CAYUSE Human Ethics: Faculty Advisor – Protocol Submission Guide

Student Access to the Cayuse System

- Students will need to be setup in Cayuse otherwise they will not have access to the system.
- The faculty advisor can submit the access request on behalf of the entire class, for specific individuals, OR students may submit their own request using the <u>Cayuse</u> <u>Access Request Form</u>.

Pro Tip: If most of a class will need access, submit the access request in advance for the entire class. It is okay to submit for the entire class even if some students may not need to submit to the IRB.

The PI must certify the application before the submission will be routed to the IRB office:

- The Faculty Advisor and all student PI's must certify the application to initiate the IRB review process.
- The system will send each PI an email stating the application is awaiting their certification. However, you do not need to wait for the email, you can certify directly from your Cayuse Dashboard.

Faculty Advisor "Approval" Certification

You will receive an email "Initial Submission Requires Certification"

 From: WP-IRB-uat-do-not-reply@cayuse.com

 Sent: Tuesday, November 19, 2024 11:20 AM

 To: Julie Moore <<u>cayusechairwpu@gmail.com</u>>; LeMay, Duncan <<u>ga-lemayd3@wpunj.edu</u>>; Julie Moore <<u>cayusechairwpu@gmail.com</u>>; LeMay, Duncan <<u>ga-lemayd3@wpunj.edu</u>>; Julie Moore <<u>cayusechairwpu@gmail.com</u>>; Subject: Initial Submission Requires Certification

TO: Julie Moore,Duncan LeMay, Julie Moore
Department of Biochemistry - TEST
FROM: William Paterson University Institutional Review Board
DATE: Nov 19, 2024 11:20:17 AM EST
RE: Initial Submission Requires Certification
STUDY #: IRB-FY2025-45
STUDY TITLE: Test Protocol (1)
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 William Paterson University Institutional Review Board. Please log into Cayuse IRB Cayuse IRB; review and certify this submission.
WIlliam Paterson Institutional Review Board

William Paterson University of New Jersey 1800 Valley Road Wayne, NJ 07470

OR You can go directly to Cayuse to Certify:

Logging In (Recommended Browsers: Google Chrome or Firefox)

Step 1: Navigate to the WPU Cayuse Login Portal: https://wpunj.app.cayuse.com/

Step 2: Enter your login information.

Your username and password are the same as your standard WP credentials. This will take you through the DUO process.

Step 3: Click "Sign in".

Once logged in to the system, you will be taken to the Cayuse HomeScreen:

Kayuse platform Home			🏹 Products 👻	A Noah Congelliere
	Му	7 Tasks	I	+ New Task
Assigned to Me Created by Me	Open All			
Task \$	Task Type	From Assigned To	Created Last Activity	Due 🔻 Status
	No Sc	aved Tasks		

Step 4: Click on the "Products" and select "Human Ethics."

		Role:	Researcher 🔻	52	Products 🔹	💄 Bridget Watson 👻
√leetings	Reporting	More			Home]
				\langle	Human Ethics	+ New Study
				ן ר	Outside Interests	
O Awaiting horization		ל	0 Pre-Review		Sponsored Projects	2 nder Review

This should take you to the Human Ethics Dashboard. (You can also click on Dashboard to return to this screen.)

Cayuse Human Ethics		Role: Researcher 👻 🔊 Products 🔹	🖌 🛓 Julie Moore 🔻
Dashboard Studies Submissions Task	cs Meetings		
In-Draft	Awaiting prization	Under Review	+ NewStudy Post Review →
My Studies IRB-FY2025-43 Maureen's Reviewer Test Screens IRB-FY2025-41 Education Major (Case Study Test) 4 IRB-FY2025-38 Test Protocol Submission 2 (Under Studies) IRB-FY2025-24 Kate October 8 IRB Application IRB-FY2025-25 Kate October 8 Exempt Review	My Tasks IRB-FY2025-41 Certify Submission IRB-FY2025-38 Certify Submission IRB-FY2025-25 Complete Submission IRB-FY2025-26 Complete Submission IRB-FY2025-21 Complete Submission	Submissions by Type Renewal Initial Modification Incident Withdrawal Closure Legacy	1 12 1 0 0 0 0 0
View All	View All		
Approved Studies IRB-FY2025-24 Kate October 8 IRB Application IRB-FY2025-16 Kate Test Routing 2	Studies Expiring in 30 days *	Expired Studies	2

In the My Task section of the Human Ethics Dashboard there will be a list of protocols which require an action from you.

