

Institutional Biosafety Committee VERAS Help Guide

Welcome to the Vandals Electronic Research Administration System (VERAS) Institutional Biosafety Committee (IBC) module. This manual provides basic information about the Study Assistant module and will guide you through the process of creating an IBC Protocol application and submitting it to the IBC as well as making changes to approved protocols.

As you navigate the IBC Protocol Study application, please contact the IBC (208)-885-7258 or <u>ibc@uidaho.edu</u> if you have any questions.

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Create a New IBC Protocol

- 1. Login to http://veras.uidaho.edu/
- 2. Find *My Workspaces*, then hover over "Study" and select "Study Workspace" pictured below:

My Workspaces 🖃	Study		
Research Workspace	\$		
Conflict of Interest	•		
Project Assistant	•	Operations	Tasks
Study	•		
Special Purpose Submission	on Forms 🕨 🕨	Study Workspace	S
	Start a Study Submission	Create a New Study	asks
	View My Studies	View My Studies	
View My Studies Submiss		Start a Study Submission Form	
		View My Studies Submissions	
	Track Approvals	My Current Approvals	

3. Select "Create a New Study."

University of Idaho	Hello Joe Vandal			(?) Help 🕞 Tutorial	🛔 Hy Profile -
My Workspaces 🗃	Study Assistant				
	Featured Study Op	perations	Tasks	_	í.
	Create a New Study		View All Tasks	0	
	Start a Study Submission Form		View Study Tasks	0	
	View My Studies				
	View My Studies Submissions				
	Track Approvals				
	Forms Pending Submission	0			

- 4. Select "Study Application Institutional Biohazard Committee (IBC)" then
- 5. Complete the questions in each section then press Save and Continue to Next Section

General Information:

- i) Complete the application to the best of your ability.
- ii) Selections in Section 7 (*Project Information*) will populate additional sections. Select all categories that apply to your research.
- iii) select ⁽²⁾ Help on the top right of the screen to download additional templates for biological agents, animal materials, and recombinant DNA.
- iv) The following tabs and buttons are available throughout the protocol application:

University	Account: Joe Vandal Department: UI - Academic Support Programs Path: Home > study mgmt.	Selecting "Back" will take you to the previous "Path"
Complete/edit current or My previously viewed application sections	eference Title Read-only view of all tant Study Application - IBC (Version 1.0)	ed Back
Section view of Application	Completed sections Print Friendly Save Section Save ar Entire view of the Application Save Section Sav	nd Continue to Next Section
1.0 General Information Control General Informatio Control General Information Control General Information Contro	1.0 General Information	Select to move to the next section
3.0 🗎 Key Personnel		

- 6. A validation check is conducted, and incomplete elements will display in red.
 - a. Click on each element, update the item, then click "Validate and Save" to proceed.
- 7. Initial Review Submission Packet is then displayed.
 - a. Select *"Save and Continue to Next Section"* when finalized, then *signoff and submit* to submit application.
- 8. Under the *IBC Principal Investigator Agreement*, select *"Approve"* and submit your application by clicking on the *"Save Signoff"* button

1 Joe Vandal as Principal Investigator do you Approve or Deny this submission?	Approve Deny	Comments:	Click here to add comments.
			2. Save Signoff

Once you have done this your submission will be sent to IBC for review. The status of your application will show "*Pending - Submitted for Initial Review.*"

Note: Other study roles may author any of the IBC forms. Instead of seeing the approve and signoff as above, other study roles besides the PI, will need to select "*Notify PI to Signoff*." The PI will receive an email and home screen task notification to review and signoff on the submission. The PI must sign off on the submission before it is sent to the IBC for review and approval.

Copy an IBC Protocol in VERAS (3 Year Renewal)

Follow these instructions to copy a previously approved IBC Protocol. If a pop-up asks you to convert to a newer form version, select "*Convert to New Form Version*." Make sure to review and update the entire protocol.

