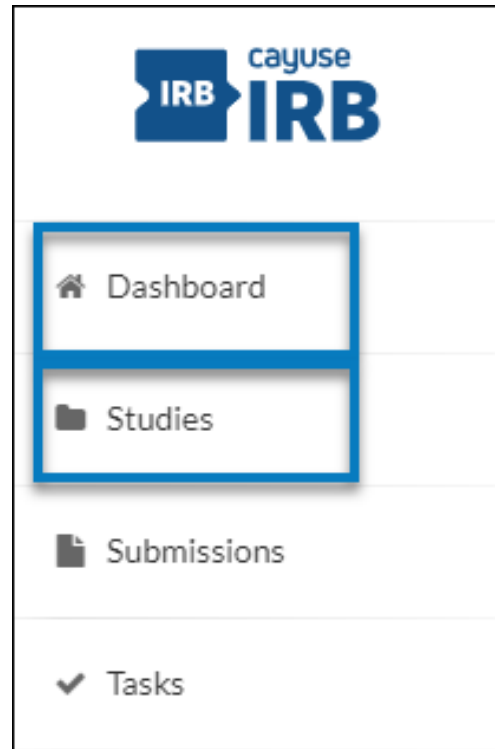
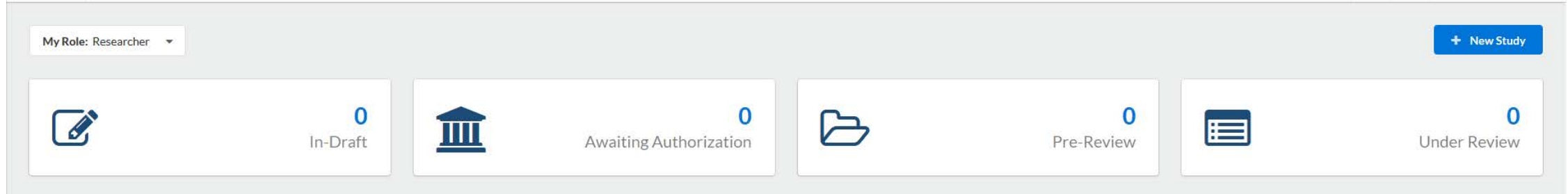


Creating a New Study (Initial Submission) in Cayuse

As an IRB Researcher, you can create a new study from your Dashboard or the Studies page within Cayuse IRB.




Click  in the upper right-hand corner of your Dashboard or the Studies page.





My Role: Researcher ▼ + New Study



Status	Count
In-Draft	0
Awaiting Authorization	0
Pre-Review	0
Under Review	0

Enter the title of your study. The title can be up to 600 characters long. Click  to save your study

