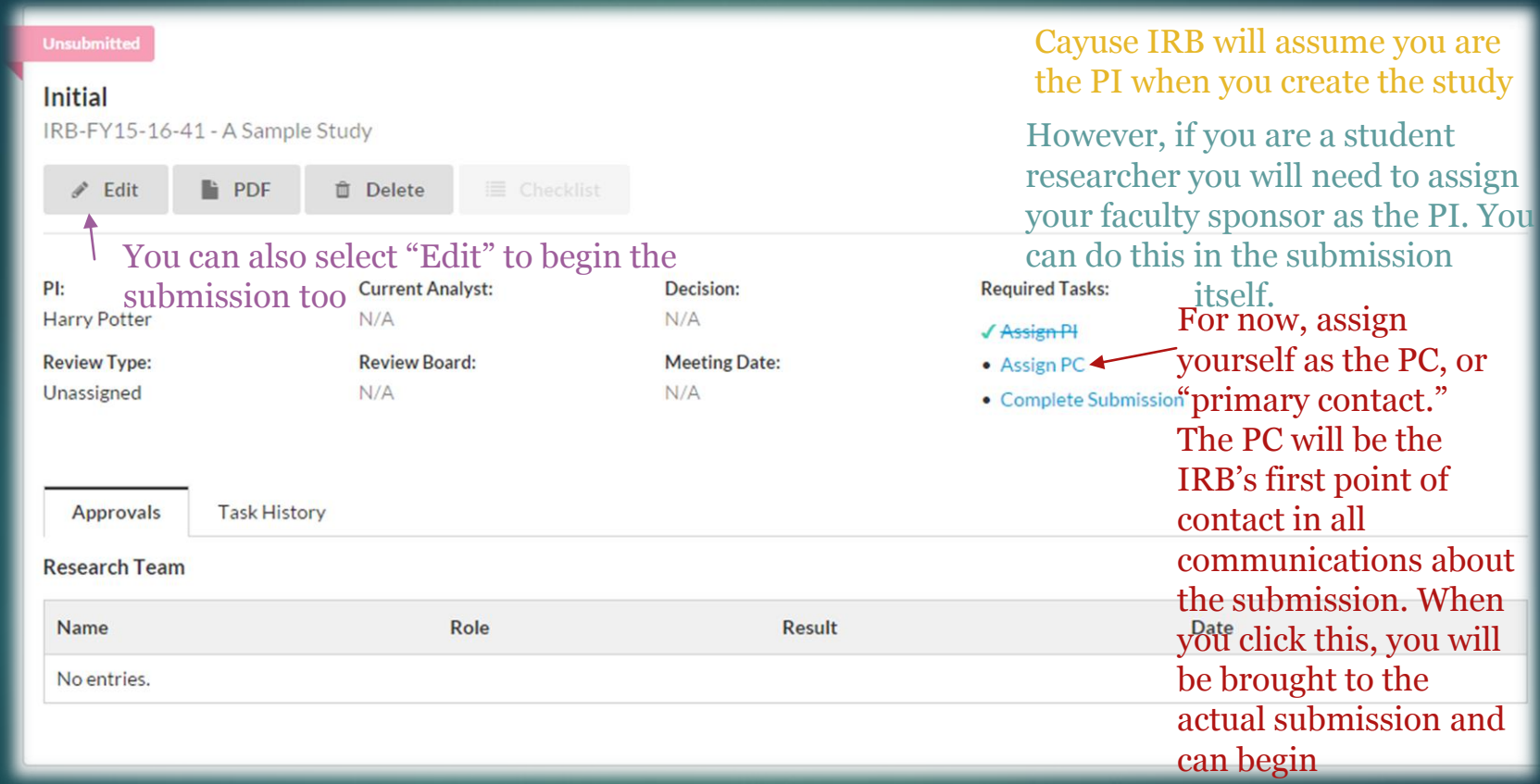

cayuse IRB
My Role: Researcher
Dashboard
Ida Pl
Dashboard
Studies
Submissions
Tasks
Help
Other ways to access the same things
Shows the statuses of your submissions
Notifications will appear here. Click bell to view
New Study
2
In-Draft
0
Awaiting Approval
0
Pre-Review
9
Under Review
My Studies
Shows all your 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
Shows all incomplete tasks
IRB-FY15-16-29
Complete Submission
IRB-FY2016-10
Complete Submission
View All
Submissions by Type
Shows you all your submissions
Initial 10
Withdrawal 1
Modification 3
Renewal 0
Incident 1
Closure 0
Legacy 0
Approved Studies
Shows you your approved studies
IRB-FY15-16-27
Cayuse training
Studies Expiring in 30 days
Shows soon-to-expire studies
Expired Studies
Shows expired studies


