

# VERAS Guide - Addressing IBC Stipulations

## Introduction

This manual will guide you through the process of addressing IBC stipulations or clarifications sent to you from the Committee. All requests for clarifications, additional information, and recommendations for the submission will be returned to the PI through the VERAS system in the form of *Stipulations on a Submission Response form*. The PI must respond to and address each stipulation to the satisfaction of the Committee, update/revise the Study Application according to the stipulations, and return the submission to the Committee for review before approval is granted.

Contact the IBC (208-885-7258 or [ibc@uidaho.edu](mailto:ibc@uidaho.edu)) if you have any questions.

Let's get started!

## Notification

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

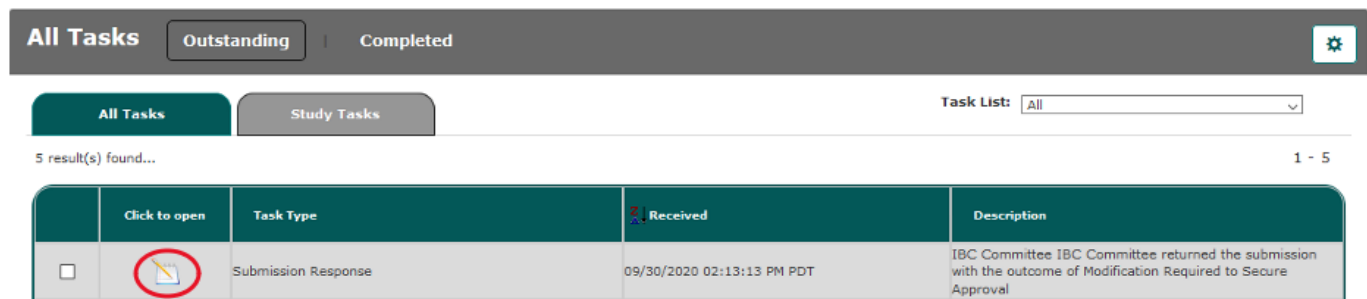
## Login

<https://veras.uidaho.edu/>, use your UI Network ID and password to login.


## Task

A task on the VERAS homepage called "Submission Correction" or "Submission Response" will remain on your home screen, no matter what workspace you are in, under **All Tasks** until you respond to the corrections and return the form to the Committee.

Select the pencil/paper icon to open the task.



The screenshot shows the 'All Tasks' section of the VERAS interface. At the top, there are tabs for 'All Tasks', 'Outstanding', and 'Completed'. Below this, there are two main tabs: 'All Tasks' (selected) and 'Study Tasks'. A 'Task List' dropdown menu is set to 'All'. Below the tabs, it says '5 result(s) found...' and '1 - 5'. A table displays the task details:

	Click to open	Task Type	Received	Description
<input type="checkbox"/>		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

## IBC Review Response Form

Open the "Submission Response" task to go directly to the *IBC Review Response Form*.

You will need to complete the form by reviewing and responding to the stipulations, revise the Study Application/protocol addressing all the stipulations, then submitting the form to the Committee.

## Section 1 - Addressing the Stipulation

Section 1.3 of the *IBC Review Response Form* will list the stipulations sent to you by the Committee.

1. Review the stipulation description and what is being requested
2. Follow the steps described for *Revise Existing Study Application*

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3. Indicate whether you accept the stipulation
4. Briefly tell the Committee how you have addressed the request

1.3 The following lists the questions and comments related to your IBC or modification request:

Please address the issues in the new version of your IBC and/or modification form. You cannot make changes to the IBC/modification until you create a new version on the next screen.

Select "Yes" to accept the stipulation. "No" responses are **only** acceptable where IBC Reviewer comments did not get incorporated into the document. Be sure to explain any "No" responses in the text box provided.

