



NOVA SOUTHEASTERN UNIVERSITY
Institutional Review Board

IRBMANAGER USER MANUAL

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1. What is IRBManager?

The Nova Southeastern University Institutional Review Board uses an electronic submission system, IRBManager™, for submitting all protocols to the IRB Office for review. IRBManager is a web-based system accessible anywhere with an Internet connection, that supports electronic submissions of new IRB studies along with Amendment and Continuing Review for submissions originally completed in the system. It is also a fully interactive client portal that includes and accepts documents submitted to the IRB, approval memos, informed consents, expirations, electronic signatures, automated email notifications, tracking and IRB distribution. IRBManager is a 21 CFR, Part 11 compliant system and contains a verification process for new users.

All study documents submitted to the IRB 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 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 in order 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".
5. After completing the registration process, please complete the *Researchers Qualifications xForm* found under the "Actions" section (see Section 4.a. of manual for more information), located on the left-hand side of your dashboard.

Please Note:

- NSU researchers must use their official NSU email address when registering for IRBManager. If not, they will be required to change their contact email to their NSU email address prior to their study being reviewed.
- Personal email accounts are not permitted because all official correspondences from the IRB Office can only be sent to your official NSU email address per NSU policy.
- 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.).
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 studies and forms that you have submitted to the IRB,
2. View all protocols to which you are associated,
3. Submit forms to the IRB,
4. View contacts that have access to your study/site
5. Track progress/status on all information submitted to the IRB.
6. Reviews that you may have pending with Faculty Advisors or Thesis/Dissertation Chairs and College Representatives.

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 assistant, 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 IRB 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.
- **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, such as this User Manual
- **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 IRB. 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 an Amendment by clicking on the folder with the green plus sign  icon (when you hover the mouse over the icon, the words “Copy for Amendment” should appear).

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

- **Help** – gives you contact information to the IRB Office for support with IRBManager. You may also contact the IRB Office directly at 954-262-5369 or email at irb@nova.edu.
- **[Your Name’s] Settings** – allows you to change specific profile information (i.e. password, phone number, 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 IRB Office. These xForms presently include the *Researchers Qualification*, *New Protocol Submission*, *Amendment*, *Continuing Review*, and *Closing Report* Forms. These forms must be submitted via the IRBManager electronic submission system in order to be reviewed by the IRB Office. Below are instructions for submitting each form in IRBManager.

a. Submit the Researchers Qualification Form

This form is where researchers document their qualifications to conduct research with human participants and provide proof of current Human Subjects Protection Training, such as CITI. This form needs to be completed by **all** study team members prior to submitting your *Initial Submission Form*. It is the responsibility of the Principle Investigator to ensure that all study team members complete the form.

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 Actions (left-side tool bar) select the 'Researchers Qualification Form'
5. Follow instructions to complete the electronic *Researchers Qualification Form*.
6. Once the form has been submitted, it is locked from editing.

If "**MISSING**" appears in your CITI expiration field, then please enter the alternate email address you used when registering with CITI in the 'CITI Alternate Emails' field located in the Researcher Information block. It may take a few hours for this information to update in the system and update both your *Researchers Qualification Form* and *New Protocol Submission Form*.

If you need to edit a submitted *Researchers Qualification Form*, please contact the IRB Office so that the form may be re-opened for editing.

b. Submit a New Study


This form is used to submit a new study for review by the IRB Office.

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

For more information regarding completing the content of this form, please see New Protocol Submission Form Guide on our website.

c. Submit an Amendment

If you need to modify or amend an *active* study in IRBManager, the *Amendment Form* will need to be completed and submitted for review by the IRB Office prior to implementation.

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 Documents & Forms (left-side tool bar) select the 'xForms'
5. Find the Protocol Code (IRB Number) for the study you wish to amend/modify.
6. Select the folder with the green plus sign  (when you hover the mouse over the icon, the words "Copy for Amendment" should appear).
7. Follow instructions to complete the electronic *Amendment 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 for Continuing Review for Expedited or Full Board Studies

Study approval is only good for the period of time stipulated on the approval letter you received from the IRB Office. Continuing Review is required no less than once annually and must occur for any active Expedited or Full Board protocol including those where the only activity that remains is data analysis. Please submit your *Continuing Review Form* at least three months prior to current review date so that your study may be reviewed and approved without any lapse in approval. If your study was Exempted, you are **NOT** required to submit for Continuing Review.

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 Documents & Forms (left-side tool bar) select the 'xForms'
5. Select the Protocol Code (IRB Number) for the study you wish to file a Continuing Review for.
6. Select 'Start xForm' on the left side of the screen.
7. Select the 'Continuing Review Form'.
8. Follow instructions to complete the electronic *Continuing Review Form*.
9. Electronically sign your submission by entering your password.
10. Click "Next" then click "Submit" to submit the form for review.

e. How to Submit a Closing Report Form

If your research has concluded, please complete a Closing Report Form. This form must be submitted within 30 days of the conclusion of research activities (all intervention/interaction with human subjects AND data analysis has ended).

