



IBC IRBMANAGER USER MANUAL

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1. What is IRBManager?

The Nova Southeastern University Institutional Biosafety Committee (IBC) uses an electronic submission system, IRBManager™, for submitting 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 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 IBC such as Permits, Standard Operating Procedures (SOP), and any other training certifications.

All study documents submitted to the IBC will be maintained in the system and be accessible by Users given access to the study. It is highly recommended that you maintain your own copies of these documents outside of the system.

2. IRBManager User Accounts/Login

a. Creating an IRBManager Account

IRBManager is **not** an NSU-dedicated system YET so your NSU email and password will **not** work when logging in. New users must first create a new user account. Please follow the directions below instructions to create your new user account for IRBManager.

1. IRBManager access link: <https://nova.my.irbmanager.com/Login.aspx>
2. Click on "Click here to register".
3. Enter the requested information into the registration form.
4. Once completed, click "Register".

Please Note:

- NSU researchers must use their official NSU email address when registering for IRBManager.
- For researchers without an NSU email (i.e., a non-NSU student, staff, or faculty), please enter an email account used for professional correspondence.
- Do not include your N-number as part of your name.
- Do not include the degree you are seeking as your "Degree". Only include degrees you have "earned."

b. Logging into IRBManager

1. IRBManager access link: <https://nova.my.irbmanager.com/Login.aspx>
2. Enter your username.
3. Enter your password (if you have forgotten your password, please see next section 2.c. below).
4. Select “Login.”
5. You are now logged into IRBManager and are viewing your Dashboard.

c. Forgot Password

There is no penalty for resetting your password and you may reset it as many times as you would like. If you have forgotten your password:

1. Select ‘forgot password’ on the login screen.
2. You will be asked to provide your email address and Client ID (nova) to retrieve your password.
3. Within a few minutes, you will receive an email containing instructions for resetting your password.
4. Once logged in, you will be asked to change (personalize) your password.

d. Locked Out of IRBManager

If locked out of the system due to several failed login attempts (entering a bad password):

1. Select ‘forgot password’ on the login screen.
2. You will be asked to provide your email address and Client ID (nova) to retrieve your password.
3. Within a few minutes, you will receive an email containing your new (reset) password.
4. Once logged in, you will be asked to change (personalize) your password.

3. IRBManager Home Page

Immediately upon login, you will have the ability to


1. View all protocols and forms that you have submitted to the IBC,
2. View all protocols to which you are associated,
3. Submit forms to the IBC,
4. View contacts that have access to your study/site
5. Track progress/status on all information submitted to the IBC.

a. Top red tool bar is **HOME**; you will see the following information on the **HOME** page:

- **Active Protocols** – allows you to view all active protocol numbers (studies) submitted in IRBManager and those in which you are associated with as a collaborator, co-investigator, research personnel, etc.
- **Active xForms** – allows you to view all forms that have been started and submitted, along with the status of each form (i.e., those that have not yet been submitted, those being processed, those awaiting your attention, etc.)
- **Open Events** – allows you to view all Events (forms/requests) that have been submitted to IRBManager but have not yet been completed/distributed by the IBC Office.

- **My IRB Nos** (bottom of screen) – allows you to view all active studies submitted in IRBManager. You can click on the protocol number to open the study file, which will show study information, contacts, events, attachments, etc.
- **Find Protocol** (top- right tool bar) – allows you to search for a study per the sponsor, protocol number, PI name, etc.

b. **Left-side tool bar**, you will see the following sections:

- **Actions** – allows you to select, complete and submit a new form to the IRB under the ‘xForms’ subheading. If you are an IBC member, you will also see your open reviewer events, and agendas & minutes under the ‘Reviewer’ subheading.
- **Recent Items** – allows you to view the 7 most recent items you have accessed.
- **Messages** – allows you to view system-wide messages posted by IRBManager.
- **Useful Links** – allows you to access information posted by IRBManager.
- **My Documents & Forms** – allows you to add attachments by clicking on “User Attachments” – these will be maintained on your HOME page and not associated with a study.
This link also allows you to view forms that you have started (in progress) and forms that you have previously submitted to the IBC. When you click on ‘xForms’ a list of these forms will appear, and you have the option to open the form to complete/submit or click on the red X to delete the form if the form hasn’t been approved. For studies that have already been approved, you will have the option to submit a *Three Year Renewal Application* by clicking on the folder with the green plus sign  icon (when you hover the mouseover the icon, the words ‘Copy for 3 Year Submission’ should appear). Note *Three Year Renewal Application* can also be created directly from your protocol site page; please refer to Section 4b. of this manual for instructions.