**Stipulation 1 out of 2:**

**Description:**  
Section 5.5., please select the decontamination method for *Liquid Waste*.

**1. Review the stipulation description and what the committee is requesting**

**Stipulation Type:** (Stipulation must be addressed)

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	Study Application - Institutional Biohazard Committee (IBC ) (Version 1.0) Section: Scope of Work Question: Please select your waste decontamination method(s) (biohazardous waste policy)?	Revise Existing

**2. Follow the steps described for Revise Existing Study Application**

**Do you accept this Stipulation?**  N/A  Yes  No

**3. Indicate whether you accept the stipulation**

**4. Briefly tell the committee how you have addressed the request**

Provide an explanation on how you addressed this Stipulation:

5. Select once all stipulations sent have been addressed.

## How to Revise Existing Study Application

For the first stipulation, you will be asked to revise the existing Study Application.

1. Select
2. Confirm you want to create a revision of your application

**Confirm the adding a revision.**

Are you sure you want to create a revision?

3. A new version of your study application will be created, and will open to the section in the study application the first stipulation is connected to, for example:

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My Workspaces | IBC Number: **IBC-20020** | Short Reference Title: 5/8/2020 - test 9.9 | PI: Vandal, Joe | Study Assistant | Study Application - Institutional Biohazard Committee (IBC) (Version 1.2) | Back

Print Friendly | Save Section | Save and Continue to Next Section

Section view of Application | Entire view of the Application

5.5 Please select your waste decontamination method(s) (biohazardous waste policy)?

**Modifications Required:**  
Section 5.5., please select the decontamination method for *Liquid Waste*.

A. Liquid waste

- Chemical disinfectant (with contact time specified in biosafety manual)
- Autoclave
- Other

B. Solid waste

- Autoclave
- Incinerate
- Other

C. Sharps waste (placed in hard walled, puncture resistant, single use container)

- Address the stipulation as applicable
- Make sure after any changes made, you select  or
- Once addressed, select the right hand  to return to the *IBC Review Response Form*
- On the *IBC Review Response Form*, you will see two versions of the *Study Application*: Version 1 was the original application and Version 1.2, in this example, is the revised application.
- Select "Complete Action"

**Stipulation 1 out of 2:**

**Description:**  
Section 5.5., please select the decontamination method for *Liquid Waste*.

**Stipulation Type:** (Stipulation must be addressed)

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	Study Application - Institutional Biohazard Committee (IBC) (Version 1.2)	<input type="button" value="Compare Application Version"/> <input type="radio"/> Complete Action <input checked="" type="radio"/> Incomplete Action
		Study Application - Institutional Biohazard Committee (IBC) (Version 1.0)	
		Section: Scope of Work	
		Question: Please select your waste decontamination method(s) (biohazardous waste policy)?	

Links to Components (These are the items that are linked to this stipulation)

The **Action Status** will turn green and be marked as "Complete."

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Complete	Study Application - Institutional Biohazard Committee (IBC) (Version 1.2)	<input type="button" value="Compare Application Version"/> <input checked="" type="radio"/> Complete Action <input type="radio"/> Incomplete Action
		Study Application - Institutional Biohazard Committee (IBC) (Version 1.0)	
		Section: Scope of Work	
		Question: Please select your waste decontamination method(s) (biohazardous waste policy)?	

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- If addressing more than one stipulation, scroll to the next stipulation on the *IBC Review Response Form* and select the newest revised study application version to open and address the next stipulation sent.

**Stipulation 2 out of 2:**

**Description:**  
Section 6.2., please add the autoclave location.

**Stipulation Type:** (Stipulation must be addressed)

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	Study Application - Institutional Biohazard Committee (IBC) (Version 1.2)	<input type="button" value="Compare Application Version"/> <input type="radio"/> Complete Action <input checked="" type="radio"/> Incomplete Action
		Study Application - Institutional Biohazard Committee (IBC) (Version 1.0) Section: Location Question: Autoclave Location: (If applicable)	

Links to Components (These are the items that are linked to this stipulation)

## Section 2 – Submission Documents

The table in section 2 will list the documents associated with this submission.