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Dashboard	Studies	Submissions	Tasks	Meet	tings			
Ø	In-Draft →		Awai Authoriza	ting tion ≯		Pro Revie	e- w	=
My Studies				My Tasks				
IRB-FY2025-43	Maureen's Revie	wer Test Screens	IR	8-FY2025	-41	Certify Submi	ission	
IRB-FY2025-41	Education Major	r (Case Study Test) 4	4 <u>IR</u>	B-FY2025	-38	Certify Submi	ssion	
	Test Protocol Su Studies)	bmission 2 (Under	IR	B-FY2025	-25	Complete Sub	mission	
IRB-FY2025-38	a constrainty		IR	B-FY2025	-26	Complete Sub	mission	
IRB-FY2025-38	Kate October 8	RB Application						

Step 5: Click on the link next to each of the protocols that indicates "Certify Submission."

• You are listed as the faculty advisor or a Co-PI on a study and will need to certify the protocol in order for it to proceed to be submitted to the IRB.



This will open the protocol and bring you to this screen.

Human E	thics				Role: Researcher	- 4	Products 🔻	🎍 Julie Moore
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tudies / <u>Study Detail</u>	s / Submission Details							
V In-Draft Submission i	s with researchers	2 Awaiting Auth Submission is aw approval	Iorization laiting certification or	> 3	Pre-Review Submission is being prepared for review	> 4	Under-Review Submission is with r	eviewers
Awaiting Certification]		24					
Initial IRB-FY2025-41 -	Education Major (Case S	tudy Test) 4					Bouting	
View	PDF 👻 🛱 Delete						Return	Certify
View	PDF - Delete	Decision:	Policy:		Required Tasks:		Return	Certify

To review the protocol, click on gray "View" to review it in Cayuse OR click on "PDF" to view it in PDF form.

Dashboard	Studies	Submission	s Tasks M	Aeetings			
Studies / Stud	<u>y Details</u> / Submis	ssion Details					
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040	mission is with resea	archers	approval	re	iview	 Submission is with re- 	viewers
Awaiting Cert	ification		approval	re	view	Submission is with re-	viewers
Awaiting Cert	ification	e Meler (Case S	approval		view	. Submission is with re-	viewers

If no changes are needed: approve the protocol

- 1. Click on the blue "Certify" button.
- 2. Click on "Confirm" to submit.



Dashboard St	tudies Submissions Tasks						
Q Click to search	1						٥
IRB#	Submission	Status	Review Type	PI	My Assignment	Decision	Create Date 🔻
IRB-FY2025-47	Test Protocol 3 Initial	Unsubmitted	N/A	Julie Moore	Primary Contact, Co-Principal Investigator		11-19-2024
IRB-FY2025-46	Test Protocol 2 Initial	 Awaiting Certification 	N/A	Julie Moore	Primary Contact		11-19-2024
IRB-FY2025-45	Test Protocol (1) Initial	 Awaiting Certification 	N/A	Julie Moore	Primary Contact, Investigator, Co-Principal Investigator		11-19-2024
IRB-FY2025-41	Education Major (Case Study Test) 4 Initial	 Unsubmitted 	N/A	Julie Moore	Primary Contact, Co-Principal Investigator		11-07-2024
IRB-FY2025-38	Test Protocol Submission 2 (Under Studies) Initial	Under Pre-Review	N/A	Julie Moore	Primary Contact, Co-Principal Investigator		11-07-2024

The successfully submitted protocol status will show as "Under Pre-Review"

OR

If you determine that changes are needed:

- 1. Return the protocol to the student.
- 2. Please communicate any changes or revisions with the student. This will be done outside of the Cayuse system. Please note that your communication with the student will be the only notification the student receives informing them of the needed revisions to the protocol.

To Return the protocol to the student, click on the blue "Return" button.

Human E	thics				Role: Researcher		Products	 Julie Mod
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idies / Study Details	s / Submission Details							
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Awaiting Certification	Education Major (Case	Study Test) 4					Routir	ng:
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Awaiting Certification Initial IRB-FY2025-41-1 SView	Education Major (Case :	Study Test) 4					Routin	ng: eturn Certify
Awaiting Certification	Education Major (Case : PDF -	Study Test) 4	sion: F	Policy:	Required Tasks:		Routin	ng: eturn Certify

This will reopen the protocol and allow the student to make edits to the protocol directly inside Cayuse. The student will need to re-certify the protocol.

Each time the student makes a change, they will be required to re-certify. As a Co-Pi or Faculty Advisor, you will also be required to re-certify the protocol.

*Pro Tip: You can view the protocol history using the Task History Tab toward the bottom of the screen. This is accessed only from within the protocol.

