IRB Manager for New Users: Training manual

For questions, please contact the NSU IRB Office:

Nova Southeastern University
Institutional Review Board
William Smith, IRB Director (954-262-5311)
Randy Denis, IRB Specialist (954-262-5368)
Crystal Bass, IRB Administrative Assistant (954-262-5369)
IRBManager access link: https://nova.my.irbmanager.com/Login.aspx

New Users:
* Username: newuser (all lowercase)
* Password: newuser (all lowercase)
* Client: Nova
Dashboard Features:
* Links you to the CITI training website.
* Ability to see all protocols linked to your account.
* Review status of your IRB application.

To begin a new IRB application:
* Click: Start an xForm
Steps:
- Under ‘Actions’, click: ‘Start xForm’

Please note:
- You can start an xForms for:
  - New Protocol Submission Form/Initial IRB Application (new IRB application)
  - Amendment Form
  - Continuing Review Form
  - Closing Report
  - Additional Forms
To start a new IRB application:

- Under ‘Forms’, click on ‘New Protocol Submission’ to start a new IRB application.

Please note:

- The first document available to the entire university will be the New Protocol Submission Form.
- All other IRB forms will be posted in this section.
- The New Protocol Submission Form has been updated with new sections, questions, and other items have been re-organized.
- Unlike the paper-based application, the e-form is customizable to your specific research protocol needs. This saves time and trees!
New Protocol Submission
General Information

General Information Page:

* 1.A. Center Representative email (see latest roster on IRB website)
* 1.B. Submitter (automatically generated)
* 1.D. Principal Investigator (may be different from the submitter)

Additional information is found on the next pages about the various features.
Located at the TOP LEFT of the screen:

- Allows the PI the option to add individuals to the development of the document. This feature is helpful when various researchers are working on the IRB application.

- You determine the access level for each individual:
  - **Edit** (the person added will be able to edit the content)
  - **Manage** (the person added will be able to edit and add/remove other collaborators)
  - **Submit** (the person added will be able to edit the content, add/remove other collaborators, and submit documents). Please note: The principal investigator will be requested to approve submissions.
Additional features

- Using the drop down menu allows you to navigate through the different pages of the application with ease. You can skip to other sections, without having to use the ‘Previous’ or ‘Next’ button.
- Information within each page is saved as you click ‘Next’. To save all pages including the page currently being worked on, select ‘Save for Later’.
- To download a PDF of this application, select ‘PDF’.
2.A. Add co-investigators and research assistants:
* Please use the ‘Add Contact’ feature to find co-investigators’ profile in IRBManager.
* If person is not identified by the system, please ask that person to create an account on IRBManager.
* Add Co-Investigators in the “Contacts” box, provide their name and provide a brief description of their background, and click on ‘Add’ to complete this section.
* For multiple investigators, continue to add the name and background information. The faculty advisor information will be requested in this section.
This page only appears if the researcher selects ‘Funded’ or ‘Funding Applied For’ in the General Information Page. This is the first conditional page.

This page asks for the name of the sponsor, the source of funding, the title (if different from this protocol), type and amount of the award.

Please use the Repeat feature to add multiple grants/sources of funding.
4.A., 4.B. & 4.C. Asks questions about where the study will occur and requests approval letters for studies occurring at a non-NSU location.

* For studies being reviewed by IRBs other than NSU’s (“Collaborative Research”), additional pages will request information about the status of that application.
**Collaborative research**

New Protocol Submission -- Non-NSU IRB Information

<table>
<thead>
<tr>
<th>5.A. Name of other institution where you will conduct the study. (Required)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>5.B. Please select this study’s status with the other IRB. (Required)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Approved</td>
</tr>
<tr>
<td>• Not yet submitted</td>
</tr>
<tr>
<td>• Submitted (not yet approved)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5.C. Level of review (if IRB reviewed) (Required)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Exempt</td>
</tr>
<tr>
<td>• Expedited</td>
</tr>
<tr>
<td>• Full</td>
</tr>
<tr>
<td>• Not yet reviewed</td>
</tr>
</tbody>
</table>

* For studies involving “Collaborate Research”, this page will collect this information.
* Use the ‘Repeat’ option to add multiple Institutional Review Board pages.
This section covers description of the purpose of the study, brief literature review, and the steps in the research study.

The next slide will provide further information about selecting procedures associated with the research methodology.
* **6.E.** Please use this section to select the different types of research methodology being used for this study.

* The definition of these various study designs can be found on our website.
7.A. For studies involving focus groups/interviews/surveys, this page asks for the names of the instruments and/or interview guides that will be used as part of the research procedures.

7.B. Please attach copies of all questionnaires, tests, surveys, and other instruments.

7.C. For studies involving surveying of the NSU population, the last question is a link to the Survey Policy.
8.A. For studies involving the collection of data from records/archives, this page requests information regarding how educational records will be accessed and how the data is being collected.

* If protected health information will be used, another section will ask about the collection of protected health information (PHI).
For studies involving the collection of data using electronic means (i.e., online survey), this section requests information regarding the website/apps being used and the protection of confidentiality.
For studies involving deceptive procedures, this page provides basic guidance regarding the Deception Policy.