- 1. Login to http://veras.uidaho.edu/
- 2. Find *My Workspaces*, then select "*Study*" and "*Study Workspace*" pictured below:

lesearch Workspace	\$		
Conflict of Interest	•		
Project Assistant	•	Operations	Task
Study	•		
Special Purpose Submissi	on Forms	Study Workspace	S
	Start a Study Submission I	Create a New Study	asks
	View My Studies	View My Studies	
	view Hy Studies	Start a Study Submission Form	
	View My Studies Submissio	View My Studies Submissions	
	Track Assessments	My Current Approvals	

- 3. Scroll down to "All Studies."
- 4. Find the protocol you intend to copy and select "Copy" under the Actions column.



5. Confirm you want to copy the protocol when the pop up appears.

Confirm the Copy		
Are you sure you want to cop	oy?	
	\frown	
	CONFIRM	CANCEL

6. Click to open the copied protocol draft that appears, titled "Copy of Original Title."



- You can now edit your protocol to include any changes from the last three years. Select
 Save and Continue to Next Section until you have completed all protocol steps.
- 8. Select A Signoff and Submit
- 9. Complete the final signoff by selecting Approve O Deny and I Save Signoff on the final screen.
- 10. You should receive an auto-generated email that you have submitted a protocol application.

Address IBC Stipulations

This manual will guide you through the process of addressing IBC stipulations or clarifications sent to you from the Committee. The PI must respond to and address each stipulation, update/revise the Study Application according to the stipulations, and return the submission for review before approval is granted.

When a submission is returned for corrections, the PI and any Study Contacts listed on the study will receive an email notification from VERAS alerting of the request.

- 1. Find the "All Tasks" section of your VERAS homepage.
- 2. Locate the IBC Stipulation in the "Submission Correction" or "Submission Response" task and click to open. This will open the IBC Review Response Form.

All Ta	All Tasks Outstanding Completed				
	All Tasks	Study Tasks	т	ask List: 📶 🗸	
5 result(s) found			1 - 5	
	Click to open	Task Type	Received	Description	
		Submission Response	09/30/2020 02:13:13 PM PDT	IBC Committee IBC Committee returned the submission with the outcome of Modification Required to Secure Approval	

3. Section 1.3 of the IBC Response form will list the stipulations sent to you from the committee. Below is an example:



- 4. To revise existing study application:
 - a) Revise the first stipulation by selecting Revise Existing
 - b) Confirm you want to create a revision of your application.

Confirm the adding a rev	vision.
Are you sure you want to cre	eate a revision?
	CONTRACTOR

c) A new version of your study application will open to the section for the first stipulation. For example:

My Workspa	aces IBC	Number: IBC-20020 Reference Title: 5/0/2020 - test 9.5 Study Assistant (Version 1.2)	C Back
		New study application version number Print Friendly Save Section Save and Continue	to Next Section
Section view	of Application	Entire view of the Application	
1.0 🗎 General	Information ^		
2.0 Setup D Access	epartment(s)	5.5 Please select your waste decontamination method(s) (biohazardous waste policy)?	
3.0 🗋 Key Per	sonnel	Modifications Required: Stipulation request corresponding to thi	s section
4.0 🗎 Funding	Source(s)	Section 5.5., please select the decontamination method for <i>Liquid</i> Waste	
5.0 🗎 Scope o	f Work		
6.0 Location	•	A. Liquid waste	Ø
7.0 Droject	Information	Chemical disinfectant (with contact time specified in biosafety manual)	
8.0 Animal Material	Activities / ls	Cther	
9.0 Biologic Recomb and Biol	al Agents (not binant DNA) logical Toxin	B. Solid waste	
CDC Sel	ect Agents	Autoclave	
10.0 Control	ed Items		
(EAR an		Other	
11.0 human	Jubjects (Use I, tissue, luids, or othe	C. Sharps waste (placed in hard walled, puncture resistant, single use container)	

- d) Address the stipulation in the protocol form.
- e) Always select Save Section or Save and Continue to Next Section after making any changes to the form.
- f) When completed, select **Back** to return to the IBC Review Response form. There will now be a new version of the Study Application.
- 5. In the IBC Review Response Form, select "*Complete Action*" and the **Action Status** will turn green and be marked as "*Complete*."