[Studies](#) / Study Details + New Submission

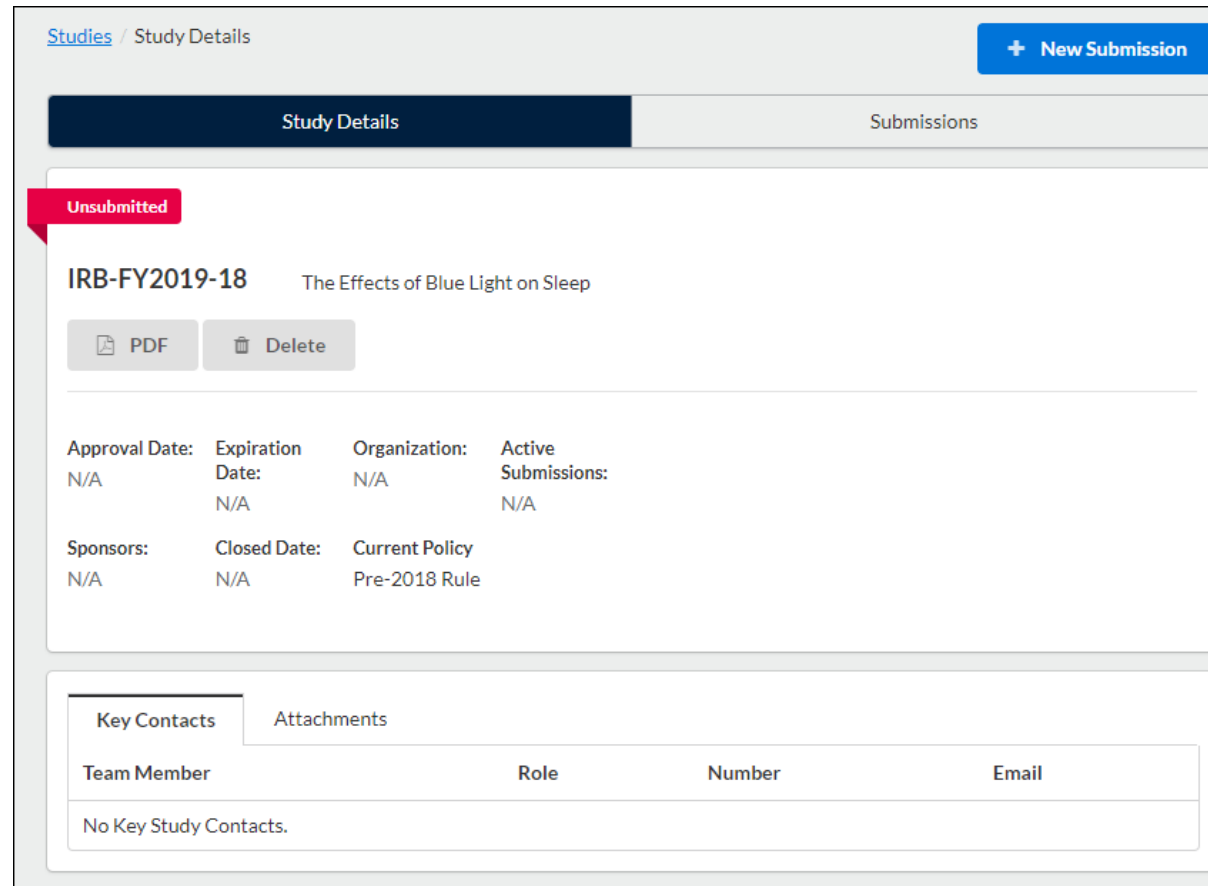
Study Details Submissions

Enter study title here  

 PDF  Delete

Approval Date: N/A	Expiration Date: N/A	Organization: N/A	Active Submissions:	Population Flags:	Additional Flags:
Sponsors: N/A	Closed Date: N/A	Current Policy			

After creating your study, you will be taken to the Study Details page. Here, you will see where important study information will populate once you begin your submission.



[Studies](#) / Study Details + New Submission

Study Details Submissions

Unsubmitted

IRB-FY2019-18 The Effects of Blue Light on Sleep


[PDF](#) [Delete](#)

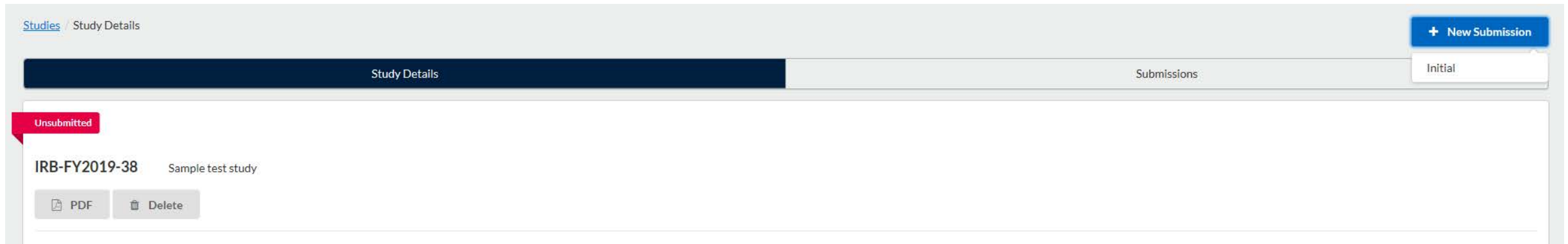
Approval Date:	Expiration Date:	Organization:	Active Submissions:
N/A	N/A	N/A	N/A
Sponsors:	Closed Date:	Current Policy	
N/A	N/A	Pre-2018 Rule	

Key Contacts Attachments

Team Member	Role	Number	Email
No Key Study Contacts.			

Once you create your study, you can begin your initial submission.

- Click on  and the Initial tab under new submission in the upper right-hand corner to start completing your form.