c. **Top-right tool bar**, you will see the following tabs:

- **Help** – gives you contact information to the IBC Administration for support with IRBManager. You may also contact the IBC Administration directly at 954-262-7590 email at IBC@nova.edu.
- **[Your Name’s] Settings** – allows you to change specific profile information (i.e., password, phonenumber, address, etc.).
- **Sign Off** – allows you to log out of the system (Note: System will log you off of the system after 2 hours of inactivity.)

4. How to Start & Submit a Form

An xForm is any form that is submitted via IRBManager for review by the IBC. These xForms presently include the *IBC Initial Submission Form*, *IBC Annual Renewal Form*, *IBC Protocol Closure Form*, *IBC Protocol Modification Form* and the *IBC Incident Reporting Form*. These forms must be submitted via the IRBManager electronic submission system to be reviewed by the IBC. Below are instructions for submitting each form in IRBManager.

IMPORTANT NOTE: It is important to note that the *IBC Annual Renewal Form*, *IBC Protocol Closure Form*, and the *IBC Protocol Modification Form* can only be initiated through your specific protocol site page so that they are associated with that specific protocol.

a. Submitting a new protocol with the IBC Initial Submission Form

This form is used to submit a new protocol for review by the IBC.

1. IRBManager access link: <https://nova.my.irbmanager.com/Login.aspx>
2. Create or log into your IRBManager account.
3. Select either “IBC”, “IACUC”, “IRB” or “Show Everything”.
4. Select **HOME** located on the top **red** toolbar.
5. Under **Actions** (left-side tool bar) select the ‘*Start xForm*’
6. Select *IBC Initial Submission Form*.
7. Follow instructions to complete the electronic *IBC Initial Submission Form*.
8. Once the form has been completed, use drop-down menu located at the top of the page to navigate to the “Principal Investigator Agreement” page.
9. Electronically sign your submission by entering your password.
10. Click “Next” then click “Submit” to submit the protocol for review.

b. Submitting a Protocol Modification Form

This form is used to submit a protocol modification or amendment to an already approved IBC protocol.

1. IRBManager access link: <https://nova.my.irbmanager.com/Login.aspx>
2. Log into your IRBManager account.
3. Select **HOME** located on the top **red** toolbar.
4. Under **My IRB Nos.** (last section towards the center of the page) select the *IRB No.* (IBC Number) in which you would like to submit a Protocol Modification for.
5. Once on the Protocol Site Page, on the left-hand side under **IBC No. Site** click *Start xForm*.
6. Once you click the *Start xForm* a new page will open that will offer several IBC forms. Select the *IBC Protocol Modification Form* link.
7. Follow instructions to complete the electronic *IBC Protocol Modification Form*. Please make sure to attach supporting documents with your submission. If you are attaching a previously approved Microsoft Word version of your protocol application, please use the Track Changes feature to identify changes.
8. Once you have completed the form and attached any supporting documents, click “Next” then click “Submit” to submit the form for review.

c. How to Submit an IBC Annual Renewal Form

NSU policy requires the IBC to review all protocols annually. Every year after the date of IBC approval, Investigators are required to submit an IBC Annual Renewal Form to keep the protocol active. Failure to complete the form can result in the suspension of the protocol for noncompliance.

Please submit your *IBC Annual Renewal Form* at least one month prior to current review date so that your study may be reviewed and approved without any lapse in approval.

1. IRBManager access link: <https://nova.my.irbmanager.com/Login.aspx>
2. Log into your IRBManager account.
3. Select **HOME** located on the top **red** toolbar.
4. Under **My IRB Nos.** (last section towards the center of the page) select the *IRB No.* (IBC Number) in which you would like to submit your *IBC Annual Renewal Form* for.
5. Once on the Protocol Site Page, select ‘*Start xForm*’ on the left side of the screen.
6. Select the *IBC Annual Renewal Form*.

7. Follow instructions to complete the electronic *IBC Annual Renewal Form*.
8. Electronically sign your submission by entering your password.
9. Click “Next” then click “Submit” to submit the form for review.

d. How to Submit an IBC Protocol Closure Form

If your research has concluded, please complete a *IBC Protocol Closure Form*. This form must be submitted within 30 days of the conclusion of research activities.