▲ Stipulation	1 out of 2:			
Description:	Description:			
Section 5.5., please select the decontamination method for Liquid Waste.				
Stipulation Ty	Stipulation Type: (Stipulation must be addressed)			
	Operation	Action Status	Component Name	Action
Links to Components (These are the items that are linked to this stipulation)	Modify Existing Attachment	Action Not Complete	Study Application - Institutional Biohazard Committee (IBC) (Version 1.2) Image: Study Application - Institutional Biohazard Committee (IBC) (Version 1.0) Section: Scope of Work Question: Please select your waste decontamination method(s) (biohazardous waste policy)?	Compare Application Version

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Complete	 Study Application - Institutional Biohazard Committee (IBC) (Version 1.2) Study Application - Institutional Biohazard Committee (IBC) (Version 1.0) Section: Scope of Work Question: Please select your waste decontamination method(s) (biohazardous waste policy)? 	Compare Application Version © Complete Action () Incomplete Action

- 6. Indicate whether you accept the stipulation by selecting yes/no/NA.
- 7. Provide a brief (1-2 sentence) explanation on how you addressed the stipulation.
- 8. To address more than one stipulation, scroll to the next stipulation on the IBC Review Response Form and select the newest revised study application version to repeat the process (steps 4-7).

A Stipulation	2 out of 2:								
Description:									
Section 6.2., please add the autoclave location.									
Stipulation Typ	Stipulation Type: (Stipulation must be addressed)								
	Operation	Action Status	Component Name	Action					
Links to Components (These are the items that are linked to this stipulation)	Modify Existing Attachment	Action Not Complete	Study Application - Institutional Biohazard Committee (IBC) (Version 1.2) Image: Study Application - Institutional Biohazard Committee (IBC) (Version 1.0) Section: Location Question: Autoclave Location: (If applicable)	Compare Application Version Complete Action Incomplete Action					

- 9. Select Save and Continue to Next Section in the Review Response form until you reach the Form Has Been Completed Page.
- 10. Select Signoff and Submit on the Form Has Been Completed Page.
- 11. Under the *IBC Principal Investigator Agreement*, select "*Approve*" and submit your form by clicking on the "*Save Signoff*" button.



Note: Other study roles may author any of the IBC forms. Instead of seeing the approve and signoff as above, other study roles besides the PI will need to select "*Notify PI to Signoff*." The PI will receive an email and home screen task notification to review and signoff on the submission. The PI must sign off on the submission before it is sent to the IBC for review and approval.

IBC Protocol Amendment

Follow these steps if you are making any protocol amendments to your approved IBC protocol. If adding/removing personnel, refer to the next section of this guide.

- 1. Login to http://veras.uidaho.edu/
- 2. Find *My Workspaces*, then select "*Study*" and "*Study Workspace*" pictured below:

My Warkspace	Study		
My workspaces	Study		
Research Workspace	:	¢.	
Conflict of Interest	•		
Project Assistant	•	Operations	Tasks
Study	•		
Special Purpose Submi	ssion Forms	Study Workspace	.S
	Start a Study Submissio	<mark>n I</mark> Create a New Study	asks
		View My Studies	
View My Studies View My Studies Submissi Track Approvals		Start a Study Submission Form	
		sic View My Studies Submissions	
		My Current Approvals	

- 3. Scroll down to "All Studies" or "IBC Studies."
- 4. Select "Forms" on the protocol you want to amend.