ayuse IRB
My Role: Researcher
Dashboard
Harry Potte
Dashboard
Studies
Submissions
Tasks
Help
Open Help
Release Notes
View Dashboard Tutorial
View Visual Search Tutorial
+ New Study
0
In-Draft
1
Awaiting Approval
1
Pre-Review
6
Under Review
My Studies
IRB-FY15-16-
A Sample Study
odification
app with revisions
IRB-FY15-16-37
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


ayuse IRB
My Role: Researcher
Dashboard
Harry Potte
Dashboard
Studies
Submissions
Tasks
Help
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


My Role: Researcher
Study Details
Harry Pott
Studies / Study Details
New Submission
Study Details
Submissions
A Sample Study
Type the name of your study here. If you are submitting a student-led research study, enter "SS:" followed by your study name.
...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.

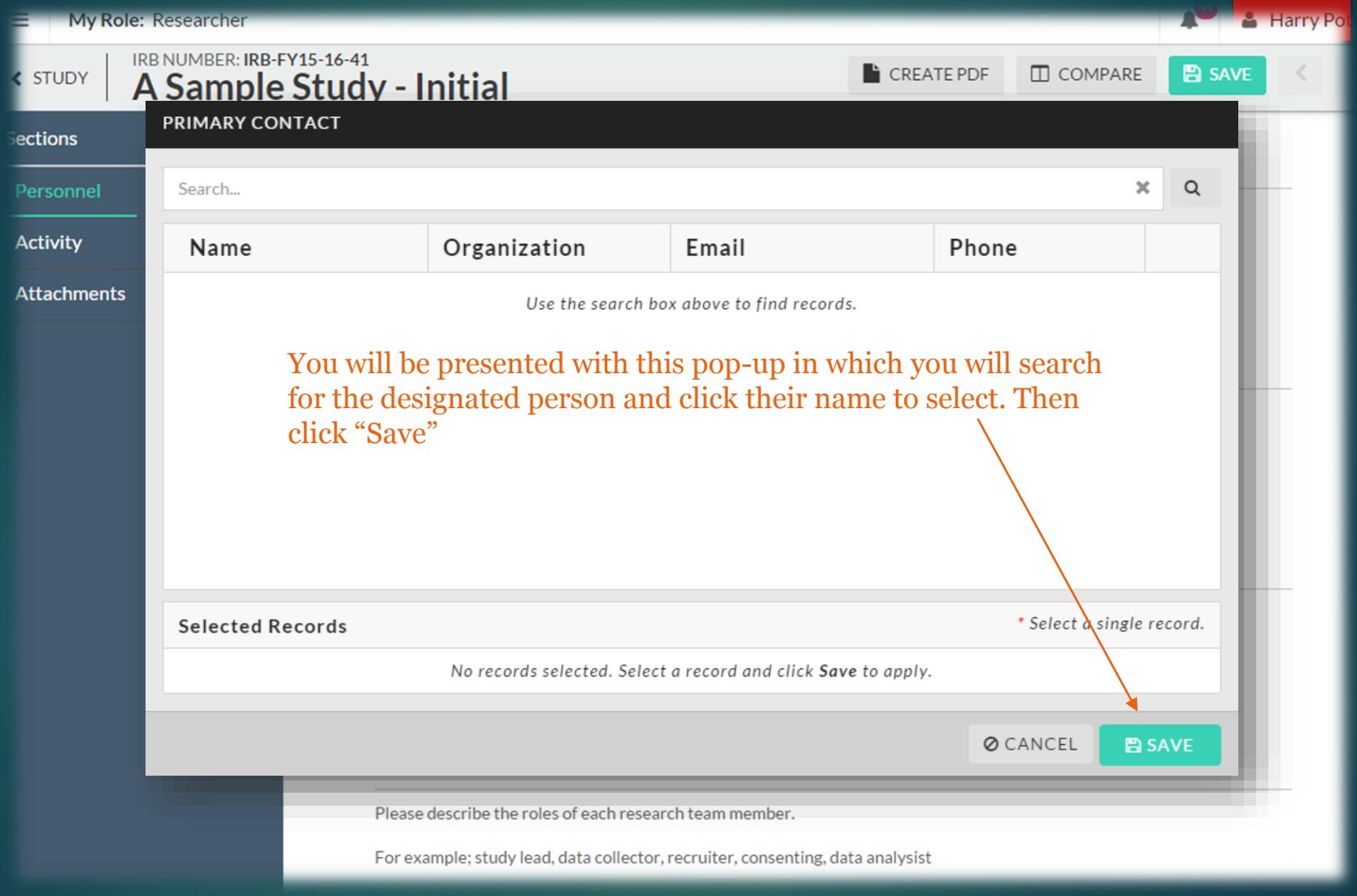

Studies / Study Details
Click “new submission” and select “Initial”
+ New Submission
Initial
Study Details
Submissions
Unsubmitted
IRB-FY15-16-41 A Sample Study
PDF
Delete
Approval Date:
N/A
Expiration Date:
N/A
Organization:
N/A
Sponsors:
N/A
Active Submissions:
N/A
Key Study Contacts
Team Member
Role
Number
Email
No Key Study Contacts.

