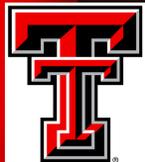


CAYUSE IRB CREATING A NEW SUBMISSION



TEXAS TECH UNIVERSITY
Human Research
Protection Program™

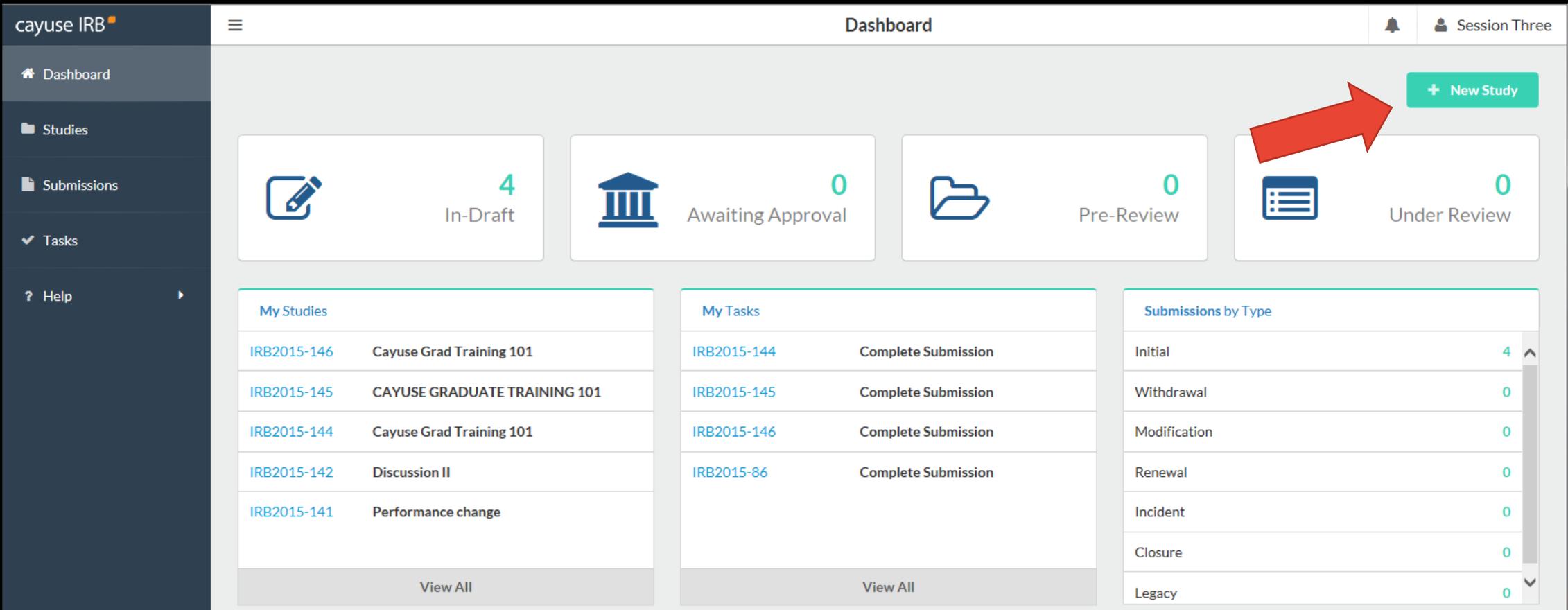
January 2016

FIELD TYPES

- *** 1.1 Review Type** - A red asterisk indicates a required answer. A green check will appear next to a section that is complete. A submission is forwarded for certification or review when all required questions are answered.
- **Boolean boxes** – Once a box in a question is checked, some answer **must** be made.
- **Check boxes** – Boxes can be checked and unchecked. Checking a box will commonly solicit more information below the topic.
- **FIND PEOPLE** - Clicking on this box allows the user to select the names of faculty, staff, and/or students. Names not found in the system require a “User Access Request Form” to be sent to the HRPP/IRB for processing. Find the form at hrpp.ttu.edu.
- **Free text fields** – Information can be typed into these fields or copied and pasted from another document.
- **ATTACH** - MS Word or Adobe .pdf documents can be attached.

CREATING A NEW STUDY

- Click on the  button in the top right corner of the screen.



The screenshot displays the cayuse IRB Dashboard. The top navigation bar includes the logo 'cayuse IRB', a hamburger menu, the title 'Dashboard', a notification bell, and the user name 'Session Three'. A sidebar on the left contains navigation links for Dashboard, Studies, Submissions, Tasks, and Help. The main content area features four summary cards: 'In-Draft' (4), 'Awaiting Approval' (0), 'Pre-Review' (0), and 'Under Review' (0). A red arrow points to the '+ New Study' button in the top right corner. Below the cards are three data tables: 'My Studies', 'My Tasks', and 'Submissions by Type'.

