



IRBMANAGER

IACUC Reviewer User Guide

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Introduction

Starting September 1st, 2021, the Nova Southeastern University Institutional Animal Care and Use Committee (IACUC) will use an electronic submission system, IRBManager™, for submission of all protocols to the IACUC for review. IRBManager is a web-based system accessible anywhere with an Internet connection, that supports electronic submissions of new IACUC Protocol Submissions along with Amendments and Annual Renewals for submissions originally completed in the system. It is also a fully interactive client portal that includes and accepts documents submitted to the IACUC such as Permits, Memorandum of Understanding (MOU), and CITI Training Certificates.

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

Once a new IACUC protocol application is submitted through the IRBManager™ system, a series of events initiate that require action based on your role in the IACUC. 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.

Veterinarian Pre-review Instructions

1. Once a new protocol submission with USDA Pain Categories D and/or E has been submitted in the IRBManager system, you will receive an automated email that looks like this:

New IACUC Amendment Requires Vet Review

 IRBManager on behalf of IRB Inbox <no-reply@nova.my.irbmanager.com>
To: Janice Roldan

Phish Alert

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

Dear Veterinarian,

A new IACUC Amendment has been submitted to NSU IACUC that requires veterinarian review before full committee review.

Submission title minor amendment title change
Submitted by: no-one

To go directly to the form, please click [IACUC Initial Submission Form](#)

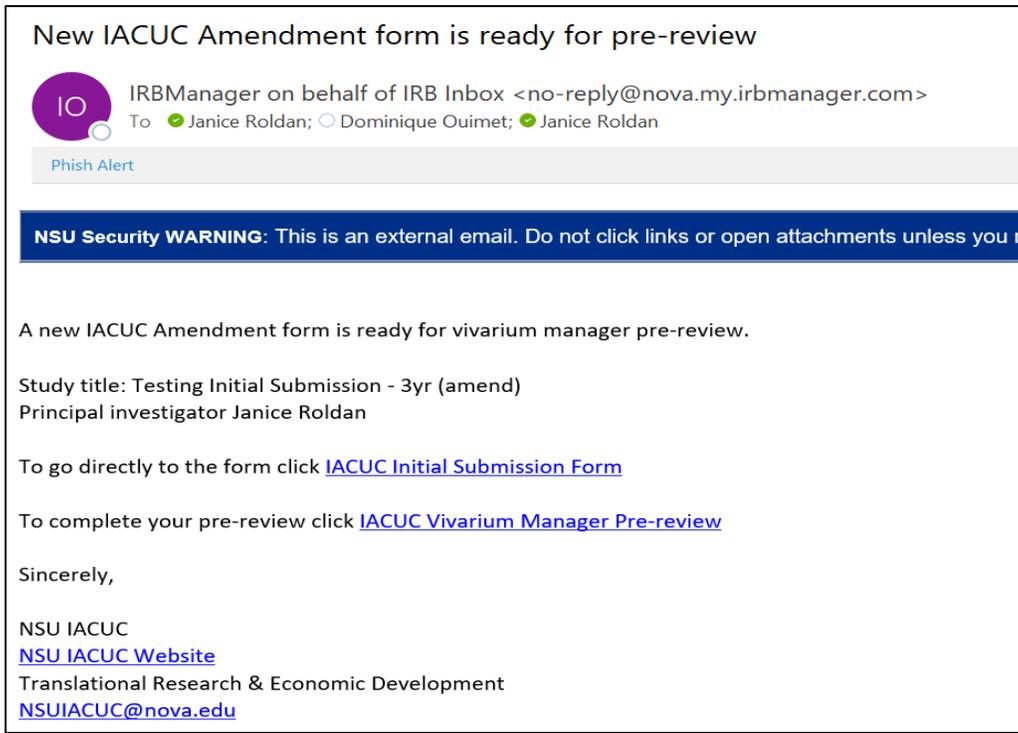
Sincerely,

NSU IACUC
[NSU IACUC Website](#)
Translational Research & Economic Development
NSUIACUC@nova.edu

2. From the email, click on the [“IACUC Initial Submission Form”](#) link to access the IACUC Protocol application page.
3. Once the link opens, 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 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 unchecked. You may add multiple notes per section.
4. 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.
5. Once you have finished entering your summary, click *“next”* at the bottom of the page then click *“submit”* on the next page.
6. Once the PI resubmits the revised protocol application, the above process will repeat itself until you select *“Ready for review.”*

Vivarium Manager Pre-review Instructions

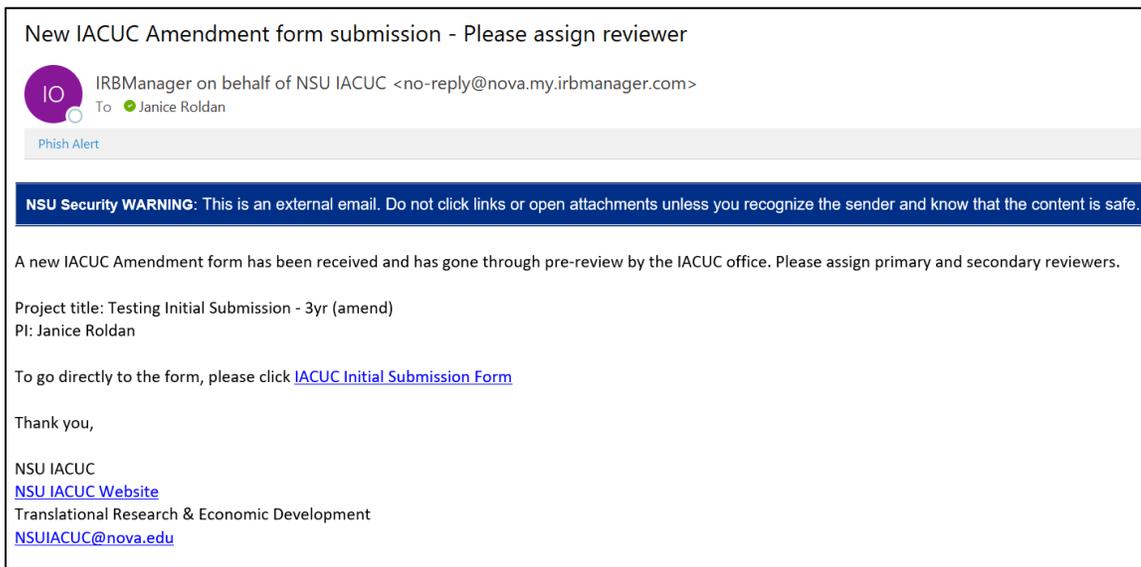
1. Once a new protocol submission or an amended application has been submitted in the IRBManager system, you will receive an automated email that looks like this:



2. From the email, click on the “[Initial Submission Form](#)” link to access the IACUC Protocol application page.
3. 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 unchecked. You may add multiple notes per section.
4. 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 review*” or “*No, changes required before committee 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.
5. Once you have finished entering your summary, click “*next*” at the bottom of the page then click “*submit*” on the next page.
6. Once the PI resubmits the revised protocol application, the above process will repeat itself until you select “*Ready for review.*”

Chair Reviewer Assignment Instructions

1. Once a new protocol submission has been submitted in the IRBManager system, and has been pre-reviewed by both IACUC administration and the vivarium manger, you will receive an automated email that looks like this to assign primary and secondary reviewers:



2. From the email, click on the “[IACUC Initial Submission Form](#)” link to access the IACUC Protocol application page.
3. Once the link opens, you can complete a quick review of the protocol submission form to determine which reviewer would be the best fit for the protocol. You may “*add notes*” to a particular section of the protocol for a reviewer to pay particular attention too. If you do “*add notes*,” please make sure the “*Internal*” checkbox is checked.
4. Once you are done reviewing the form and adding any comments, click “*next*” at the top or the bottom of the page. Select your determination of “Ready to be sent to reviewers. Please do not select “Needs to be sent back to the PI for further review (do not select)” as that feature currently is not in use and is only a place holder. There is a text box available for you to provide any comments to the assigned reviewers if you wish. You may then select the “Primary reviewer” and “Veterinarian reviewer” from the drop-down lists.
5. Once you have finished entering your summary, click “*next*” at the bottom of the page then click “*submit*” on the next page.

IACUC Reviewer Instructions

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

IACUC Amendment form submission for secondary/veterinarian reviewer

 IRBManager on behalf of NSU IACUC <no-reply@nova.my.irbmanager.com>
To  Janice Roldan

Phish Alert

Dear Janice Roldan,

You have been assigned as a veterinary reviewer for a new IACUC Amendment form for review.

Protocol Title: Testing Initial Submission - 3yr (amend)
Principal Investigator: Janice Roldan
Protocol number:

To go directly to the form click: [IACUC Initial Submission Form](#)

To start your reviewer comments form: [IACUC Full Committee Review](#)

Sincerely,

NSU IACUC
[NSU IACUC Website](#)
Translational Research & Economic Development
NSUIACUC@nova.edu

(See next page for next step)

2. You can access the protocol submission form two ways via the links in the email. The “[IACUC Initial Submission Form](#)” link will take you directly to the protocol submission form. The “[IACUC Full Committee Review](#)” link directs you to the IACUC Reviewer Form which looks like the below image.

Review Assignment

Review Type: IACUC Full Committee Review
Reviewer: Roldan, Janice M.B.A.
Review Item: [IACUC Initial Submission Form](#)

Assigned: 05/24/2021 by Roldan, Janice M.B.A.
Due: 05/25/2021

Review xForm

Collaborators Page 1 of 1

IACUC Reviewer Checklist -- Reviewer Determination

Click on the above Review Item link titled "IACUC Initial Submission Form" to access the protocol application. Review the protocol application and click "add note" to the sections that require clarification and/or correction from the PI. These notes will only be visible to IACUC administration. [Add Note](#)

If the protocol requires clarifications and/or corrections, please select "Request Modifications to Secure Approval" in the Outcome dropdown menu.