Human Eth	nics			Role: Researcher	 Produ 	cts 🔻 🛔 Julie Moor
hboard Stud	es Submissions	Tasks Meetings				
1 In-Draft Submission is with	researchers	Submission is awaiting cert approval	fication or 3 Submiss review	sion is being prepared for	A Under- Submissi	Review ion is with reviewers
nsubmitted nitial RB-FY2025-41 - Ed Ø Edit PDF	ucation Major (Case Study	Fest) 4				
l: ulie Moore eview Type: I/A	Current Analyst: N/A Review Board: N/A	Decision: N/A Meeting Date: N/A	Policy: Post-2018 Rule	Required Tasks: <u>Assign Pi</u> <u>Assign PG</u> Complete Submission		
Approvals Tas	k History Attachments					
Name	Role		Routing Action		Completion Date	
Julie Moore	Principal Investig	gator	Returned for Edit	:	11-19-2024 11:48 A	м
Duncan LeMay	Co-Principal Inve	stigator	Certified	:	11-19-2024 11:39 A	м
Duncan LeMay	Co-Principal Inve	estigator	Submission Complete	d	11-19-2024 11:39 A	м
		ator	Returned for Edit		11-19-2024 11:34 A	M
Julie Moore	Principal Investig	a con				

If you've certified the protocol, you will also receive an email:



When A Protocol is Sent Back by IRB

The IRB may send the protocol back to you for revisions/edits/clarifications:

The Faculty Advisors and Student Investigators will receive an email informing them:



Either the student(s) or the faculty advisor(s) can edit/revise the protocol.

Once edits/revisions are made, the protocol will need to be resubmitted and re-certified.

*All PI's will be required to recertify the protocol. The faculty advisor will also need to re-certify the protocol.

To just re-certify a protocol, follow the steps in the "Faculty Advisor "Approval" Certification" section.

Editing/Revising A Sent Back Protocol

Step 1: Login to Cayuse and navigate to the tasks tab (see pg. 2 for more details)

/ Humar	1 EUNICS					
ashboard	Studies Subm	issions Tasks	Meetings	Reporting Mo	ore	
Q Click to se	arch					0
IRB#	Task	Study Title		Submission Type	My Assignment	Tasked Date 🔻
IRB-FY2025-71	Complete Submiss	sion Test Protocol 21		Initial	Principal Investigator, Primary Contact	02-21-2025
IRB-FY2025-93	Complete Submiss	sion Testing Previous	y Approved Protocol	Initial	Primary Contact, Principal Investigator	12-13-2024

Step 2: Click and open the protocol that was sent back.

- Make sure to toggle from "Study Details" to "Submissions" and open your submission if you are not brought directly to the window below.
- The ribbon on the protocol will say "Reopened".
- Click on "Edit".

1 Submission is	with researchers	Awaiting Authorization Submission is awaiting certification approval	or 3 Submission review	iew n is being prepared for	4 Under-Review Submission is with reviewers
nitial RB-FY2025-43 -	Maureen's Reviewer Test Scre PDF ▼	ens			
l: ulie Moder eview Typ I/A	Current Analyst: Maureen Peters Review Board: N/A	Decision: N/A Meeting Date: N/A	Policy: Post-2018 Rule	Required Tasks: Assisn Pi Assisn PC Complete Submission	
Approvals	Task History Attachments				
Research Team	IBAKTINGUN Y PALBOINTENING				

*Pro Tip: You can view the protocol history from the Task History Tab located toward the bottom of the screen. This is accessed only from within the protocol submission

itial				
RB-FY2025-41 - Educ	ation Major (Case Study	Test) 4		
🖋 Edit 🛛 PDF	▼ Delete			
1:	Current Analyst:	Decision:	Policy:	Required Tasks:
ulie Moore	N/A	N/A	Post-2018 Rule	Assian PI
eview Type:	Review Boar	Meeting Date:		
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Approvals Task I Name	History Attachments Role	N/A	Routing Action	Assistify Complete Submission Completion Date
Approvals Task I Name Julie Moore	History Attachments Role Principal Investig	N/A gator	Routing Action Returned for Edit	Assert 15: Complete Submission Completion Date 11-19-2024 11:48 AM
Approvals Task I Name Julie Moore Duncan LeMay	N/A History Attachments Role Principal Investig Co-Principal Investig	N/A gator estigator	Routing Action Returned for Edit Certified	Assistific Complete Submission Completion Date 11-19-2024 11:48 AM 11-19-2024 11:39 AM
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Approvals Task H Name Julie Moore Duncan LeMay Julie Moore Julie Moore Duncan LeMay	History Attachments Role Principal Investig Co-Principal Investig Co-Principal Investig Co-Principal Investig	n/cmgpter N/A gator estigator estigator gator estigator	Routing Action Returned for Edit Certified Submission Completed Returned for Edit Certified	Complete Submission Completion Date 11-19-2024 11:48 AM 11-19-2024 11:39 AM

Step 3: Navigate to the parts of the protocol that need revision.