My Studies	
IRB2015-146	Cayuse Grad Training 101
IRB2015-145	CAYUSE GRADUATE TRAINING 101
IRB2015-144	Cayuse Grad Training 101
IRB2015-142	Discussion II
IRB2015-141	Performance change
View All	

My Tasks	
IRB2015-144	Complete Submission
IRB2015-145	Complete Submission
IRB2015-146	Complete Submission
IRB2015-86	Complete Submission
View All	

Submissions by Type	
Initial	4
Withdrawal	0
Modification	0
Renewal	0
Incident	0
Closure	0
Legacy	0

CREATING THE STUDY TITLE

- Enter the name of the study.
- Click on the blue checkmark.

Study Details Submissions

ENTER THE NAME OF THE STUDY HERE 

 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.			

CREATING THE INITIAL SUBMISSION

- Notice the new IRB number and the title.
- Click on the **+ New Submission** button and then **Initial**

The screenshot displays a web application interface for 'Study Details'. At the top, there is a navigation bar with a hamburger menu icon, the title 'Study Details', a notification bell icon with a red '1', and a user profile icon labeled 'Session Three'. Below the navigation bar, the breadcrumb 'Studies / Study Details' is visible. The main content area features a tabbed interface with 'Study Details' and 'Submissions'. The 'Submissions' tab is active, showing a list of submissions. A red box highlights the submission 'IRB2015-328 Cayuse IRB - TEST STUDY' under the 'Unsubmitted' status. Below this submission are 'PDF' and 'Delete' buttons. A red arrow points to the 'IRB2015-328' text. To the right, a red arrow points to the '+ New Submission' button, and another red arrow points to the 'Initial' dropdown menu that appears below it. At the bottom of the page, there are five columns of information: 'Approval Date: N/A', 'Expiration Date: N/A', 'Organization: N/A', 'Sponsors: N/A', and 'Active Submissions: N/A'.

Study Details

Studies / Study Details

Unsubmitted

IRB2015-328 Cayuse IRB - TEST STUDY

PDF Delete

Approval Date: N/A

Expiration Date: N/A

Organization: N/A

Sponsors: N/A

Active Submissions: N/A

+ New Submission

Initial

ENTERING THE STUDY

- Notice the new screen name – Submission Details
- Notice the In-Draft stage status
- Click on the Edit button to begin the study entry.

Studies / Study Details / Submission Details

1 **In-Draft**
Submission is with researchers

2 **Awaiting Approvals**
Submission is awaiting certification or approval

3 **Pre-Review**
Submission is being prepared for review

4 **Under-Review**
Submission is with reviewers

Unsubmitted

Initial
IRB2015-327 - Cayuse IRB - TEST STUDY

Edit PDF Delete Checklist

PI:	Current Analyst:	Decision:	Required Tasks:
Session:	N/A	N/A	✓ Assign PI
Review:	Review Board:	Meeting Date:	• Assign PC
N/A	N/A	N/A	• Complete Submission

THE SECTION MENU⁷

The image shows a screenshot of a web-based submission form. On the left is a vertical 'Sections' menu with 18 items, each with a partial green line at the bottom. A yellow border highlights the menu. A red arrow points from the 'IS1 - Review Type' item in the menu to the corresponding section in the main form area. Another red arrow points from the 'IS5 - Expedited Review' item in the menu to the 'Expedited' radio button in the form. The main form area shows the 'IS1 - Review Type' section with the following content:

IS1 - Review Type

* 1.1 Review Type

Select the appropriate review type.

Exempt

Expedited
Project involves no more than ordinarily encountered in da

Full Board

1.2 External Research

Collaboration

International research.
* List the country and/or region

* Does the country or region where the research is conducted have a human subjects protection program?
<http://www.hhs.gov/ohrp/ir/>

Yes
* Attach any documents

No

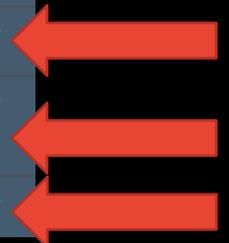
* Does this country have any research involving human subjects?
 Yes
 No

- Note the various sections of the submission form.
- The sections that appear are related directly to the type of review selected. When Expedited is checked, sections IS5 and IS11 appear. Those sections are not available if the Exempt level of review is selected.
- Note the partial green line below the section. A partial green line at the bottom of a section indicates there are required fields that have not been answered.

THE SECTION MENU

IS2 - Research Team	✓
IS3 - Funding	✓
IS5 - Expedited Revi...	✓
IS7 - Rationale	✓
IS8 - Human Subjects	✓
IS9- Recruitment Pr...	✓
IS10 - Data Collectio...	✓
IS11 - Consent, Asse...	✓
IS12 - Participant Co...	✓
IS13 - Privacy, Confi...	✓
IS14 - Benefits, Risk,...	✓
IS15 - Conflicts of In...	✓
IS16 - Training	✓
IS17 - Additional Inf...	✓
IS18 - Comments	✓

- When a section has been completed, a green check will appear opposite the section name.
- **NOTE:** If nothing is to be entered in sections 15-17, open up the section and close it. A green check mark will appear.