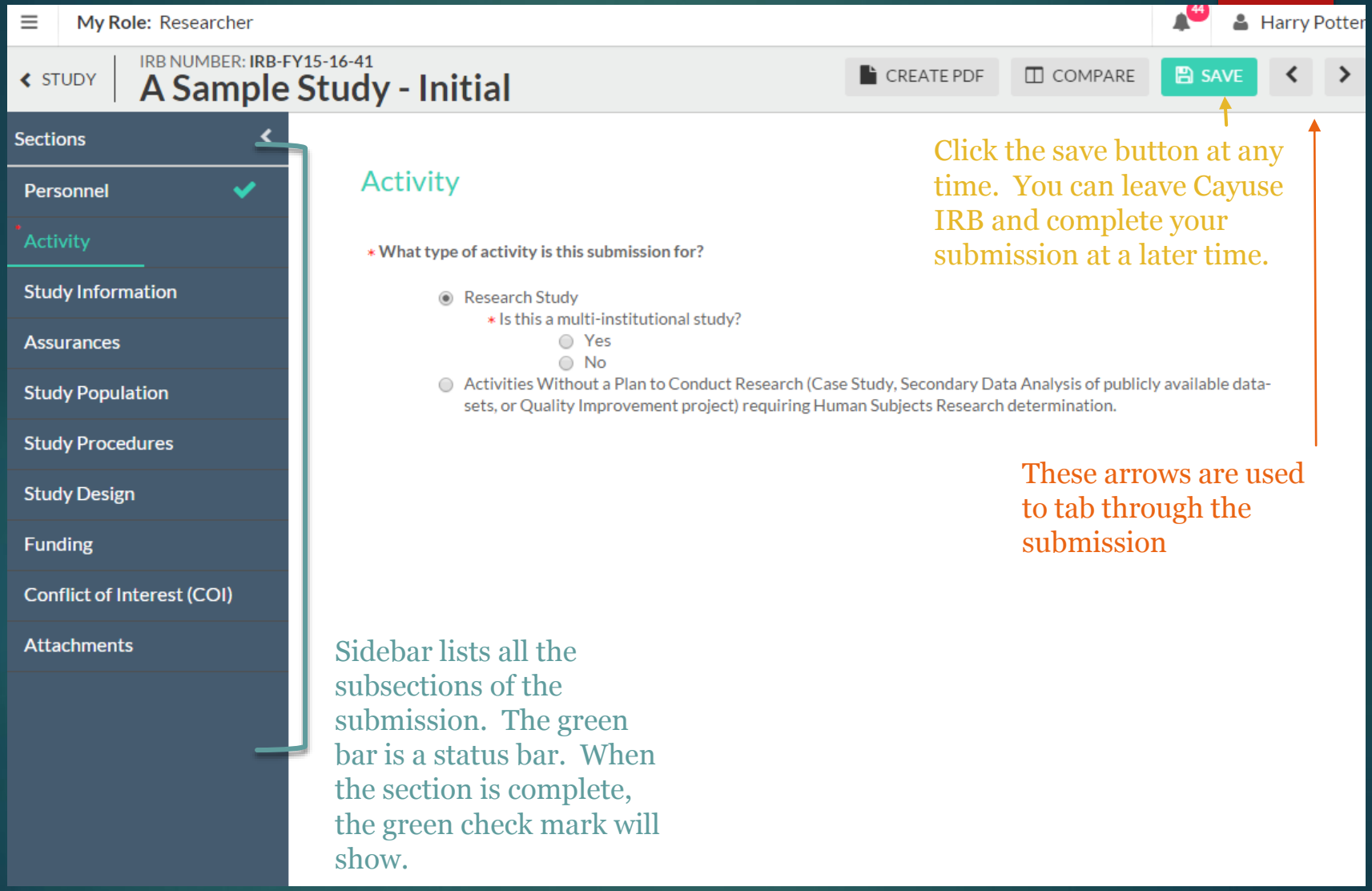


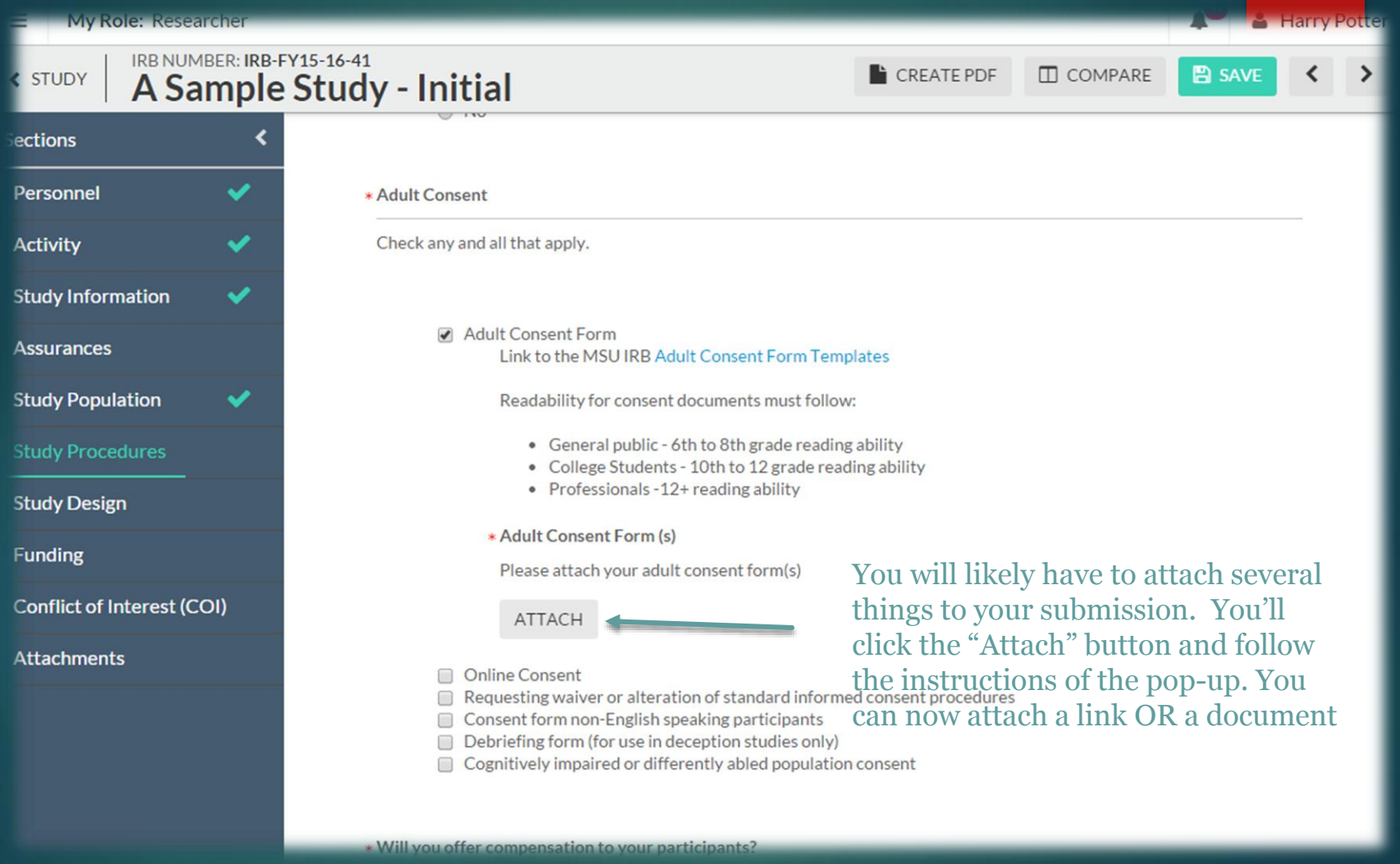
Cayuse IRB will assume you are the PI when you create the study

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.