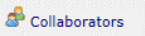
1. IRBManager access link: <https://nova.my.irbmanager.com/Login.aspx>
2. Log into your IRBManager account.
3. Select 'Home' located on the top **red** toolbar.
4. Under My Documents & Forms (left-side tool bar) select the 'xForms'
5. Select the Protocol Code (IRB Number) for the study you wish to file a Closing Report for.
6. Select 'Start xForm' on the left side of the screen.
7. Select the 'Closing Report Form'.
8. Follow instructions to complete the electronic *Closing Report Form*.
9. Electronically sign your submission by entering your password.
10. Click "Next" then click "Submit" to submit the form for review.

f. Adding a Colleague to Assist with the Completion/Submission of an xForm

In IRBManager, only the person who started (authored) the xForm may edit/submit the submission unless the xForm author adds others as Collaborators. Collaborators can be given different levels of access which may be one or a combination of the following:

1. Edit—may make edits to the submission xForm
2. Manage—may add other Collaborators to the xForm
3. Submit—may submit the completed xForm

To add a Collaborator:

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 Documents & Forms (left-side tool bar) select the 'xForms'
5. Select the Protocol Code (IRB Number) for the study you wish to add a collaborator to.
6. On the top of the page you will see the option to add collaborators
 - o Click on this icon 
7. Once selected, enter the email(s) of the person(s) you wish to add as a collaborator to this submission (they must already be a registered User in the IRBManager system).
8. Select the type of permission you want them to have (i.e. Edit, Edit and manage, Edit, manage, and submit).
9. You may also add notes to the collaborator.
10. Select "Add" to send the email.
11. The person you requested will receive an email with a direct link to the form inviting them to be a collaborator on the submission. This email should be saved as it provides a link for accessing the protocol.
12. When a protocol is submitted and returned for revisions, the PI will have to re-add any Collaborators as desired.

5. How to Find Your Approved Study Documents

a. Access to Study Summary Page (SSP)

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

1. Active studies are available on your **HOME** page listed under 'My IRB Nos'
 - a. To access the study file, select the protocol number under 'My IRB Nos'.
 - b. This will take you to the Study Summary 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 Summary Study Page view, you can view all protocol, PI, 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 IRB. The IRB completion dates of each Step are found under 'Actual' date.

c. Save/Print Copy of Study File

1. On the Summary Study Page view, select the study 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 Memo and stamped recruitment materials, consent/assent forms, etc. are located in IRBManager.

1. On the Summary Study Page view, select the study you wish to view approval documents for.
2. Select 'Attachments' and all your approval documentation will be there for your use and download.
3. 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 IRB. Once you have submitted an xForm to the IRB the Event will appear in your Study Summary Page (SSP).

f. Attachments

To view attachments to an Event, you must be in the Study Summary Page (SSP) 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 IRB. 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 IRB Office 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 study record: On top-right tool bar, click in 'Find Protocol' search feature – allows you to search for a study record per the sponsor name, protocol number, PI name, etc.
- To filter for similar study records (i.e. studies 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):

Collaborators - allows you to select a colleague to assist with the completion/submission of a form. Refer to Step 2.f. for more details.

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 IRB Office at 954-262-5369 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 your Faculty Advisor, Thesis/Dissertation Chair, College Representative, or by the IRB Office. 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

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 *New Protocol Submission Form* it is **locked from editing** until it has been reviewed (depending on the stage) by either the:

- Faculty Advisor or Thesis/Dissertation Chair
- College Representative
- IRB Office
- IRB Chair

If you need to make edits prior to review, please contact the IRB Office 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 request for revision.
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 "Principal Investigator Assurance and Obligations" 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 IRB Office requires signatures on the New Protocol, Continuing Review, Amendment, and Closing Report forms. The Principal Investigator (PI) is required to sign off on the form before submitting and in the case of student PIs, their Faculty Advisor or Thesis/Dissertation Chair as well. 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. Please note that for student PIs, Faculty Advisor or Thesis/Dissertation Chair will also have 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 smart phone or tablet to submit xForms in the IRBManager system.

8. IRBManager Help & Support

- For general questions or assistance with forms or system navigation contact the IRB Office at 954-262-5369 or email at irb@nova.edu.
- For help with passwords, refer to Step 2.c. and 2.d.
- Please refer to our 'Frequently Asked Questions' section on our website at <http://www.nova.edu/irb/manual/faq.html> for common questions regarding the IRB process and IRBManager.