# **Cayuse How-Tos**

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### **Accessing Cayuse IRB**

1. Click on the blue button on the IRB's main web page.



- 2. Log in using your Liberty username and password.
  - If you receive the "forbidden" message when you attempt to log in, this means we'll need to manually create your profile in Cayuse. Click <u>here</u> to request a profile.
- 3. On the next screen, please click the down arrow next to **Products** and choose **Human Ethics**:

cayuse platform Home						Products	
	м	ly Tasks				Home Human Ethics	New
					Assigned to Me Creater	d by Me	Open
Task ≎	Task Type	From	Assigned To	Created \$	Last Activity	Due 👻	Status
	Nos	Saved Tasks					

4. You should now be at the dashboard screen:

cayuse								🌲 🔺 Keanu Reeves
Dashboard	Studies	Submissions	Tasks					
								+ New Study
		<b>2</b> In-Draft	<b>1</b>	Awaiting Authoriza	tion	Pre	0 e-Review	<b>0</b> Under Review
My Studies				My Tasks			Submissions by Type	
IRB-FY19-20-26	I love the IR	B!		IRB-FY19-20-30	Complete Submission		Renewal	0
IRB-FY19-20-30		udy title. There are ma	ny others like it,	IRB-FY19-20-26	Complete Submission		Initial	2
	but this is m	ine.					Modification	0
							Incident	0
							Withdrawal	0
							Closure	0
							Legacy	0
		View All			View All			
Annround Stur	llec			Studiae Evolving in 30	dave 👻		Evolved Studies	

5. If you ever have questions while using Cayuse, contact the IRB. You can also click the orange question mark in the lower right corner. The help button has videos, a search feature, and may on occasion provide important announcements from Cayuse.

## **Creating an IRB Application (New Study)**

- 1. Click + New Study in the upper right-hand corner of your Dashboard *or* the Studies page.
- 2. Enter the title of your study. The title can be up to 600 characters long.



3. Click to save your study.

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:

tudies / Study D	etails				+ New Submis
	Study	Details			Submissions
Unsubmitted					
IRB-FY2019	<b>7-18</b> The	Effects of Blue Li	ght on Sleep		
D PDF	🛍 Delete				
Approval Date: N/A	Expiration Date: N/A	Organization: N/A	Active Submissions: N/A		
Sponsors: N/A	Closed Date: N/A	Current Policy Pre-2018 Rule			
Key Contact	ts Attach	ments			
Team Membe	r		Role	Number	Email
No Key Study	Contacta				

You can rename your study up until the completion of a withdrawal or admin closure submission. From the Study Details screen, hover over the study title and click within the field to edit.

Once you create your study, you can <u>begin your initial submission</u>. Click on the upper right-hand corner to start completing your forms.

### Filling out an IRB Application (Initial Submission)

After you create a new study, you can begin completing forms for your initial submission by clicking on **New Submission**, and then clicking **Initial** from the drop-down menu.

1	🛔 Larry	LeadPrincipalInvestigator
		+ New Submission
	Subr	Initial

Submission information will populate beneath the Submission Details tab. The person who creates the study is added as the Primary Contact by default, but this can be changed when editing the submission. Make sure to not remove yourself from all roles and to Save, or you will not be able to access your submission once you leave.

Click on <sup>e Edit</sup> to begin your submission forms. You will always be able to return to your incomplete submission by clicking this button.

Once on the initial submission form, you can return to the Submission Details page by clicking on **Study** in the upper left-hand corner of the screen.

≡ Menu		
	The Effect	<sup>Y2019-18</sup> ts of Blue Light on

Use the buttons to toggle between sections. You can also click on a section name in the menu at left to jump to that section:



# **Application Question Types**

There are several types of questions that are included on the submission forms:

• Radio Buttons: Select one of the available options.



• Check Boxes: Select one or more of the available options.

