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 ibr@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.

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
VERAS Guide - Addressing IBC Stipulations

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

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

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:
4. Address the stipulation as applicable

5. Make sure after any changes made, you select or 

6. Once addressed, select the right hand to return to the IBC Review Response Form

7. 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.

8. Select “Complete Action”

The Action Status will turn green and be marked as “Complete.”
VERAS Guide - Addressing IBC Stipulations

9. 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.

Section 2 – Submission Documents

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

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 **Save and Continue to Next Section**.

**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**.

Complete the addition by “drop file” or upload the documents and entering in the applicable information.
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 X 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.
VERAS Guide - Addressing IBC Stipulations

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

Section 3 – Response Complete

Select [Save and Continue to Next Section] or [Signoff and Submit]

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