The screenshot displays a web interface for managing studies. At the top left, there is a breadcrumb trail: [Studies](#) / Study Details. In the top right corner, there is a blue button labeled "+ New Submission". Below this, a dark blue bar contains two tabs: "Study Details" (which is active) and "Submissions". To the right of the "Submissions" tab, there is a dropdown menu with "Initial" selected. Below the tabs, a red notification box on the left says "Unsubmitted". The main content area shows the study ID "IRB-FY2019-38" and the name "Sample test study". Below this, there are two buttons: "PDF" (with a document icon) and "Delete" (with a trash icon).

Click on Complete Submission to start completing your application

[Studies](#) / [Study Details](#) / Submission Details

- 1 In-Draft**
Submission is with researchers
- 2 Awaiting Authorization**
Submission is awaiting certification or approval
- 3 Pre-Review**
Submission is being prepared for review
- 4 Under-Review**
Submission is with reviewers

Unsubmitted

Initial
IRB-FY2019-38 - Sample test study


[Edit](#) [PDF](#) [Delete](#)

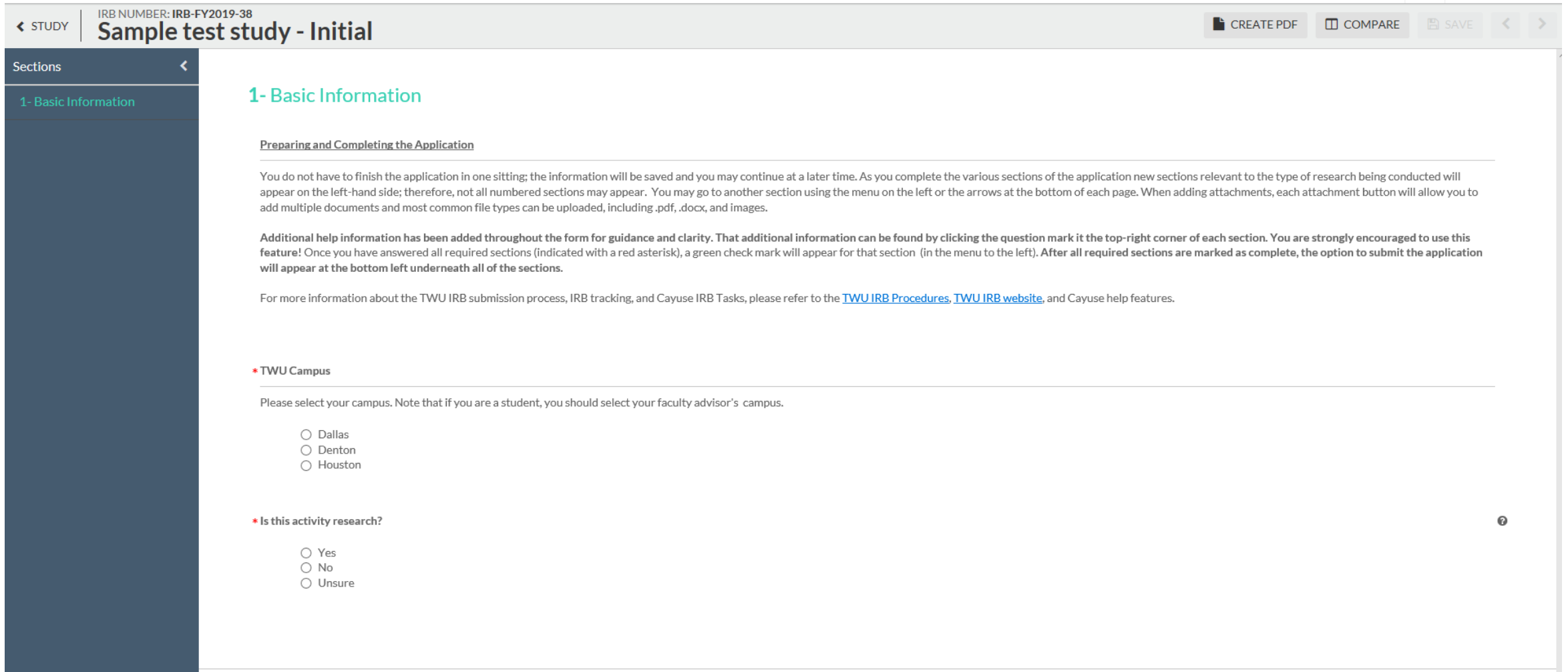
PI:	Current Analyst: N/A	Decision: N/A	Policy: Pre-2018 Rule	Required Tasks: <ul style="list-style-type: none">Assign PI✓ Assign PCComplete Submission ←
Review Type: N/A	Review Board: N/A	Meeting Date: N/A		

[Approvals](#) [Task History](#)

Research Team

Name	Role	Result	Date
No entries.			