Inclusion Criteria	
<ul> <li>Cognitively impaired</li> <li>Individuals who are in Pregnant women</li> <li>Prisoners</li> </ul>	l adults not yet adults (under 18 years of age)

• Date Picker: Click within the field to browse for a date.

Start Date	
Ĩ	<b>***</b>
~	

• **Text Box:** Provide a short answer to the stated question (200-character limit). If you need to enter multiple lines of text, the box will expand to fit.

Location 1		
1		

• **Text Area:** Provide a detailed answer to the stated question. You can use formatting such as bold, italics, underline, strikethrough, bulleted lists, numbered lists, and hyperlinks.

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		be th ester		pose,	speci	fic ain	ns, or	objectives. State the hypotheses	
	в	I	U	s	:=	:=	œ		
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- You can also add PNG or JPG images using the image button . Once your image is inserted, you can edit the image by clicking on the image and then clicking Edit.
- **Person and Sponsor Finders:** While every initial submission will require you to add a Primary Contact and Principal Investigator, you may need to add a faculty sponsor or other people within your submission. Click on the finder button to bring up a search dialogue.



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

				×
Name	Organization	Email	Phone	
Bella Bellason 🖑	Laboratory Medicine	bellason@cayuse.com	555-222-1111	+
Isabella Isabellason	Biochemistry	isabellason@cayuse.com	555-222-3333	+
Selected Decords			* Salact a cir	ade reco
Selected Records		et a record and click <b>Save</b> to appl	* Select a sir	ngle recon

• Attachments: Upload one or more files to the study by clicking ATTACH . Cayuse IRB supports the following file types:

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, xlsm
Microsoft PowerPoint	ppt, pps, pptx, pptm, ppsx, ppsm, sldx, sldm

You can also include hyperlinks as "attachments" by choosing Add Link from
the + drop-down menu.

	+ (m	
	Add Link	
	Add File	
s pr	oject.	

To delete an attachment, click the **\*** icon next to the attachment.

**Please note:** Some questions have \* next to the question number. This indicates a required question.

Sections with unsaved changes have an asterisk next to the section name:



### **General How-To Questions**

### How do I find help within the application?

If there is help text for a question, you can click on the 0 button to view the additional information for that question.



### Why is there a red lock on a section?

**Please note:** Cayuse IRB will warn you with a red lock icon if another user is currently editing a section. You won't be able to edit that section until they're done with their edits.



### How do I submit my application?

The **Complete Submission** button will only appear when you have green check marks next to all of your sections. If one of your sections doesn't have a check mark and you aren't sure why, click on the section to search for any required questions you may have missed. Once you have filled out every section of your submission and have added all required attachments, a **Complete Submission** option appears beneath **Routing** within the menu:



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



Upon confirmation, the status of your submission will change on the Submission Details page:



#### How do I change my study title?

To change your study title, click on the study number in My Tasks on your Cayuse Dashboard, then click **Study Details** on the upper left-hand side of the page. Next, hover over the study title and click on the pencil that appears to the right of the existing title. Then, make your edits, and click the green check:



### **Certifying and Returning an Application**

Once you have clicked "complete submission," your application is sent to the PI and other study personnel for certification. Research team members will receive an email letting them know that the submission needs to be certified. When a researcher or faculty sponsor certifies the submission, they are asserting the submission is complete and accurate and are accepting their researcher/faculty sponsor responsibilities.

If the PI or the faculty sponsor decides that changes need to be made, they will send the submission back. All research team members will receive an email notifying them of the change in status so they can make the necessary edits and complete the submission once more. Once all study personnel have certified the submission, the submission will be routed to the IRB. The submission may be returned at any point for edits or clarification.

**Completing Submission as a PI:** If you are a PI completing your submission, you should be able to then certify the submission right away.

**Co-PIs:** Liberty University requires that any Co-PIs on the study also certify the submission. These individuals also have the ability to return to the submission to the research team.

**Faculty Sponsor:** Liberty University requires that the faculty sponsor on the study also certifies the submission. These individuals also have the ability to return to the submission to the researcher/research team.