BC Studies Recently Used Study Status Search for RB Number, Title, Alias Search									
IACUC		•							
result(s) found 1 - 5									
Study Title	Principal								
ihort Reference Title	Investigator								
Test 6/4				\sim					
	madel tes	\downarrow			Ø				
1 0/4	vandal, Joe	Histo	ry Items	Forms	Hide	Copy		Corr	
at 5/8/2020 BME				\sim					
/2020 - test 9.9	Vandal, Joe	<u> </u>	2		Ø			Č2	
itudy ihor it 6/ it 5/ it 5/	IACUC y Title t Reference Title 4 8/2020 BME 20 - Lest 5.9	IACUC Title Principal Reference Title Reference Title 4 4 9/2020 BME 20 - Test 9.9 Vandal, Joe	IACUC Principal Tate Principal Reference Tatle Investigator 4 vandal, Joe <u>1</u> 6/2020 BME 20 - Cett 5-9 Vandal, Joe <u>1</u> Histo	IACUC Tatio Principal Reference Tatle Vandal, Joe Vandal, Joe Va	IACUC Title Principal Investigator Generation Gene	IACUC Intel Principal Investigator Actions Reference Intel 4 andali, Joe Intel History Intel Farmer I	LACUC Principal Excessigator Actions 1 table Principal Excessigator Actions 4 constraints Actions Actions 4 constraints Actions Actions 4 constraints Actions Actions 20 - best 5.9 Vandal, Joe History Actions	IACUC Title Principal Investigator References Title Generation Market Market	IACUC Table Principal Investigator Investiga

- 5. A popup will appear. Locate and select "IBC Amendment Form"
- 6. Select the option below that best applies:

to start a new Submission for the form you want

to finish an incomplete form

to see the versions of the form you currently have

- Complete Section 1 of the Institutional Biosafety Committee Application for Protocol Modification.
 Select Save and Continue to Next Section
- Complete Section 2 by selecting all applicable categories for the changes being requested. Select
 Save and Continue to Next Section
- 9. Complete Section 3 by describing the modification(s) you are requesting and justifying the request

with a few sentences. Select Save and Continue to Next Section

VERAS Help Guide Institutional Biosafety Committee IBC Protocol Amendment

- 10. Complete Section 4 by revising your study application to include the details of your amendment request:
 - a. Select Click here to attach the application
 - b. Click the "Add Revision" icon in the Create a Revised Application button.



c. Confirm you want to create a revision of your Study Application

Confirm the adding	g a revision.
Are you sure you wa	nt to create a revision?
	CONFIRM
	CONFIRM

- d. If a pop-up appears informing you that a "New Form Version has been Published" select "Cancel Conversion – Retain Current Version."
- e. You can now make all applicable updates to the study application.
 - i. Save your section or select Save and Continue to Next Section when you are making changes.
 - ii. Once updated, select **Back** in the top right corner of your web browser to return to the Amendment form.
- f. The revised study application will be listed in the Application Attachment table.
 - i. If the application needs additional edits, select the pencil/paper icon in the **Edit/View** column to reopen the application to make updates.

Unattach	Revise/ Attach	Edit/ View	Title
8		>	Study Application - Institutional Biohazard Committee (IBC) (Version 1.1)

- ii. If you need to detach the application, click the icon in the *"Unattach"* column. This will remove the version from the amendment form.
- 11. Section 5 will allow you to attach or update other study documents, if applicable. Select Save and Continue to Next Section when finished.
- 12. On the Form Has Been Completed page select Signoff and Submit
- 13. Under the IBC Principal Investigator Agreement, select "Approve."
- 14. Click on the "Save Signoff" button to submit your form.

Joe Vandal as Principal Investigator do you Approve or Deny this submission?	Approve Deny	Comments:	Click here to add comments.
			2. Save Signoff

Once submitted, the PI and Study Contact will receive an auto-generated confirmation email of the submission.

Note: Other study roles may author any of the IBC forms. Instead of seeing the approve and signoff as above, personnel will need to select "*Notify PI to Signoff*." The PI will receive an email and home screen task notification to review and signoff on the submission. The PI must sign off on the submission before it is sent to the IBC for review and approval.





IBC Personnel Amendment

Add the PI, Lab Manager, and any other personnel you want to have access to the protocol. All personnel that will be handling Select Agents or Export Control items will need to be included in the protocol.