Begin by selecting the appropriate campus. Answering questions will open up additional sections on the left. Please note: Some questions have  next to the question number. This indicates a required question.



← STUDY | IRB NUMBER: IRB-FY2019-38
Sample test study - Initial CREATE PDF COMPARE SAVE ← →

Sections <

1- Basic Information

1- Basic Information

Preparing and Completing the Application

You do not have to finish the application in one sitting; the information will be saved and you may continue at a later time. As you complete the various sections of the application new sections relevant to the type of research being conducted will appear on the left-hand side; therefore, not all numbered sections may appear. You may go to another section using the menu on the left or the arrows at the bottom of each page. When adding attachments, each attachment button will allow you to add multiple documents and most common file types can be uploaded, including .pdf, .docx, and images.


Additional help information has been added throughout the form for guidance and clarity. That additional information can be found by clicking the question mark in the top-right corner of each section. You are strongly encouraged to use this feature! Once you have answered all required sections (indicated with a red asterisk), a green check mark will appear for that section (in the menu to the left). After all required sections are marked as complete, the option to submit the application will appear at the bottom left underneath all of the sections.

For more information about the TWU IRB submission process, IRB tracking, and Cayuse IRB Tasks, please refer to the [TWU IRB Procedures](#), [TWU IRB website](#), and Cayuse help features.

*TWU Campus

Please select your campus. Note that if you are a student, you should select your faculty advisor's campus.

- Dallas
- Denton
- Houston

* Is this activity research? 

- Yes
- No
- Unsure

Person and/Sponsor Finders: Begin by adding the Principal Investigator. Depending on the people involved you may have to add other people or sponsors to different sections within your submission. The person who creates the study is added as the Primary Contact by default, but this can be changed when editing the submission. Click on the finder button to bring up a search dialogue.

- Sections <
- 1- Basic Information ✓
- 2- Research & Review ✓
- 3- Study Personnel Information
- 4- Study Design & Method...
- 5- Subject Information
- 6- Subject Recruitment
- 7- Study Procedures
- 9- Study Instruments

3- Study Personnel Information

*What is your status at TWU?

- Faculty
- Student
- Staff
- Other

Study Personnel

Note: If you cannot find a person in the people finder, please contact the IRB Office.

*Principal Investigator

Provide the name of the Principal Investigator of this study.

FIND PEOPLE 

*Primary Contact

Provide the name of the Primary Contact of this study.

Name	Organization	Address	Phone	Email	Trainings	
Applicant name	Nursing - Houston	Texas Woman's University 6700 Fannin, Houston, TX 77030-2343		research@twu.edu	View	x

Co-Principal Investigator(s)

Provide the name(s) of Investigator(s) for this study.

FIND PEOPLE 

Other TWU Research Team Members

Provide the name(s) of other TWU research team members for this study. Note: If you cannot find a person in the people finder, please contact the IRB Office.

FIND PEOPLE

Human Subjects Training Certificates

If a research team member has not completed the CITI human subjects training but has a current NIH certificate (must be less than 3 years old), please attach it here.

Find People – To add study personnel information in Section 3

- Search for the individual or sponsor that you wish to add, select them from the list, and click **Save**.