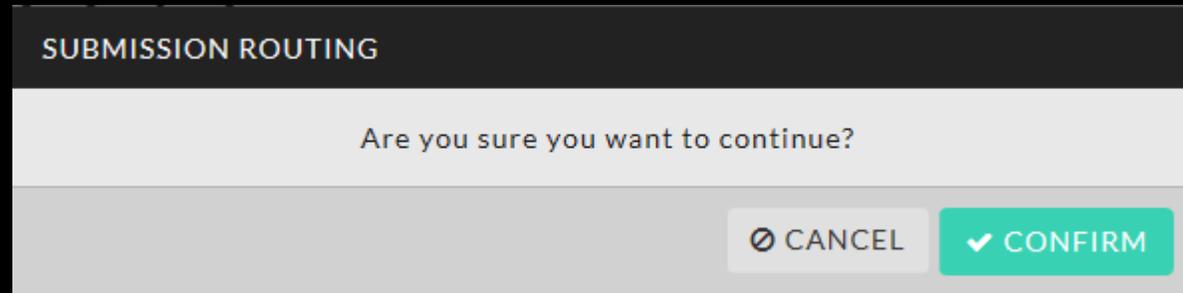


COMPLETING A SUBMISSION

- A Routing and COMPLETE SUBMISSION option will be available at the bottom of the menu once each section is checked.

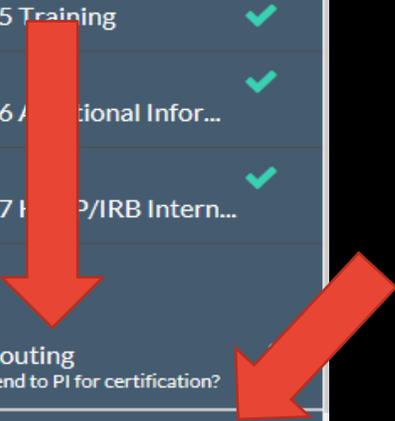
- Click on 

- A Submission routing window will appear.



- Click  > The study is now waiting **Certification**.

- 1 General Informati...
- 2 Research Team ✓
- 3 Funding ✓
- 5 Expedited ✓
- 7 Rationale ✓
- 8 Human Subjects ✓
- 9 Recruitment Proce... ✓
- 10 Data Collection P... ✓
- 11 Consent, Assent... ✓
- 12 Participant Paym... ✓
- 13 Privacy, Confide... ✓
- 14 Benefits, Risk & L... ✓
- 15 Training ✓
- 16 Additional Infor... ✓
- 17 IRB Intern... ✓
- Routing
Send to PI for certification?
- COMPLETE SUBMISSION >



SUBMISSION PROCESS COMPLETE¹⁰

- Notice both the Awaiting Approvals stage status and the Awaiting Certification label.
- (PI View) - Observe that routing allows for the PI to return it back for revisions, or;
- The PI can certify the study and forward it to the HRPP.

The screenshot displays the 'Submission Details' page for a study titled 'IRB2015-327 - Cayuse IRB - TEST STUDY'. The submission process is shown in four stages: 1. In-Draft (Submission is with researchers), 2. Awaiting Approvals (Submission is awaiting certification or approval), 3. Pre-Review (Submission is being prepared for review), and 4. Under-Review (Submission is with reviewers). The 'Awaiting Approvals' stage is highlighted with a red oval. A tooltip labeled 'Awaiting Certification' is also highlighted with a red oval. Below the submission details, there are buttons for 'View', 'PDF', 'Delete', and 'Checklist'. On the right side, there are 'Routing:' buttons for 'Return' and 'Certify', with a red arrow pointing down to the 'Certify' button and another red arrow pointing up to the 'Return' button. The page also shows the PI (Session Three), Current Analyst (N/A), Decision (N/A), Required Tasks (N/A), Review Type (N/A), Review Board (N/A), and Meeting Date (N/A).

Submission Details

Studies / Study Details / Submission Details

In-Draft
Submission is with researchers

2 Awaiting Approvals
Submission is awaiting certification or approval

3 Pre-Review
Submission is being prepared for review

4 Under-Review
Submission is with reviewers

Awaiting Certification

Initial
IRB2015-327 - Cayuse IRB - TEST STUDY

View PDF Delete Checklist

Routing: Return Certify

PI: Session Three
Current Analyst: N/A
Decision: N/A
Required Tasks: N/A
Review Type: N/A
Review Board: N/A
Meeting Date: N/A

QUESTIONS

Contact the HRPP/IRB

806-742-2064 or

hrpp@ttu.edu