Selecting will allow you to attach new components to the submission

Select to view previous versions

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	Revisions	All Submission Components Previous Rounds & Currently Attached
<b>Submission Form(s)</b>							
<input type="checkbox"/>	<input type="checkbox"/>						IBC - Review Response Form - IBC - (Version 1.0)
<input type="checkbox"/>	<input type="checkbox"/>						Initial Review Submission Packet - (Version 1.0)
<b>Application</b>							
<input type="checkbox"/>	<input type="checkbox"/>						Study Application - Institutional Biohazard Committee (IBC) - (Version 1.2)

You can choose to add or revise any existing document on your study, or you can add a brand-new document.

Once all documents are updated and added select

## How to add New Documents

Select **Add New Component**, then select “Other Study Document”, when the window refreshes select either **Add Multiple Documents** or **Add a New Document**.

Path: Home > study mgmt.

**Attach Study Document(s)**

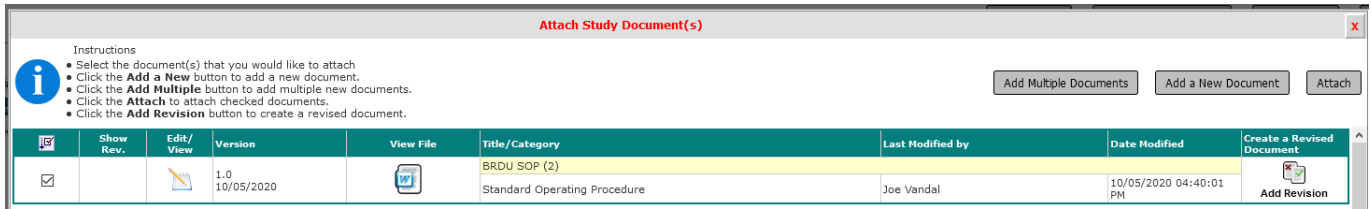
**Instructions**

- Select the document(s) that you would like to attach.
- Click the **Add a New** button to add a new document.
- Click the **Add Multiple** button to add multiple new documents.

Show Rev.	Edit/View	Version	View File	Title/Category	Last Modified by	Date Modified	Create a Revised Document
No documents have been added.							

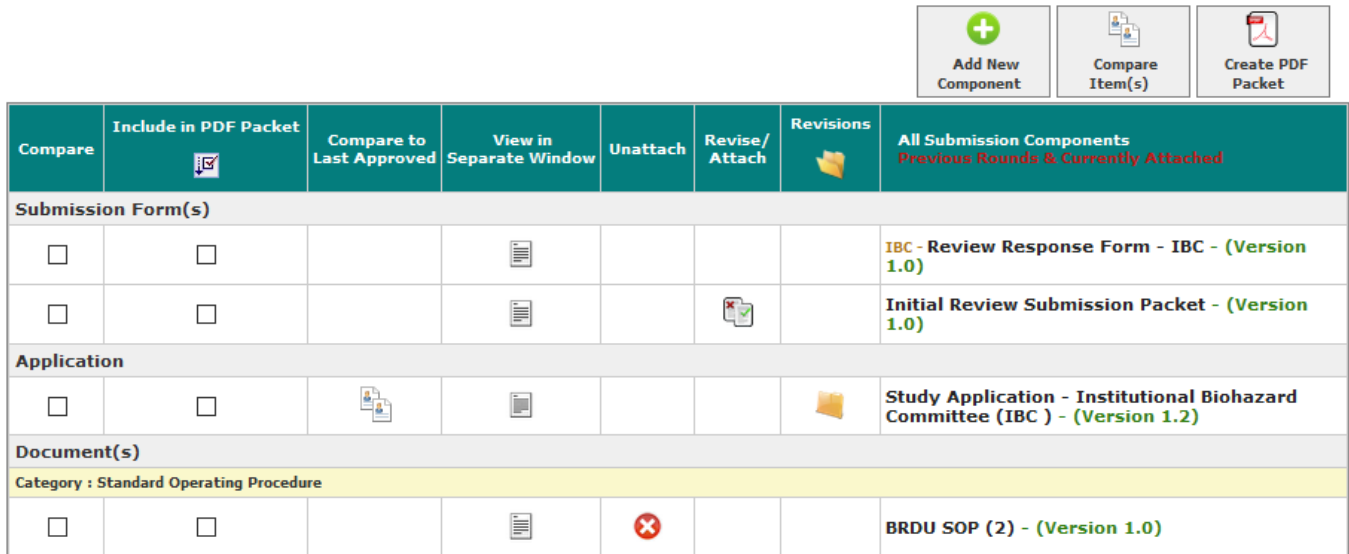
Complete the addition by “drop file” or upload the documents and entering in the applicable information,