- They are the sections with a comment bubble on the left.
- The number indicates how many items need to be revised in the section. The sections marked with checkmarks do not require revisions



Step 4: Within the section, find the "Expand Comments" bubble and click on it to see the reviewer's feedback.

SUBMISSION DETAILS	IRB I	NUMBER: IRB-FY2025-43 aureen's Reviewer Test Screens - Initial	<
Sections	<	This section asks about the procedures participants will undergo and how data will be collected and recorded.	
Getting Started W	~		
Key Study Personnel	~	 Research Procedures: Please describe ALL the study procedures participants will undergo. 	0
Study Summary	~	 Provide details of any interactions, interventions or experiments with human subjects Include the number of study visits/sessions and the length for each (e.g., 30 minutes per week for 3 weeks for a total time of 1.5 hours), and the 	
Funding and Support	~	timetable for study completion. See Help text for more guidance 	
Oversight Determi	~	8 I ⊻ ∻ ≔ ≔ ∞ ⊆	
External Collaborat	~	Research Procedures test	1
Exemption Eligibility	~		
Exempt Categories	~		
Methods and Procedures	1		
Data	~		
Data and Sample Tr	~		
Attachments	~	Expand Comments	
		Data collection	0
Routing Send to PL for certification?		This section asks about the methods and precedures related to collecting and preceding presents data. Additional superiors should precedure	-

Step 5: Enter the revised information for each section with a comment and change the dropdown under "Reply" from "Not Addressed" to "Addressed".

S	\$			
ng Started W	~			
Study Personnel	~	Collapse Comments		_
ly Summary	~	Maureen Peters Today at 3:26 PM	Reviewer's feedback	
ding and Support	~	Please provide more details. Reply	Reviewer 5 leeuback	
ersight Determi	~	Not Addressed 💌		
ternal Collaborat	~			
emption Eligibility	~	Data collection	Change to addressed when done	
empt Categories	~	This section asks about the methods a	nd procedures related to collecting and recording research data. Additional questions about managing,	
		safeguarding, storing and sharing data	will be asked in other sections of the application.	

A time stamp will display and the dropdown will show "Addressed" when complete.

External Collaborat	✓	
Exemption Eligibility	~	Collapse Comments
Exempt Categories	~	Maureen Peters Today at 3:26 PM Please provide more details.
Methods and Proce	~	Reply Addressed Today at 3:40 PM by you
Data	~	
Data and Sample Tr	~	
Attachments	~	Data collection

Step 6: After addressing all comments, Complete the Submission. (You may also do this in the application in the "Complete Submission section.)

• Remember, you can't re-submit your protocol until all comments have been addressed.

Oversig	ht Determi	✓	o facilitate ease of review,	please upload documents in the proper attac
Attachm	nents		tudy documents reviewed	l and approved by an external IRB should be ι icted by HRPP staff).
Routing		i i	Jse the "Additional Docum nstructed to do so by HRPI	ents" attachment point only if you cannot find P staff.
Send to Pl	for certification?			
COMPLE	TE SUBMISSION	Awaiting Authorizatio	tudy Procedures and Com	nponents
In-Draft Submission is with	h researchers	Awaiting Authorizatio Submission is awaiting cert approval	hcatlon or 3 Pre-Review Rication or 3 Pre-Review	eing prepared for 2 Under-Review Submission is with reviewers
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COMPLE In-Draft Submission is with submitted itial B-FY2025-37 - Ex Edit PDI	tresearchers	Awaiting Authorizatio Submission is awaiting cert approval	Policy: Post-2018 Rule	eing prepared for 4 Under-Review Submission is with reviewers

Step 7: Certify the Protocol

• The Faculty Advisor and all student PI's must certify the application to initiate the IRB review process.

- If you are the PI, you will need to "Certify" the application when you resubmit it.
- IMPORTANT! All PI's listed on the study are required to "certify" the resubmission of the application.
- The system will send each PI an email stating the application is awaiting their certification. However, you do not need to wait for the email, you can certify directly from your Cayuse Dashboard.

fization ting certification or	3	Pre-Review Submission is being prepared for review	4	Under-Review Submission is with reviewers
				Routing: Return Certify

Approvals

Once the Protocol is Reviewed and Approved you will be notified by email that your Approval notice can be found in the Letters Tab of the Submission Details page.