1. IRBManager access link: <https://nova.my.irbmanager.com/Login.aspx>
2. Log into your IRBManager account.
3. Select **HOME** located on the top **red** toolbar.
1. Under **My IRB Nos.** (last section towards the center of the page) select the *IRB No.* (IBC Number) in which you would like to submit your *IBC Protocol Closure form* for.
2. Once on the Protocol Site Page, select ‘*Start xForm*’ on the left side of the screen.
3. Select the *IBC Protocol Closure Form*.
4. Follow instructions to complete the electronic *IBC Protocol Closure Form*.
5. Electronically sign your submission by entering your password.
6. Click “Next” then click “Submit” to submit the form for review.

5. How to Find Your Approved Study Documents

a. Access to Protocol Site Page

There are two ways to access your protocol once it has been approved (please note that pending forms will not appear in this section).

1. Active protocols are available on your **HOME** page listed under **My IRB Nos**
 - a. To access the protocol file, select the protocol number under **My IRB Nos**.
 - b. This will take you to the Protocol Site Page view.
2. You can locate specific protocols by using the ‘Find Protocol’ search feature located on the red **HOME** tool bar.

b. Access to Study File

On the Protocol Site Page view, you can view all protocol, PI, approval letters and site details and the events (forms) that have been submitted under ‘*Events*’. Click the event link to view the steps that have been/will be taken by the IBC. The IBC completion dates of each Step are found under ‘*Actual*’ date.

c. Save/Print Copy of Study File

1. On the Protocol Site Page view, select the protocol you wish to view approval documents for.
2. Scroll to the bottom of the page and select “PDF”.
3. This will download a PDF copy of the submission to your computer which may then be saved and/or printed for your use and records.

d. Access to Approval Documents

All approval documents including Approval Letters are located in IRBManager.

1. On the Protocol Site Page view, under the IBC No. – Site Attachments section, you will find all associated approval documents related to that protocol.
2. Click on the approval attachments and a PDF copy of the approval documents will automatically be downloaded to your computer which may then be saved and/or printed for your use and records.

e. Events

Events are defined as forms/requests you are submitting to the IBC. Once you have submitted an xForm to the IBC the Event will appear in your Protocol Site Page.

f. Attachments

To view attachments to an Event, you must be in the Protocol Site Page and have the Event open. On the left side tool bar, click on '*Attachments*' to review the documents you have submitted and the actions taken by the IBC. You can also retrieve your attachments by clicking on the column labeled '*ATT*' and selecting the number listed below it. This will take you directly to the Attachment page view. IRBManager approval documents will be posted under a sub-heading labeled '*Generated Documents*'. The system accepts all file types with no size limits.

g. Steps (Status of Submission)

Steps are defined as actions to be taken by IBC Administration on an Event. You may view the steps (action/status) being taken on a form anytime by opening the form under '*Events*'. (Remember that an Event is the form/request that has been submitted.) Steps exist to provide you with a "real time" status on Events.

h. Filtering/Searching

There are a couple of ways to search for study information/files.

- To filter for a protocol record: On top-right tool bar, click in 'Find Protocol' search feature – allows you to search for a protocol record per the sponsor name, protocol number, PI name, etc.
- To filter for similar protocol records (i.e., protocols containing same site name, same PI name, or same expiration date): On the HOME page, under 'My IRB Nos' click somewhere inside of the row of the column in which you want to search (i.e., to search for the studies with the same site name click in the one of the rows that indicate the site name). The result of the search will place a yellow highlighted border around all records that contain the site name. You can filter the same way while in an Event for similar Event types.

6.Forms and Navigation Tips

a. Form Navigation Buttons (top of each page):

Page titles/headers - allows you to "jump" between pages of the form before completing all required questions on a page. Click on the drop down to choose the page you wish to jump to. If all required questions are not completed when you submit, you will receive a message that the form is not complete. Please make sure to click "Save" located at the bottom of the page you are currently working on prior to "jumping" to another page.

Page numbers - shows "Page x of y" on each page of the form.

Next - saves the current page and takes you to the next page in the form once all questions have been answered. If you have not completely answered each question or are missing a required attachment, you will get a red error message alerting you to complete that section before you may click "Next" to save current page and move to the next page.

b. Form Navigation Buttons (bottom of each page):

Previous - takes you back to the previous page.