**Recertification:** If the submission does get returned to the research team, all previous certifications are cleared. All individuals who were required to certify the submission in previous rounds of routing must recertify every time the submission is returned before it can move forward.

#### How to review and certify a submission:

You should receive an email instructing you to certify the submission (remember to check your junk folder if you do not see an email):

DATE: Jan 13, 2020 3:33 PM EST RE: Initial Submission Requires Certification STUDY #: IRB-FY19-20-73 STUDY TITLE: Certify this Study!

The Initial submission for the above-referenced study has been completed. This submission requires your approval as a member of the research team before it can be submitted to the Liberty University IRB. Please log into Cayuse IRB <u>Cayuse IRB</u>; review and certify this submission.

Thank you, Research Ethics Office 434-592-5530

If you click the link, you will be prompted to log in to Cayuse IRB. Log in and navigate to the dashboard.

You can then access the study by selecting the task in your **notifications** or by clicking on the study in the "**My Tasks**" tab:



Select the study that needs to be reviewed and certified. You will then be taken to the submission details page. Once on the submission details page, you will need to review the study. You can do this by clicking **view** or by downloading a **pdf** version of the application:

V In-Draft Submission is with r	researchers	2 Awaiting Authorization Submission is awaiting certification	n or approval 3 Pre-Revi Submission	ew n is being prepared for review	4 Under-Review Submission is with reviewers
Awaiting Certification					
Initial IRB-FY19-20-73 -	ify this Study!				
Tiew PDF					Routing:
	Current Analyst:	Decision:	Policy:	Required Tasks:	
PI: Connor Bryant	N/A	N/A	Post-2018 Rule	N/A	

If after reviewing the study you find that edits need to be made, click return:

2	Awaiting Authorization     Submission is awaiting certifi	ication or approval		Pre-Review Submission is bein	ig prepared for review		4 Under-Re Submission	eview n is with reviewers	
!								Routing	
								Return	Certi
rent Analyst:	Decision:				Required Tasks:				
		Post-2	018 Rule		N/A				
iew Board:	Meeting Date: N/A								
	rent Analyst:	elete rent Analyst: Decision: N/A iew Board: Meeting Date:	elete rent Analyst: Decision: Policy: N/A Pols-2 iew Board: Meeting Date:	rent Analyst: Decision: Policy: N/A Post-2018 Rule iew Board: Meeting Date:	rent Analyst: Decision: Policy: N/A Post-2018 Rule iew Board: Meeting Date:	elete rent Analyst: Decision: Policy: Required Tasks: N/A Post-2018 Rule N/A iew Board: Meeting Date:	elete rent Analyst: Decision: Policy: Required Tasks: N/A Post-2018 Rule N/A iew Board: Meeting Date:	elete rent Analyst: Decision: Policy: Required Tasks: N/A Post-2018 Rule N/A iew Board: Meeting Date:	elete Policy: Policy: Policy: Required Tasks: N/A Post-2018 Rule N/A iew Board: Meeting Date: Policy: Post-2018 Rule N/A Post-2018 Rule Policy: Poli

Once **return** is selected, any member of the study team will be able to make edits to the application:

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	t on is with researc	hers	> 2	Submission is awaiting ce		val 🔰 🕃
Unsubmitted						
Onsubmitted						
		•				
Initial						
	)-73 - Certify tl	his Study!				
IRB-FY19-20						
	)-73 - Certify tl	his Study!				
IRB-FY19-20						
IRB-FY19-20				Decision:		Policy:
IRB-FY19-20		🛍 Delete		Decision:		Policy:
IRB-FY19-20	PDF *	🛍 Delete		Decision: N/A Meeting Date:		Policy: Post-2018 F

If after reviewing the study you find that it is ready for submission to the IRB, click certify:

<ul> <li>In-Draft Submission is with</li> </ul>	researchers	2 Awaiting Authorization Submission is awaiting certification	on or approval 3 Pre-Revi	ew n is being prepared for review	4 Under-Review Submission is with reviewers	
vaiting Certification						
<b>itial</b> B-FY19-20-73 - Cer	tify this Study!					
I View PDF	▼ Delete				Routing: Return	Certify
nnor Bryant	Current Analyst: N/A	Decision: N/A	Policy: Post-2018 Rule	Required Tasks: N/A		•
	19/5	19/75	1030 2010 Kulc	1973		

### How to Find and Respond to Revision Requests

When your study is returned to you in Cayuse IRB, you will need to re-open your study and find the revision request comments. To re-open your study, go to your Cayuse dashboard, and click on "My Tasks." Your study should appear in this tab. The task should state "Complete Submission." **Click on the study in need of revisions**:

IRB#	Task	Study Title
IRB-FY19-20-97	Certify Submission	MPH Training
IRB-FY19-20-127	Complete Submission	Test Study

Once you are on the study details page, **click on "edit" to re-open your study**:

1	In-Draft Submissi	t on is with r	esearc	hers		2	Awai Subm
Reop	ened						
Init	<b>ial</b> FY19-20	-154 - Ti	tle				
			-			klist	

Once you have opened your study, **revision comments appear to the right of the sections** with a comment bubble and the number of revisions requests in that section:

SUBMISSION DETAILS	Th
Sections	<
Basic Project Inform	×
Participant Informat	× .
Recruitment	× .
Consent	*
Procedures	9
Data Security	9
Risks & Benefits	× 1
Attachments	×

To make revisions, **click on the section with the revision request comments**. You should then be able to see where exactly a revision was requested by looking for the numbered comment bubble:



You will then have the option to **make the change within the application** itself, **or reply to the reviewer's comment** directly. Once you have addressed the revision request, you can mark the revision request as "Addressed."



Once all revision requests have been addressed, each section should have a green check mark, and the "Complete Submission" button should appear underneath the application sections. Click **complete submission to re-submit the application**. You and your faculty chair *(if applicable)* will once again be asked to **certify the submission**. Once certified, the IRB receives the revised application for review:



### How to Make Changes to an Approved Study (Modification)

To make changes to an approved study, you will need to create and submit a modification submission. To start, find the study that you need to make changes to by **clicking on the studies tab**:



Next, click on the specific study you need to change:

	Active Archive			
	Q © Status: Approv	ved		
	IRB#	Study Title	Status	Ы
	IRB-FY21-39	Study One	<ul> <li>Approved</li> </ul>	Researcher One
	IRB-FY21-26	Study Two	Approved	Researcher Two
	\_/ <u>IRB-FY21-18</u>	Study Three	Approved	Researcher Two
1	RB-FY19-20-23	Yet another study	Approved	Mickey Mouse

This takes you to the **study details** page. Once on this page, click the button. You will then want to select **modification**:

+ New Submission

Role: Researcher V Parkson Role: Researcher V Reversion New Submission Renewal Modification Incidev Closure Click on Edit to begin your submission:

Studies / Study Details / Submission Details								
1 In-Draft Submission is with researchers								
Unsubmitted Modificatio IRB-FY21-26								
edit مراجع	PDF 🔻	🛱 Delete						
PI: Researcher Two	D	<b>Current Analyst:</b> N/A	:					

Once you click **edit**, you will be asked whether or not a modification is *actually* required (based on a list of provided examples). If after reviewing the list, you determine that a modification is **not** necessary, **please select "No"** and delete the modification submission.

\* Based on the above information, do you need to make changes to the project?



If you determine that a modification **is necessary**, you will need to answer "Yes." You will then be provided with an exact copy of your original, approved submission. You will then be able to click through the application to make any changes to this copy.

\* Based on the above information, do you need to make changes to the project?



Once you have made the necessary changes, you will need to **click "Complete Submission**" and then **certify your submission**:

