IRBMANAGER

IBC Reviewer User Guide

Table of Contents

Introduction

Starting October 1st, 2022, the Nova Southeastern University Institutional Biosafety Committee (IBC) will use an electronic submission system, IRBManager™, for submission of all protocols to the IBC for review. IRBManager is a web-based system accessible anywhere with an Internet connection, that supports electronic submissions of new IBC Protocol Submissions along with Protocol Modifications, Annual Renewals, and Protocol Closures for submissions originally completed in the system. It is also a fully interactive client portal that includes and accepts documents submitted to the IBC such as Permits, Standard Operating Procedures (SOP), and training certifications.

All individuals involved in research with biological agents, including investigators (P.I. and Co. P.I.), members of the research team (i.e., research personnel), and IBC members must create an IRBManager™ account.

Once a new IBC protocol application is submitted through the IRBManager™ system, a series of events initiate that require action based on your role in the IBC. Completion of these steps is required to move the application to the next stage of its review. Please refer to the instructions for each review stage below on how to complete your review.

IBC Office Pre-review Instructions

Once a new protocol submission, protocol modification, annual renewal or protocol closure form has been submitted in the IRBManager system, you will receive an automated email that looks like this:

1. From the email, click on the "IBC Initial Submission Protocol Form" link to access the IBC Protocol application page.

2. Once the link opens, you will complete your pre-review of the form as you would normally review a protocol. For sections in which you have concerns or require clarifications/modifications click "*add note*" on the top of that section and add your comments. If there are multiple questions within a particular section, you can select the particular question your note is referring to using by the drop-down options within the "*add note*" feature. Note that these notes can only be visible to PI as long as the checkbox for "Internal" is <u>unchecked</u>. You may add multiple notes per section.

3. Once you are done reviewing the form and adding all your comments, click "*next*" at the top or the bottom of the page. Select your determination of either "*Ready for review*" or "*Requires changes before review*." There is a summary text box available for you to provide a summary of your concerns or requested changes. The PI will see the summary you provide in an email they receive. Please make sure to refer the PI to look at any "*notes*" you added to the application in the text box.

4. Once you have finished entering your summary, click "*next*" at the bottom of the page then click "*submit*" on the next page.

5. Once the PI resubmits the revised protocol application, the above process will repeat itself until you select "*Ready for review*."

6. After you have selected "*Ready for review*," you will be prompted to answer a few questions related to the assigned BSO, the committee meeting date in which this protocol should be reviewed, lab location information, sponsor information, and a temporary protocol code number. Once you have submitted these answers, it will be forwarded to the next stage, BSO Pre-review.

Biosafety Officer (BSO) Pre-review and Reviewer Assignment Instructions

Once a new protocol submission, protocol modification, annual renewal or protocol closure form has been submitted in the IRBManager system, and has completed the IBC Office pre-review, you will receive an automated email that looks like this:

1. From the email, click on the "Initial Submission Protocol Form" link to access the IBC Protocol application page.

2. Once the submission form opens in a new window, you will complete your review of the form as you would normally review a protocol. For sections in which you have concerns or require clarifications/modifications click "*add note*" on the top of that section and add your comments. If there are multiple questions within a particular section, you can select the particular question your note is referring to by using the drop-down option within the "*add note*" feature. Note that these notes can only be visible to PI as long as the checkbox for "Internal" is <u>unchecked</u>. You may add multiple notes per section.

3. Once you are done reviewing the form and adding all your comments, click "*next*" at the top or the bottom of the page. Select your determination of either "*Yes, ready for IBC review*" or "*Return to PI for Modifications*." There is a summary text box available for you to provide a summary of your concerns or requested changes. The PI will see the summary you provide in an email they receive. Please make sure to refer the PI to look

at any "*notes*" you added to the application in the text box. **Note** that if you return to the PI for modifications, the form will return to Data Entry and will not be considered officially submitted yet and cannot be added to the agenda for committee review.

4. Once you have finished entering your summary, click "*next*" at the bottom of the page then click "*submit*" on the next page.

5. Once the PI resubmits the revised protocol application, the above process will repeat itself until you select "*Ready for IBC review*." Once you select "*Ready for IBC review,*" you will then be prompted to assign a primary and secondary reviewer.

6. Once you have finished entering the assigned reviewer names, click "*next*" at the bottom of the page then click "*submit*" on the next page.

IBC Reviewer Instructions

Once you are assigned as a reviewer, you will receive an automated email that looks like this:
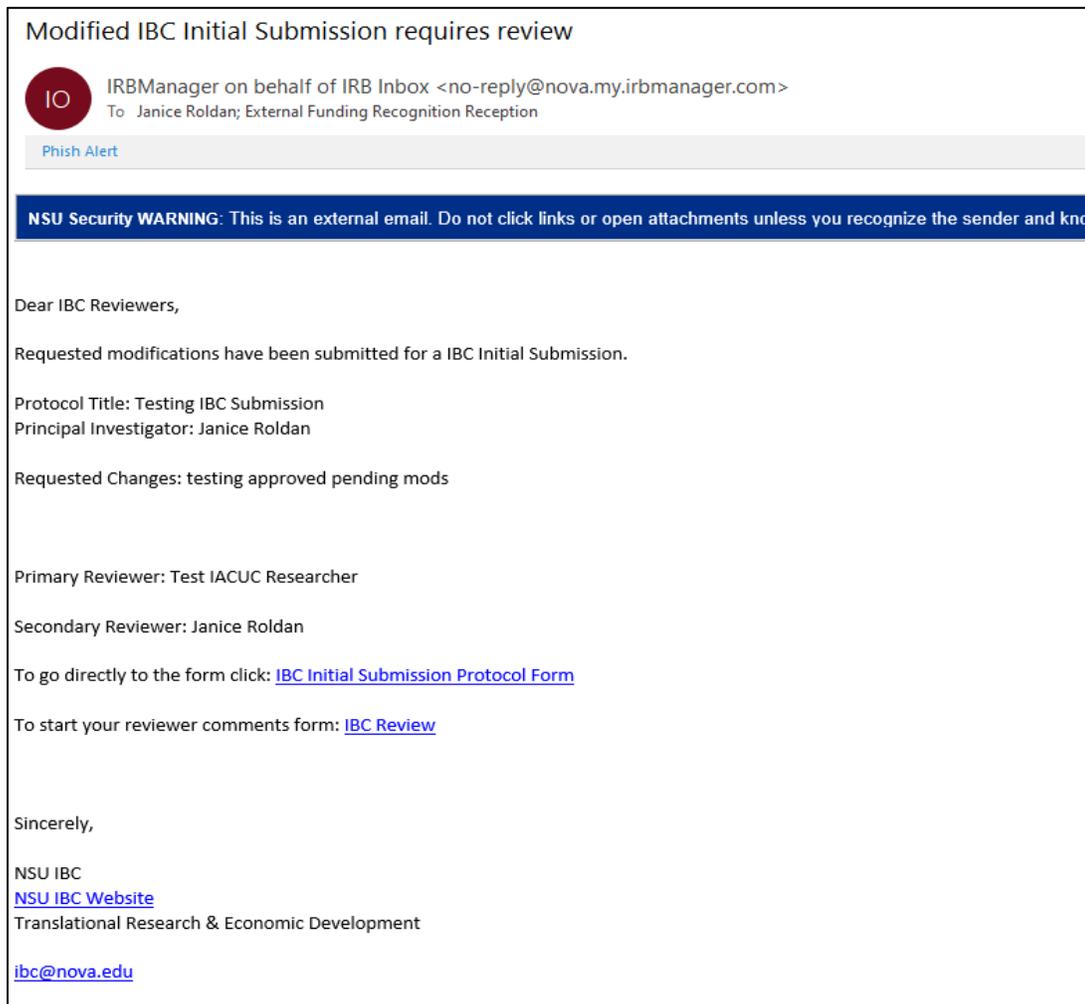

1. You can access the protocol submission form two ways via the links in the email. The "IBC Initial Submission Protocol Form" link will take you directly to the protocol submission form. The "IBC Review" link directs you to the IBC Reviewer Form which looks like the below image.

Review Assignment

Review Assignment	
Review Type: IBC Review	**Assigned:** 07/12/2022 by Roldan, Janice M.B.A.
Reviewer: Roldan, Janice M.B.A.	**Due:** 07/19/2022
Review Item: IBC Initial Submission Protocol Form	

Review Result

⦿ I can do this review   ○ I cannot do this review

Outcome: [dropdown]

Summary: test

[Save]

As you can see, the IBC Reviewer Form page also has a link with instructions on how to access the "IBC Initial Submission Protocol Form." Note, for this option, you will need to have multiple windows open as you will still need to return to the IBC Reviewer Form after reviewing the protocol submission form to enter your review decision/outcome.

2. Once the protocol form opens, whether directly or in a new window, you will complete your review of the form as you would normally review a protocol. For sections in which you have concerns or require clarifications/modifications click "*add note***"** on the top of that section and add your comments. If there are multiple questions within a particular section, you can select the particular question your note is referring to by using the drop-down option within the "*add note*" feature. Note that these notes can only be visible to IBC administration as long as the checkbox for "Internal" stays checked. If you want to add a note to the PI, unclick the "Internal." You may add multiple notes per section.

3. Once you are done reviewing the form and adding all your comments, return to the IBC Reviewer Form browser tab, if opened in a separate browser tab, or

   if you used the direct link to the IBC Initial Submission Protocol Form, click "*next*" at the top or the bottom of the page.

4. Next you will select your determination of either "*Approved*" or "*Approved Pending Modifications*," or "*Not Approve*."   There is a summary text box available for you to provide a summary of your concerns or requests, if any exist. This summary is for IBC administration only.

5. Once you have finished entering your summary, click "*save*" at the bottom of the page and your review will be automatically submitted.

6. If the submission was *"Approved Pending Modifications,"* you will receive an additional automated email when the requested modifications have been submitted. The email will look like this:

Modified IBC Initial Submission requires review

IRBManager on behalf of IRB Inbox <no-reply@nova.my.irbmanager.com>
To   Janice Roldan; External Funding Recognition Reception

Phish Alert

NSU Security WARNING: This is an external email. Do not click links or open attachments unless you recognize the sender and kno

Dear IBC Reviewers,

Requested modifications have been submitted for a IBC Initial Submission.

Protocol Title: Testing IBC Submission
Principal Investigator: Janice Roldan

Requested Changes: testing approved pending mods

Primary Reviewer: Test IACUC Researcher

Secondary Reviewer: Janice Roldan

To go directly to the form click: IBC Initial Submission Protocol Form

To start your reviewer comments form: IBC Review

Sincerely,

NSU IBC
NSU IBC Website
Translational Research & Economic Development

ibc@nova.edu

7. You can access the protocol submission form two ways via the links in the email. The "IBC Initial Submission Protocol Form" link will take you directly to the protocol submission form. The "IBC Review" link directs you to the IBC Reviewer Form which looks like the below image.

8. As mentioned in step 3 above, the IBC Reviewer Form page will also haves a link with instructions on how to access the "IBC Initial Submission Protocol Form." Note, for this option, you will need to have multiple windows open as you will still need to return to the IBC Reviewer Form after reviewing the protocol submission form.

9. Follow steps 3-6 to complete your review of the requested modifications. Note that changes to the protocol form will have the section highlighted.