Next - saves the current page and takes you to the next page in the form.

Save for Later - saves the progress in the current form to finish later (if you meant to move to the next page, you can click on the browser's back button and click the 'Next' button)

PDF - allows you to save the form as a PDF file. You may also save and print the PDF version. If you plan to close the form following selecting PDF, ensure you Save for Later.

Print – allows you to print the form. This will be an option at the end of the form and prior to submission.

c. Required Fields

- Questions that are required are indicated as “Required”. This means that you must provide an answer before submitting the form.
- When “Required” questions are left blank, an error message will alert you in red text as to which questions have information missing.
- When “Required” attachments are not uploaded, an error message will alert you in red text as to which questions have attachments missing.

d. Attachments

- When an attachment is required or may be necessary, the question will provide you with the option to upload a file. This will be evident for those questions that contain an upload browser. The system accepts all file types with no size limits.
- Some questions may only allow one attachment (such as the consent form pages), for those questions that may require more than one attachment the system will allow for multiple files to upload one at a time. If for some reason you are not allowed to upload more than one attachment, please contact the IBC Administration at IBC@nova.edu for assistance.
- To attach a file, click on 'Add Attachment' (the upload browser), enter the name of the file (optional), press 'Select' and locate the file from your computer files then press 'Attach'. You will then see the attachment on the form view.

e. Notes

In the top right corner of each question select “Add Note”, enter your comments/questions and select OK. The note will be highlighted in green. **DO NOT** delete any notes made by the IBC Administration or review members. The “Add Note” feature may be used for the following:

1. Submitter clarifying a comment to a “Yes/No” question.
2. Reviewers making comments or requests for revisions on a submission.
3. Submitter responding to reviewer comments without making changes to the protocol (i.e., You asked about X and my protocol doesn't address it for Y reason).

f. Making Revisions and/or Requested Modifications

Until you have submitted your protocol, you are free to make as many edits as you would like to the submission. Once you have submitted the *IBC Initial Submission Form* it is **locked from editing** until it has been reviewed (depending on the stage) by either the:

- IBC Administration
- Biosafety Officer (BSO)
- IBC Chair
- IBC Reviewer

If you need to make edits prior to review, please contact the IBC so that we may reopen your

submission form. Otherwise wait until the reviewer has sent it back 'Data Entry Stage' for revisions.

Once the submission has been reviewed and it has been determined that revisions are necessary the protocol will be sent back to the 'Data Entry Stage' for the PI to make the required edits.

1. The PI will be notified via email of the requested for modifications.
2. Click on the link provided in the email notification and it will take you directly to your submission or follow the instructions provided in section 5 to locate the study.
3. All required edits will be in **green** highlighted text boxes. **DO NOT DELETE THESE BOXES AFTER MAKING REVISIONS!!!**
4. Make all the requested revisions to the protocol by either editing question answers or using the 'Add Note' feature to send a note to the reviewer.
5. Once all edits have been made, use drop-down menu located at the top of the page to navigate to the "PI Agreement" page.
6. Electronically sign your submission by entering your password.
7. Click "Next" then click "Submit" to re-submit the protocol for review.

g. Signatures

The IBC requires PI signature on the *IBC Initial Submission Form, IBC Annual Renewal Form, IBC Protocol Modification Form and IBC Closure Report Form*. If someone other than the PI completed the form, the PI will be sent an email instructing them to perform a final review of the form and sign off on the submission.

This is accomplished via electronic signature. The electronic signature requires the PI to enter their password, which will represent their signature. The PI will be required to re-sign after each revision/re-submission.

7. System Requirements

Supported Operating Systems (OS) and Browsers

- The system is compatible with the following operating systems: Current versions of Windows, Linux, and OS X (Mac).
- The system is compatible with the following internet browsers: Firefox, Chrome and Safari on supported OS.
- While smart phones and tablets may be able to access the IRBManager system, the site will not display properly, and some features may not be available. It is advised that you do not use a smartphone or tablet to submit xForms in the IRBManager system.

8. IRBManager Help & Support

- For general questions or assistance with forms or system navigation contact IBC Administration at 954-262-7590 or email at IBC@nova.edu.
- For help with passwords, refer to Step 2.c. and 2.d.