Reviewing a Protocol

Board Members

After logging in, select Human Ethics from the Products drop-down.

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						(Human Ethics	+ New Study	

Make sure Reviewer is started under the Ro button.	le drop-down. Click on highlighted protoc	ol under My Tasks. Th	en the Review
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Cayuse Human Ethics		Role: Reviewer 👻 🎜	AProducts 👻 🚢 Tina Aubut 👻
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Full Board Reviews →	Expedited Reviews >	Reviews	Exempt Reviews >
Submissions where I am the Primary Reviewer -	My Tasks	Submissions by Type	
	My Tasks	Renewal	0
	IRB-2023-25 Assign Analyst	Initial	
	IRB-2023-24 Assign Analyst	Incident	0
You Have No Submissions	The constant of the state of th	Withdrawal	0
		Closure	0
		Legacy	0
			20
Initial IRB-2023-17 - Study to make screens	hots Delete		

Current Analyst:

N/A

PI:

Rocco Researcher

The Checklist is more of a guidance than a requirement. However, there is a certification checkbox at the end of it to acknowledge completion of the review.

SUBMISSION DETAILS	This is a protocol to develop	PDF COMPARE SAVE < >
Sections	<	> Checklist
Getting Started	~	Danielle Jolie (Reviewer Checklist) \$
Project Personnel	Getting Started	Reviewer Checklist Submission Type
Basic Information	About Cayuse Human Ethics	
Study Design	Cayuse Human Ethics (HE) is an interactive web application. As you answer questions, new continue relevant to the two of screezes being conducted will appear on the left hand side.	Incident Renewal
Study Selection	 Sections relevant to the type of research being conducted will appear on the left-hand side. Therefore not all numbered sections may appear. You do not have to finish the application in one sitting. All information can be saved 	Comments
Study Procedures	Additional information has been added throughout the form for guidance and clarity. That	B I U S :≡ :≡
Participant Protect	 additional information can be found by clicking the question mark it the top-right corner of each section. 	
Attachments	For more information about the IRB submission Process, IRB Tracking, and Cayuse HE Tasks, please refer to the in-app help (the orange question mark near the bottom right) or contact the IRB Office: Office of Research Integrity and Outreach (ORIO) at: <u>usmorio@maine.edu</u> or 207-780-4517	
	Submit protocol for review at least thirty (30) days prior to starting data collection.	
	EMI Collaborative Boards	
	IORG#: IORG 1507 Federalwide Assurances:	

As you go through the review, you may add comments to the PI. Remember to make the comments to the PI UNRESTRICTED. There is another place under Make a Decision to leave a general message for the ORIO staff later in this process.



Initial IRB-2023-42 - This is a protoc	col to develop Review	er Guide - Ima Test			Routing: Switch Review Complete
PI: Cu Rocco Researcher Review Type: Re Expedited Bio	view Board: omedical IRB	Decision: N/A Meeting Date: N/A	Policy: Post-2018 Rule	Required Tasks: Make Decision	
Approvals Task History	Decisions Af	ttachments			

come to stan. Remember to check the button review complete:	
	1. Make a Decision—return to PI
Cancel Save	2. Result Date (today)
Pending Danielle Jolis	3. Notes, if applicable
Decision Result Date @Administrative Check-In Date	ý 11
Return to PI Clear	4. Save
Pending Uan al Categories Select the applic de categories for this decision.	5. Review Complete button
Decision 1a, Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the	· · · · ·
sists or of creases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) Select a decision	
Approved Findings	
Deferred 1 B I U & F III III III O III	
Exempt	
Exempt - Limited IRB herid	
Minor Stipulations uich [1] Researcher Notes Information entered here can be used as part of the correspondence with the tag [RESEARCH_NOTES]	
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No Human Subjects Research	
Not Expedited	
Rely on External IRB he ri	
Rely on NCI-CIRB	
Return to PI ersti	
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Under Review	
Initial IRB-2023-42 - This is a protocol to develop Reviewer Guide - Ima Test	
🖺 Review PDF 👻 🗈 Delete 🔳 Checklist	Switch Review Complete
PI: Current Analyst: Decision: Policy: Required Tasks: Rocco Researcher Danielle Iolie N/A Post-2018 Rule Mole Durition	\sim
Review Type: Review Board: Meeting Date:	
Expedited Biomedical IRB N/A	
Approvals Task History Decisions Attachments	

When the PI has responded to comments and it comes back to you:

- 1) Open the protocol from My Tasks
- 2) Click the Review button, click on each comment, then mark as Resolved or add another unrestricted comment.
- 3) Save button at top right of page. Then click Submission Details at top left of page.



Make a Decision for Exempt: Return to PI (see pg 2) and Exempt. Reviewer may choose Not Exempt if you feel the review type is not reflective of the submission, Not Human Subject Research or Expedited. Please include an explanation in the Internal Notes.

				Cancel
				Cancer
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F				
	Decision	Result	esult Date OAdministrative Check-In Date	ie
	Select a decision 👻		107-13-2023 Today 107-12-2026	
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	Exempt - Limited IRB		1. Make a Decision	
	Minor Stipulations	ablished to learn	2. Result date	If an Administrative
	No Engagement in Research	tegies, a	3. Administrative Check-in date (3 years)	check-in date is not
	No Human Subjects Research	des inter	4. Category (s)	entered on the initial
L	Not Exempt	the inv	E Eindings (on the letter) and Pessarsher	Exempt review, Cayuse
	Rely on External IRB	ar ti	Notes (on the letter) or Internal Notes	will NOT send reminders.
	Rely on NCI-CIRB	te	6 Save	It can only be entered at
	Return to PI	le		initial review!
		g	7. Review Complete button	
	Inked to the subjects; Category 2.(ii). Research that only includes observation of public behavior (including v Any disclosure of the human subjects' resp financial standing, employability, education Category 2.(iii). Research that only include observation of public behavior (including v The information obtained is recorded by th linked to the subjects, and an IRB conducts Category 3.(i)(A). Research involving benig responses (including data entry) or audiovi The information obtained is recorded by th linked to the subjects. Category 3.(i)(B). Research involving benig responses (including data entry) or audiovi Any disclosure of the human subjects' resp financial standing, employability, education	s interact isual or a onses ou hal advan s interac isual or a he investi a limited in behavi sual reco onses ou hal advan	ons involving educational tests (cognitive, diagnostic, aptitude, achievement), suditory recording) if at least one of the following criteria is met: uside the research would not reasonably place the subjects at risk of criminal or tement, or reputation; or Findings Information entered here can be used as part of the correspondence with the tag [FINDINGS]. • 8	survey procedures, interview procedures, or r civil liability or be damaging to the subjects'
	Jnder Review Initial IRB-2023-42 - This is a protocol to develop Review PDF< Review PI: Rocco Researcher Danielle Jolie Review Type: Review Board: Expedited	Reviewe	Guide - Ima Test Checklist Decision: Policy: Pequired rasks: Return to PI Post-2018 Rule Meeting Date: N/A Checklist	Routing: Switch Review Complete eck that Make a Decision is