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Once the document appears in the table, make sure the box is checked (  ) for the document then select **Attach**.

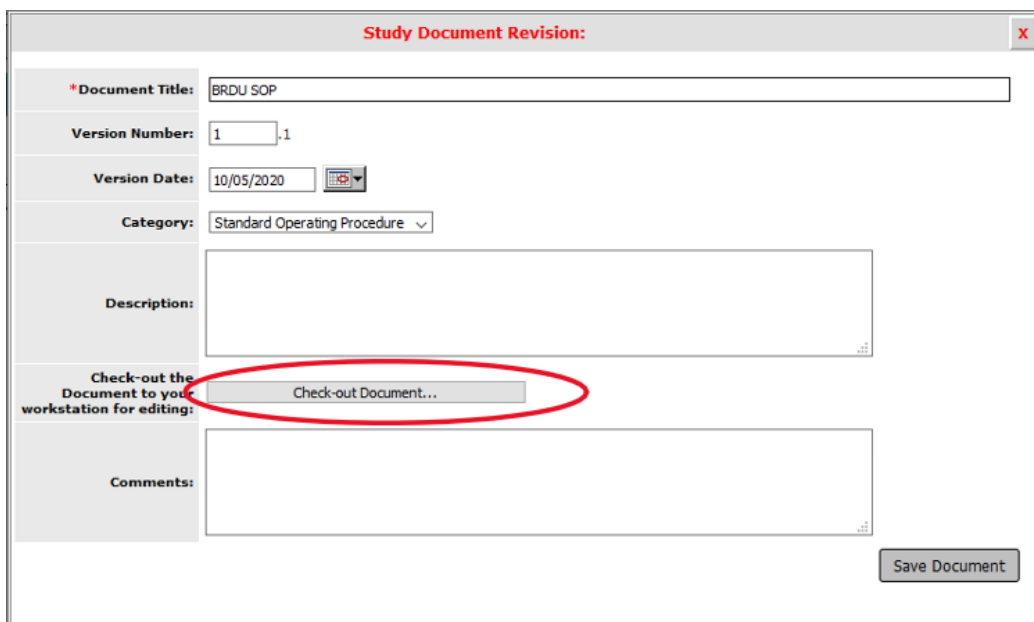
The document should show as a document for the submission.



## How to update an "Other Study Document"

To revise an existing document, you will click the in the **Revise/Attach** column.

The window will refresh and populate with details of the document you are revising, allowing you to change details and checkout the revised document. Click the **Check-out Document** button.