If you have no concerns with the submitted protocol, please select "Recommend Approval" in the Outcome dropdown menu.

Please select your determination from the drop down below. (Required) [Add Note](#) [View Audit](#)

Please provide a summary of your review and any additional concerns you may have. [Add Note](#) [View Audit](#)

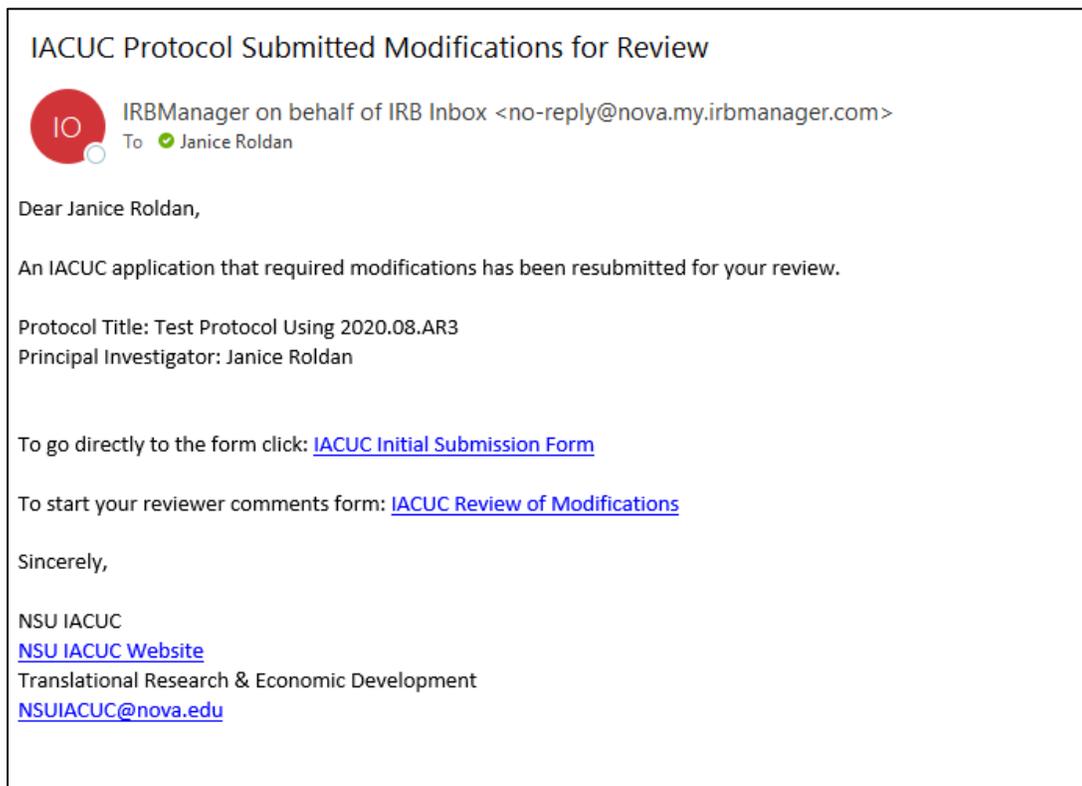
As you can see, the IACUC Reviewer Form page also has a link with instructions on how to access the “[IACUC Initial Submission Form](#).” Note, for this option, you will need to have multiple windows open as you will still need to return to the IACUC Reviewer Form after reviewing the protocol submission form. It is up to you to determine which option is best for you.

3. Once the submission 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 IACUC 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.

4. Once you are done reviewing the form and adding all your comments, return to the [IACUC Reviewer Form](#) browser tab, if opened in a separate browser tab.

If you used the direct link to the [IACUC Initial Submission Form](#), click “next” at the top or the bottom of the page.

5. Next you will select your determination of either “*Recommend Approval*” or “*Request Modifications to Secure Approval.*” 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 IACUC administration only.
6. Once you have finished entering your summary, click “next” at the bottom of the page then click “submit” on the next page.
7. If the submission “*Request Modifications to Secure Approval,*” you will receive an additional automated email when the requested modifications have been submitted. The email will look like this:



8. You can access the protocol submission form two ways via the links in the email. The “[IACUC Initial Submission Form](#)” link will take you directly to the protocol submission form. The “[IACUC Review of Modifications](#)” link directs you to the IACUC Reviewer Form which looks like the below image.

9. As mentioned in step 3 above, the IACUC Reviewer Form page will also have a link with instructions on how to access the "[IACUC Initial Submission Form](#)." Note, for this option, you will need to have multiple windows open as you will still need to return to the IACUC Reviewer Form after reviewing the protocol submission form. It is up to you to determine which option is best for you.
10. Follow steps 3-6 to complete your review of the requested modifications. Note that changes to the protocol form will have the section highlighted.