UNDEFINED



bellason

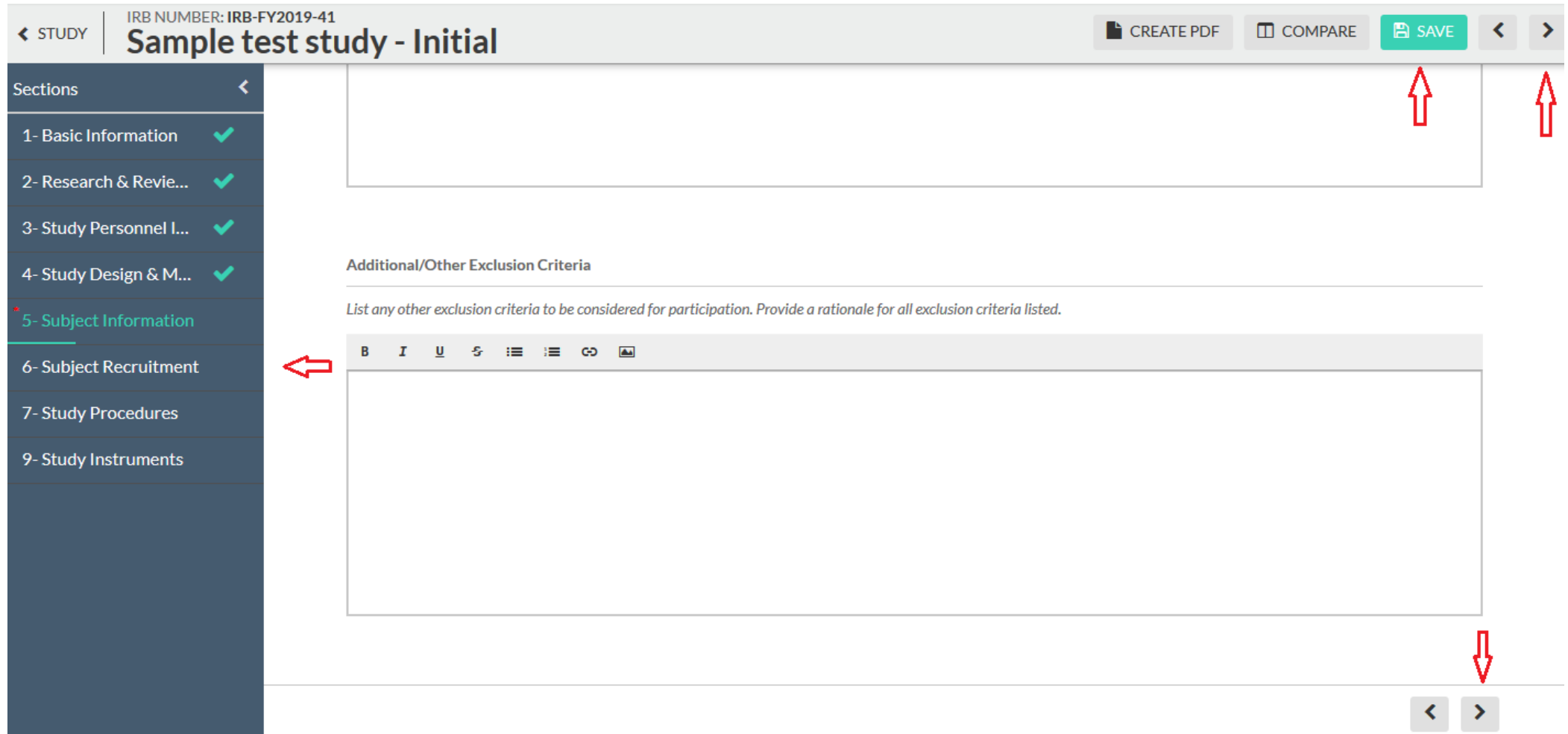
Name	Organization	Email	Phone
Use the search box above to find records.			

Selected Records * Select a single record.

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

CANCEL SAVE

Ensure that you  your progress as you move to different sections. You can move to different sections using the  or by clicking on the section/s in the left



The screenshot displays a web interface for managing a study. At the top, the header includes a back arrow, the word "STUDY", the IRB number "IRB-FY2019-41", and the study title "Sample test study - Initial". To the right of the title are buttons for "CREATE PDF", "COMPARE", "SAVE", and navigation arrows. The left sidebar, titled "Sections", lists nine items: "1- Basic Information", "2- Research & Review...", "3- Study Personnel I...", "4- Study Design & M...", "5- Subject Information", "6- Subject Recruitment", "7- Study Procedures", and "9- Study Instruments". The "5- Subject Information" item is highlighted in blue and has a red arrow pointing to it. The main content area is titled "Additional/Other Exclusion Criteria" and contains a text editor with a toolbar (B, I, U, S, list icons, link icon, image icon) and a large text input field. A red arrow points to the bottom right corner of the page, where there are two navigation arrows.