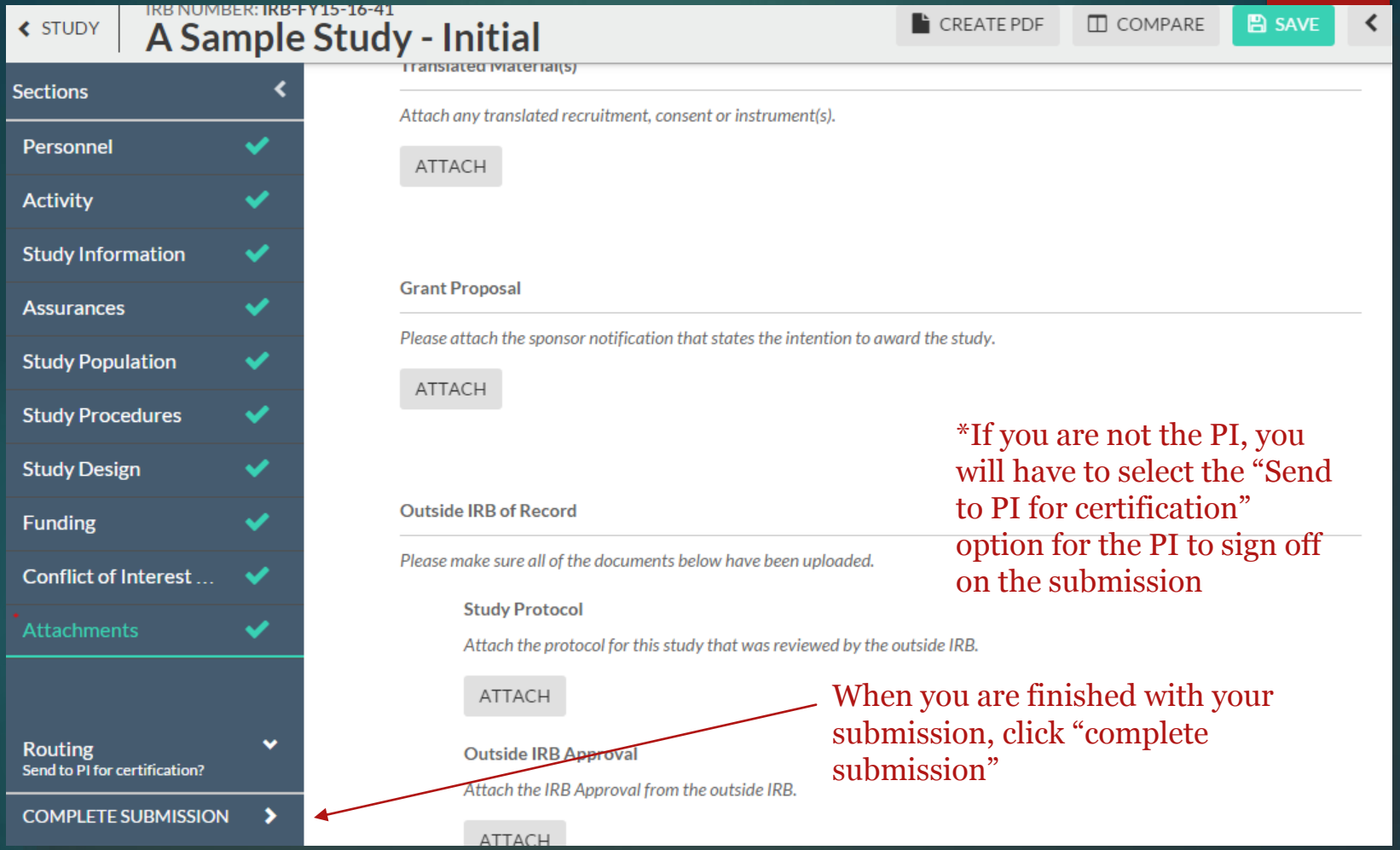
For now, assign yourself as the PC, or "primary contact." The PC will be the IRB's first point of contact in all communications about the submission. When you click this, you will be brought to the actual submission and can begin


My Role: Researcher
Harry Po
STUDY
IRB NUMBER: IRB-FY15-16-41
A Sample Study - Initial
CREATE PDF
COMPARE
SAVE
ections
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 analysist


My Role: Researcher
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.