William Paterson University Office of Sponsored Programs 1800 Valley Road, Room 218 . Wayne, New Jersey 07474 973.720.2852 • grants@wpunj.edu • wpunj.edu/osp Date: March 4, 2025 PI: Julie Moore Re: Initial - IRB-FY2025-62 Test Protocol 12 The William Paterson University UAT Tenant Institutional Review Board has reviewed the above-referenced submission and rendered the decision below. All approval letters and study documents are located in the tabs on the Submission Details page. **Decision: Approved** Decision Date: December 6, 2024 Study Admin Check-in Date: December 5, 2025 Study Expiration Date: December 5, 2025 Review Type: All reviewed research activities fall under 45 CFR 46.110. 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.) Findings: None Research Notes: None Key Principal Investigator Responsibilities:

Navigating to Your Approval Notice and Other Approval Materials under the Submission Details Page Tabs

To get to the tabs on the Submission Details page and your approval materials do the following:

Step 1: Login to Cayuse and Navigate to the Human Ethics Module (see pg. 2 for more details).

Step 2: Find the "Approved Studies" section on the homepage and click to open the approved study.

Cayuse Human Eth	ics	Tada	🔑 Products 👻 🛔
Dashboard Studie	es Submissions	тазкз	
			+ New Study
In-Dra	ft →	Awaiting Authorization	Under Review
My Studies		My Tasks	Submissions by Type
IRB-FY2025-62	Test Protocol 12		Renewal 0
IRB-FY2025-71	Test Protocol 21		Initial 36
IRB-FY2025-57	Test Protocol 10		Modification 0
IRB-FY2025-79	Test Protocol 24		Incident 0
IRB-FY2025-80	Test Protocol 25	All Tasks Complete	Withdrawal 0
			Closure 0
			Legacy 0
	View All		
Approved Studies		Studies Expiring in 30 days 👻	Expired Studies
IRB-FY2025-62	Test Protocol 12		
IRB-FY2025-71	Test Protocol 21		
IDD EV2025 57	Test Protosol 10		

Step 3: Click on the submission tab.

	Sti	udy Details		Submissions	
Approved				1	
IRB-FY2025-71	Test Protocol 21			1	
	Delete			-	
	Delete				
Approval Date:	Expiration Date:	Organization:	Active		
02-28-2025	N/A	Office of Sponsored	Submissions:		
		Department of	Sponsors:		
Admin Check-In Date:	Closed Date:	Biochemistry - TEST Current Policy	New Jersey Board of		
N/A	N/A	Post-2018 Rule	Public		
			Utilities - NJBPU		
Key Contacts	Attachments				
				 F - 1	

Step 4: Click on your approved submission.

	Study Details		Submissions
ubmission Type	Review Type	Status	Decision
nitial	Exempt	Review Complete	Exempt 02-28-2025

Step 5: Click on the letters tab at the bottom to view and download your IRB Approval notice. (Click on the other tabs to see additional approval materials)

shboard Studies	Submissions	Tasks			
Shourd States	Submissions	noto			
udies / Study Details / Submis	sion Details				
✓ In-Draft Submission is with resea	rchers	Awaiting Authorizatio Submission is awaiting cer approval	n Lification or Pre-R Submis	eview ssion is being prepared for review	VINDER-Review Submission is with reviewers
Review Complete					
Initial					
IRB-FY2025-71 - Test Proto	000121				
	Delete				
PI:		Current Analyst:	Decision:		Policy:
Julie Moore		Maureen Peters	Exempt		Post-2018 Rule
Review Type:		Review Board:			
Exempt		WPU UAT Board			
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Approvals Task Histor	ry Letters	Attachments			
Approvais	() Letters	Accounteres			
Research Team					
Name	R	ble	Resu	lt Date	
Julie Moore	Pr	incipal Investigator	Cert	ified 02-21-2	2025 3:40 PM

Step 6: Click the link under the Letters Tab to view and download the approval notice.

 In-Draft Submission is with researchers 	Awaiting Authorization Submission is awaiting certification or approval	Pre-Review Submission is being prepared for review	VInder-Review Submission is with reviewers
teview Complete nitial RB-FY2025-71 - Test Protocol 21			
PI: Julie Moore Review Type: Exempt	Current Analyst: Maureen Peters Review Board: WPU UAT Board	Decision: Exempt	Policy: Post-2018 Rule
Approvals Task History Letters	Attachments		