10.A. This section requests information about the nature of the deception, justification for the use of deception, and requests information about the debriefing procedures.

The debriefing material can be uploaded into this page.
11.A., 11.B., & 11.C. For studies involving clinical procedures, the PI will be asked information relating to the potential collection of biological specimens, use of diagnostic procedures, and/or the evaluation of best clinical/evidence-based practices.
For studies involving the administration of medications, this section will ask questions to determine the name of medications and collects other necessary information.

Studies involving FDA-approved devices for the use of the approved indication will only complete this page.

Studies involving non-FDA approved devices, or using an approved device outside of the approved indication, additional pages will need to be completed.
For studies involving the use of medical devices, this section asks questions as to the level of approval received.

- FDA-approved devices for the use of the approved indication will only complete this page.
- Studies involving non-FDA approved devices, or using an approved device outside of the approved indication, additional pages will need to be completed.
All researchers will be asked to complete this page.

The inclusion/exclusion criteria page asks questions about characteristics that will be selected to be part of the study, the number of participants, and whether the study involves the recruitment of non-English speaking participants.

If the study involves the recruitment of non-English speaking participants, the next page will ask further information.
For studies involving non-English speaking participants, recommendations are provided and a link to the online Verification of Translation Form.

This page requests for a list of languages.

The Verification of Translation Form can be uploaded into this section.
All researchers will be asked to complete this page. The content found here is almost identical to the one found on our paper-based system.

For studies not involving any of these vulnerable populations, please select ‘None of the Above’ and this will be the only page the researcher will view.

For studies involving vulnerable populations, additional pages will be added for each vulnerable group.
Researchers who checked-off 'Students/Employees' in the Vulnerable Population Page will be asked to complete this page.

This section asks questions asking to describe relationship between researcher and participants and action plan to mitigate potential coercion.
Researchers who checked-off ‘Patients of the Investigator’ in the Vulnerable Population Page will be presented with this page.

- This section asks questions asking to describe relationship between researcher and participants, action plan to mitigate coercion, and how participant can feel free to decline participation.
Researchers who checked-off ‘Children’ in the Vulnerable Population Page will be presented with this page.

This section asks questions regarding the level of risk associated with the study, the number of parents whose permission will be asked, and the extent of involvement in the decision-making process.
Researchers who checked-off ‘Cognitive Impairments’ in the Vulnerable Population Page will be presented with this page.

* In this page, please discuss the type of impairment, how competency will be determined, potential need for Legally Authorized Representative, and how competency will be maintained throughout the study.
The instructions on this page provides regulatory language regarding the inclusion of prisoners in research.

If this study involves the use of prisoners, please ensure that all of the items listed in this section are discussed/justified in this section.
All researchers will be asked to complete the Participant Recruitment Page.

This page asks information about the use of written, verbal, or visual material that will be used for recruitment purposes.

This page asks about participant compensation. If the researcher plans to compensate participants, a new page will appear requesting information about the nature of the compensation.
This page breaks depending on the type of payment that is being given to participants:

- Compensation is given to participants for their general participation.
- Reimbursement refers to a refund for expenses incurred by the participant as a result from joining the study.
- For some studies, both compensation and reimbursement may apply.
This page will be completed by all researchers.

The first question asks whether the study involves more than one group of participants.

An additional page will be completed for consent process type.

For multiple groups, click on ‘Repeat’ after the completion of the consent process page.
**Protected health information**

* This page will appear for all researchers.
* Based on the answers to two questions in this section:
  * HIPAA regulations do not apply and you do not need to complete additional pages.
  * HIPAA regulations do apply and additional pages will be added to the application to ensure compliance with the protection of private health information.
This page will be completed by all researchers.

This page asks the researcher questions about how confidentiality. The likelihood of the risk, the severity, procedures that will be used to mitigate the risks, and discussion as to the sensitivity of the questions.

If the study involves the use of sensitive questions, a further question will ask about the nature of the questions.
If the research has additional risks, in addition to ‘Loss of Confidentiality’, this page will allow for the addition of multiple risks, discomforts, and inconveniences.
Benefits to participants

This page asks about the proposed data analysis procedures being implemented, how the study will enhance scientific understanding, the potential for direct benefits, and a discussion on the benefit-risk ratio.

* This page will be completed by all researchers.
This page will be completed by all researchers.

This page requests information about how the study data will be stored, who has access, and how the research team will ensure confidentiality of the study information.

A data destruction plan is required in this section.
All researchers will be asked whether or not they have Safety Monitoring Plans. These plans are usually created for high-risk trials.
This page will be completed by all researchers and provide a place to attach additional documents that were not previously attached in the other sections.
There are two assurances and obligations sections:

- The principal investigator is asked to review the various responsibilities and check-off that they are in accord with each statement.
- For student researchers, a faculty assurance and obligation will be completed after the student submits the initial application.
- After this section, the Check & Submit page may appear if there are pages with unanswered required questions.
Please contact the NSU IRB office:
954-262-5369
X25369
irb@nova.edu

If you would like to receive periodical updates about our IRBManager system and other updates, please visit our website for updates:
http://nova.edu/irb/updates.html