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

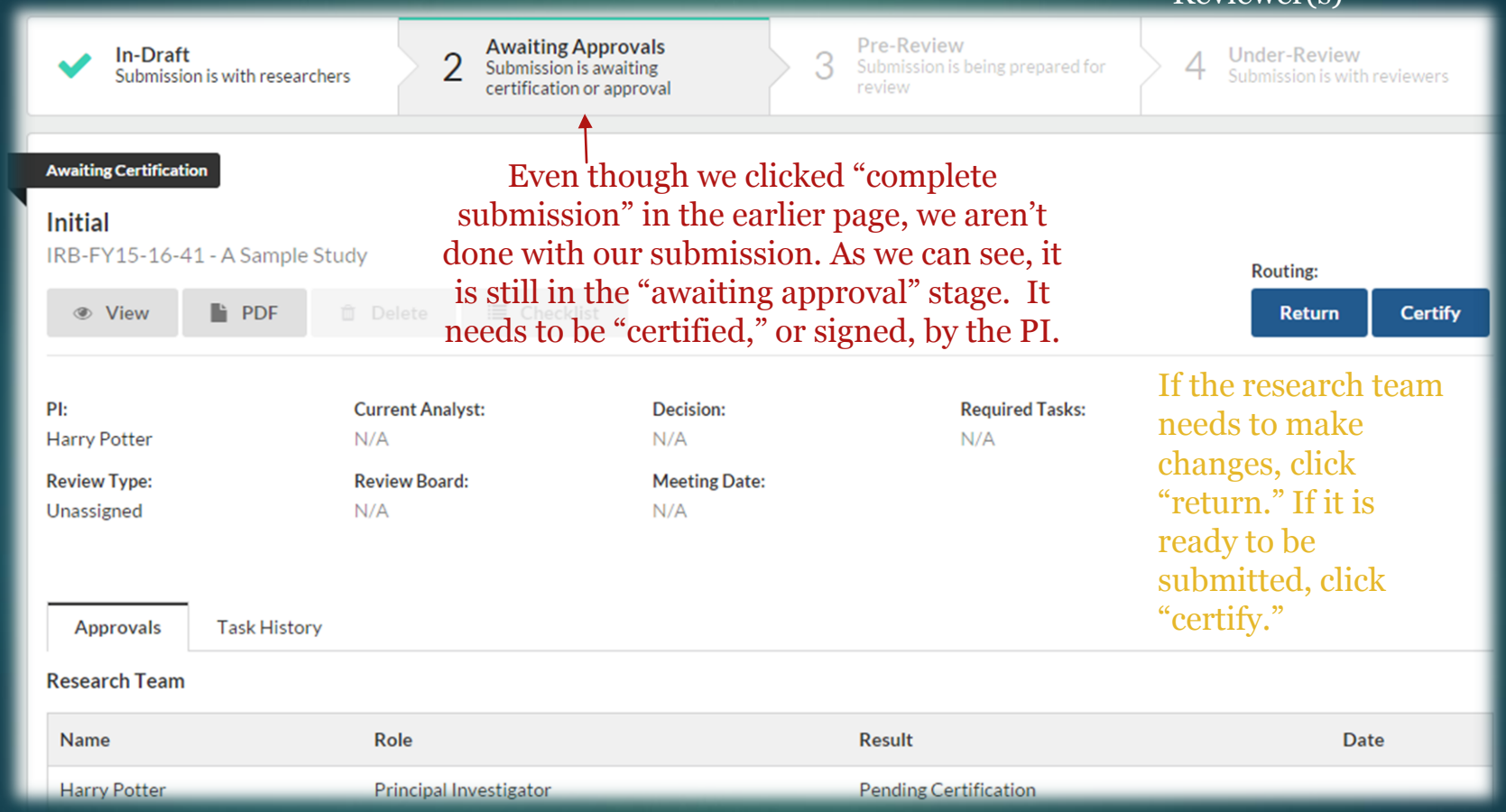


*If you are not the PI, you will have to select the "Send to PI for certification" option for the PI to sign off on the submission

When you are finished with your submission, click "complete submission"