- 1. Login to http://veras.uidaho.edu/
- 2. Scroll down to *All Studies*.
- 3. On the protocol row you want to amend, select
- 4. A pop-up window will appear, find the row for *IBC Personnel Change Only* and select
- 5. In Section 1, Protocol Information, select
- 6. A Setup Study Personnel pop-up will appear. Search by First name, Last name, or Department, then click the Find User/Search Directory button.
- 7. Click the "Select User" icon _____ to save individual users. If adding more than one user, check the boxes next to the usernames and then click Save Selected User(s).
- 8. The "Add Personnel Role" popup will appear. Select the appropriate role. See definitions below:
 - Principal Investigator You can only have one Principal Investigator listed. If requesting a change in PI, add the desired PI to the form, and when the IBC approves the change, the system will change the PI.
 - Additional Investigators –You may have any number of Additional Investigators, and after you add a user to this group, you will be able to specify their role title.
 - Research Support Staff Any non-investigator (e.g., Post Docs, Grad Student, Undergrad, Lab Manager etc.).
 - Study Contact You may add additional Study Contacts as needed. A Study Contact is a user on the study who will receive study related notifications from the system (e.g., submission notifications, submission outcome letters, etc.). The PI should be listed as the Study Contact. Examples of additional Study Contacts would include the Lab Manager or Co-PI.

* Note: If you cannot find the personnel in the VERAS User Directory, please let them know they will need to try to log into VERAS with their UI Network ID and Password. If they don't have an account, the system will direct them to create one. Once they have an account, you will be able to find them in the VERAS User Directory to add to the submission request.

- 9. **To Remove a User**: select Setup Key Study Personnel Request and a Setup Study Personnel pop-up will appear. On the left side, select Remove Personnel List
- 10. Select the user(s) you would like to remove from the study by scrolling down to the bottom of the

Setup Study Personnel window and selecting the ______ checkbox next to their name. Then click the *Save Selection* button.

- 11. To Submit a Completed Request: Select Save and Continue to Next Section Submit by clicking Signoff and Submit
- 12. Under the *IBC Principal Investigator Agreement*, select "*Approve*" and click on the "*Save Signoff*" button to submit your form.

L. Joe Vandal as Principal Investigator do you Approve or Deny this submission?	Approve	Deny	Comments:	Click here to add comments.
				2. Save Signoff

14. Once submitted, the PI and Study Contact will receive an auto-generated confirmation email of the submission.

*Note: Other study roles may author any of the IBC forms. Instead of seeing the approve and signoff as above, personnel will need to select "*Notify PI to Signoff*." The PI will receive an email and home screen task notification to review and signoff on the submission. The PI must sign off on the submission before it is sent to the IBC for review and approval.

Form has been Completed!
Please select the Signoff button below to submit your application/form. ** Note: you must still proceed to the next page to complete your signoff and start the routing process.
Exit Form Notify Pr to Bigrott Create PDF Paciat

Close a Protocol

- 1. Login to http://veras.uidaho.edu/
- 2. Scroll down to All Studies.
- 3. Find the protocol row you want to close and select Forms
- 4. A pop-up window will appear, under *IBC Renewal, Amendment & Closure Forms*, find the row for *IBC Closure Form* and select
 - a. Complete the form by selecting the applicable closure.
 - b. Select Save and Continue to Next Section
 - c. Submit by clicking Signoff and Submit
 - d. Under the *IBC Principal Investigator Agreement*, select "*Approve*" and click on the "*Save Signoff*" button to submit your form.



Print Current Approval Packet

- 1. Login to http://veras.uidaho.edu/
- 2. Scroll down to All Studies.
- 3. Find the protocol you are looking for and select \sum
- 4. On your protocol home screen, under the *Submission* tab select "*Current Approval Packet*." This button may not appear if you do not have additional items in your protocol (permits, inspection forms, etc.).

Submissions	Study Management	
		Current Approval Packet
Protocol Items		
Study Ap	plication	
Informed	Consent >	
Other Stu	Idy Documents 🔸	

5. Select the box(es) under "Include in PDF Packet" for the submission item(s) you want.

		Select items to be included in package			x
To order S the desire	Submission I d location.	tems for packet creation, please click on ite	m row and drag i	t up or down to	
in PDF Packet	Order	Submission Item Name	Date	Expiration Date	^
	1	Study Application - Institutional Biohazard Committee (IBC) Version 1.1	01/19/2021		

6. Then select "Generate PDF Packet."