Attachments: Upload one or more files to the study by clicking

STUDY | IRB NUMBER: IRB-FY2019-38
Sample test study - Initial

CREATE PDF COMPARE SAVE < >



Sections <

- 1- Basic Information ✓
- 2- Research & Review ✓
- 3- Study Personnel List ✓
- 4- Study Design & Methods ✓
- 5- Subject Information ✓
- 6- Subject Recruitment ✓
- 7- Study Procedures ✓
- 8- Informed Consent ✓
- 9- Study Instruments
- 10- Risks & Benefits
- 11- Protecting the Confidentiality

9- Study Instruments

Study Instruments

Attach any data collection instruments (e.g., data collection forms, surveys, questionnaires, interviews, focus group discussion, etc.) that will be used in the study.

* Will these instruments record any information that can identify the subjects?

Yes
 No

< >

You can also include hyperlinks as "attachments" by choosing Add Link from the + drop-down menu. Cayuse IRB supports the file types listed below



File Type	Extension
Text	txt
Adobe	pdf
Raster image formats	png, bmp, gif, tif, tiff, jpg, jpeg, jp2, jpx
Vector image formats	wmf, emf, svg
Microsoft Word	doc, docx, docm
Microsoft Excel	xls,xlsx, xlsxm
Microsoft PowerPoint	ppt, pps, pptx, pptm, ppsx, ppsm, sldx, sldm

You will be able to click **COMPLETE SUBMISSION** and submit only when you have answered all required questions in each section, see a green check mark for each section, and saved the application.

IRB NUMBER: IRB-FY2019-41

STUDY | **Sample test study - Initial**

CREATE PDF COMPARE SAVE

Sections

- 1- Basic Information ✓
- 2- Research & Review ✓
- 3- Study Personnel Information ✓
- 4- Study Design & Methods ✓
- 5- Subject Information ✓
- 6- Subject Recruitment ✓
- 7- Study Procedures ✓
- 8- Informed Consent ✓
- 9- Study Instruments ✓
- 10- Risks & Benefits ✓
- 11- Protecting the Confidentiality of Subjects ✓

Routing
Send to PI for certification?

COMPLETE SUBMISSION

Identify specific ways that the documents containing identifiable private information will be destroyed at the end of this period of time.

Shredded

No

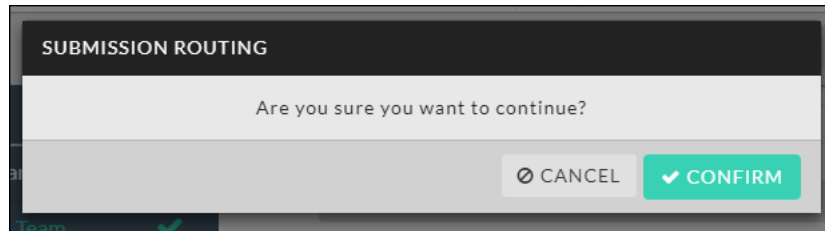
*** Electronic Transmission of Identifiable Private Information/Data**

Because the academic component of TWU is classified as non-covered HIPAA entity, identifiable health or health-related data cannot be transmitted electronically.

Does this research involve health or health-related data?

Yes No

After clicking Complete Submission, you will be prompted to **Confirm** or **Cancel**.



Once you Confirm your submission you will be directed back to study details page to Certify your submission. You will also have option to view your submission as PDF. Click certify.

In-Draft
Submission is with researchers

2 Awaiting Authorization
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
IRB-FY2019-41 - Sample test study

View PDF Delete

Routing: Return Certify

PI: PI name appears here

Current Analyst: N/A

Decision: N/A

Policy: Pre-2018 Rule

Required Tasks: N/A

Review Type: N/A

Review Board: N/A

Meeting Date: N/A


Approvals Task History

Research Team

Name	Role	Result	Date
PI name appears here	Principal Investigator	Pending Certification	

Confirm your certification. A Certify the submission notification email will go out to all your Co-investigator/s, Faculty Advisor (if PI is a student) and the Department Administrator. Once everyone listed certifies, the application gets submitted for IRB review

Certify



I confirm that I have the proper training, expertise and resources to conduct this study. I understand and accept my responsibilities as the Principal Investigator and Primary Contact for this study. I confirm that I have no significant financial conflict of interest in this project or have disclosed a conflict per institutional policies and federal requirements. I confirm that the information provided in this application is true, complete, and accurate to the best of my knowledge; that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties; and agree to accept responsibility for the oversight and scientific conduct of the project.