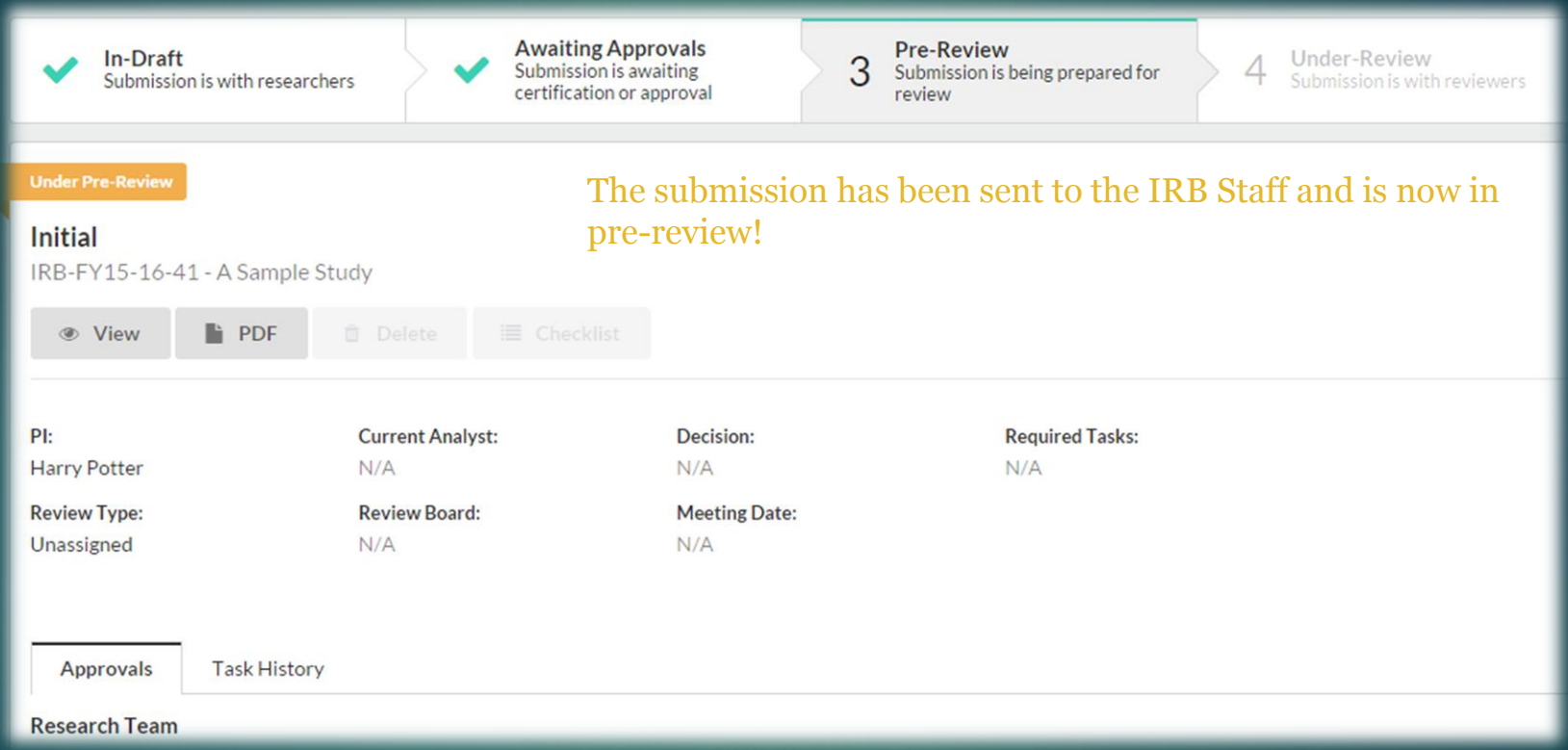
Now we are back to the general "Study page." On the study page you can see the status of your submission

In-Draft | Needs to be certified | With IRB Staff | With IRB Reviewer(s)



Even though we clicked "complete submission" in the earlier page, we aren't done with our submission. As we can see, it is still in the "awaiting approval" stage. It needs to be "certified," or signed, by the PI.