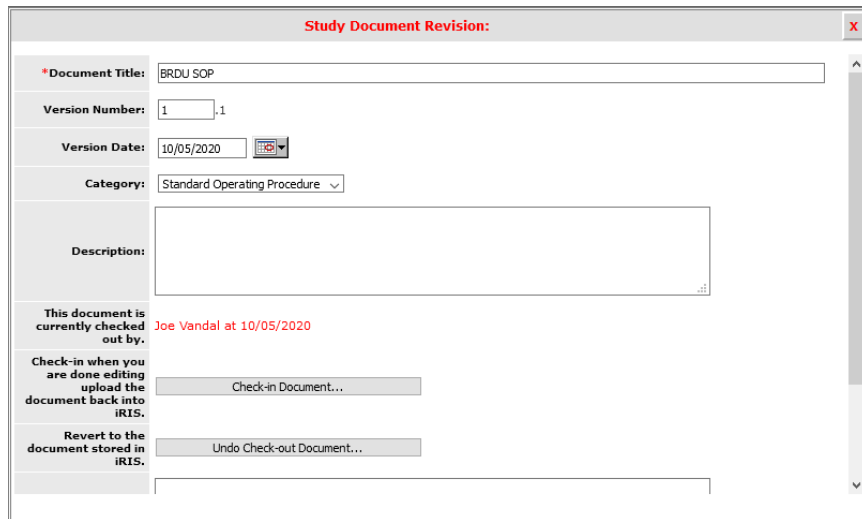


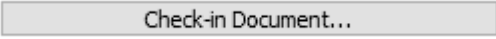
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A window will open, confirming that you want to check-out the document. Click **Confirm**. The document should automatically download. Note: different internet browsers might function differently in the way they process downloaded files.

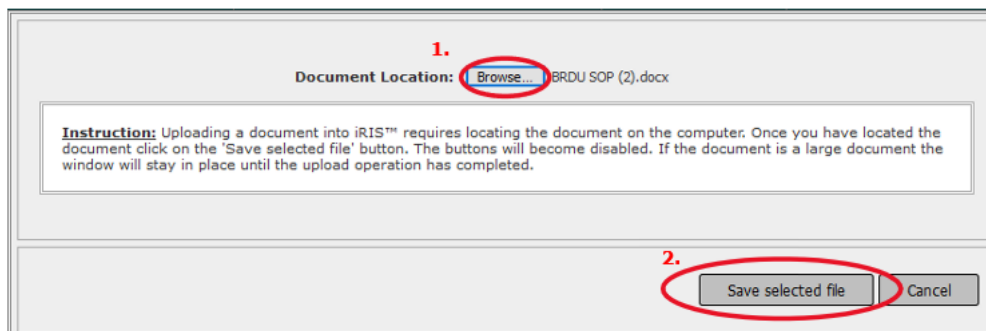
Save the document in a safe and known location so that you can check it back into the system when complete.

You will return to the Study Document Revision page. The page will indicate the document is checked out and you will have the ability to **Check-in Document** or **Undo Check-out Document**.



After you have made changes to the document in Microsoft Word, you can check it back in by clicking the  button.

A window will open, allowing you to browse your computer for the updated document you would like to upload. Click the **Save selected file** button once you specify the document location.



You will then be returned to the Study Document Revision window with the document successfully checked in and associated to the study. Click the **Save Document** to apply the changes.

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**Study Document Revision:**

\*Document Title: BRDU SOP

Version Number: 1 .1

Version Date: 10/05/2020

Category: Standard Operating Procedure

Description:

Check-out the Document to your workstation for editing: Check-out Document...

Comments: Updated contact information

Save Document

You will return to the form, and any document you selected will display in the table.

Select or Revise Existing			Add a New Document		Add Multiple Documents		
Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
	1.1	BRDU SOP	Standard Operating Procedure				11.43 KB

## Section 3 – Response Complete

Select  or

### Final Step - Signoff and Submit

A summary of the submission will be displayed.

- For your personal record, you can save the form into a single pdf document:
  - Check the boxes under the 'Include in PDF Packet' column for each document you want to be included in the single pdf.
  - Create a single pdf by selecting the 'Printable Version' icon.
- Under the *IBC Principal Investigator Agreement*, select 'Approve' and submit your form by clicking on the 'Save Signoff' button

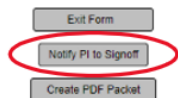
- Once submitted, the PI and Study Contact will receive an auto-generated confirmation email of the submission.

Note: Other study roles may author any of the IBC forms. Instead of seeing the approve and signoff as above, 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 signoff on the submission before it is sent to the IBC for review and approval.

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**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.



Please contact the IBC ((208)-885-7258 or [ibc@uidaho.edu](mailto:ibc@uidaho.edu)) if you have any questions.