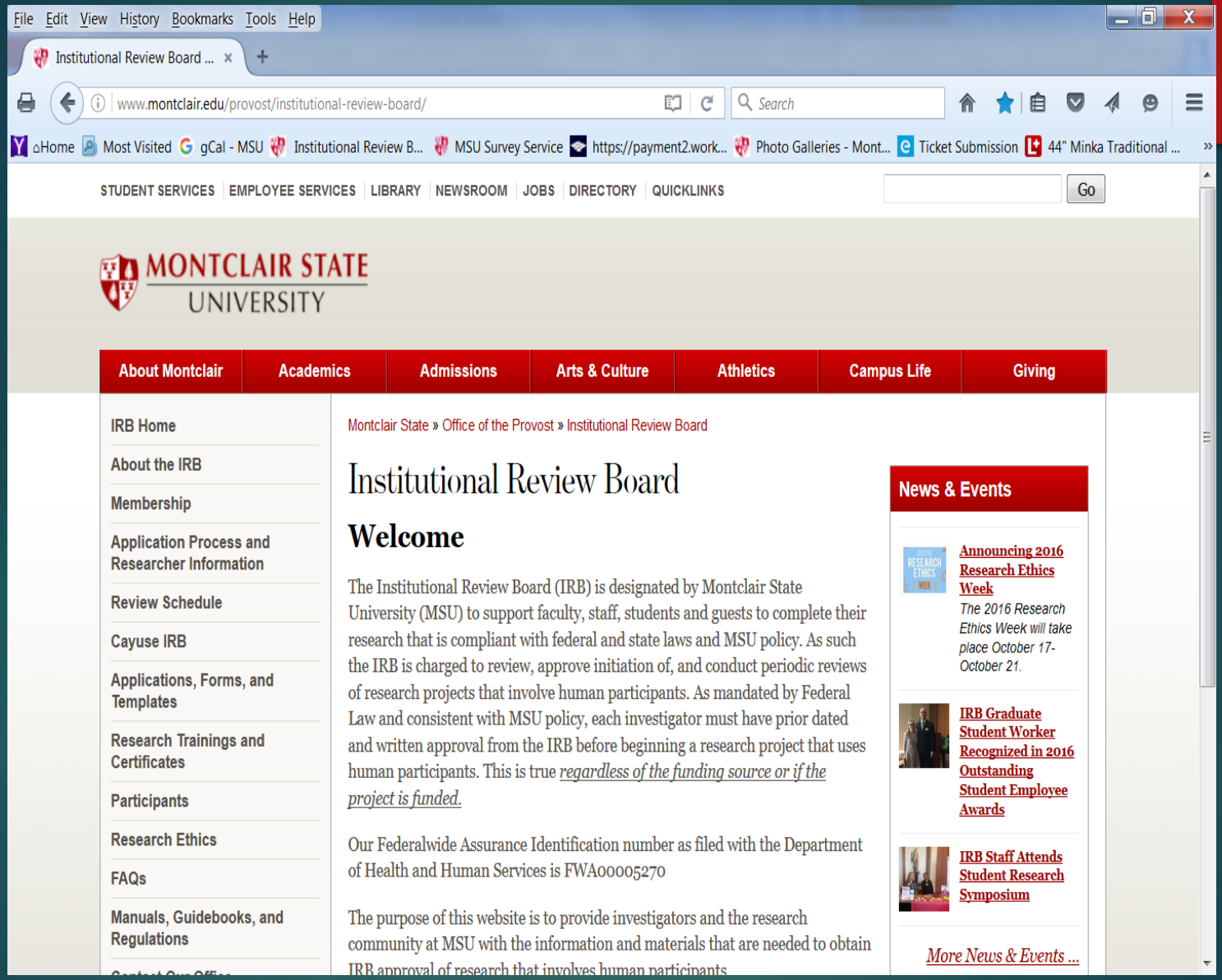
If the research team needs to make changes, click "return." If it is ready to be submitted, click "certify."



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

My Application was approved: what now?

- Use the consent form(s) and other documents for your study participants, print directly from Cayuse (everyone gets a CF copy)
- Report any adverse events to the IRB within 72 hours (Cayuse)
- Submit a Modification (amendment) if you plan to change your research protocol
- Add research team members a Modification submission to add/change personnel
- Don't let your approval expire! Your study expires on the expiration date in Cayuse, if you have not submitted a Renewal, you will have to start with a New Study submission!
- Once your study is complete and you are done with data analysis submit a Project Closure



WHERE TO FIND THE MOST RESOURCES? ONLINE!

Ask for Help

- Email us your questions, reviewboard@Montclair.edu
- Make an appointment, we can review your draft application materials **before** you submit them.
- Visit our FAQs

Contact information

- Senior IRB Coordinator: Amy Krenzer
  - reviewboard@montclair.edu
  - Ext. 7583
- Compliance Coordinator IRB & IACUC: Mylka Biascochea
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  - Ext. 3021
- Research Compliance Officer: Hila Berger
  - bergerh@montclair.edu
  - Ext. 7781
- IRB Chair: Dr. Katrina Bulkley
  - Ext. 5189
- IRB Office: NURS - 333

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Questions

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