THE INSTITUTIONAL REVIEW BOARD
TIPS FOR SUCCESS

Nova Southeastern University
Abraham S. Fischler College of Education
Institutional Review Board

Dr. Ashley Russom, NSU Institutional Review Board 2nd Vice Chair and Lead FCE IRB Representative
Dr. David B. Ross, Associate Professor
WHAT IS IRB?

- Institutional Review Board (IRB)
- IRB ensures
  - ethical and safe research is conducted at NSU.
  - federal regulations protecting human participants are followed.
  - the rights of participants are protected.
  - informed consent is given.
  - research does not place participants at unreasonable risk.

*All students must submit to IRB and obtain approval prior to conducting research*
FCE IRB REPRESENTATIVES

- Dr Ashley Russom (Lead FCE IRB Representative): russom@nova.edu
- Dr David Escobar: de186@nova.edu
- Dr Silvia Orta: ortas@nova.edu
- Dr Jennifer Reeves: jennreev@nova.edu
- Dr Gabriela Mendez: gmendez@nova.edu
- Dr Zandra Stino: stino@nova.edu
- Dr David Ross: daviross@nova.edu
- Dr Alex Edmonds: edmonds@nova.edu
- Dr Sidi Lakhdar: lakhdars@nova.edu
- Dr Jared Bucker: jared@nova.edu
HELPFUL TIPS: EARLY ON

- Early on in the dissertation process:
  - Student should communicate with the study site regarding the research project AND the process for securing approval in the dissertation process and communicate that process to the chair via ADRIANA.
  - Consider the population you will be working with (especially in terms of vulnerable populations)
  - What are vulnerable populations? Individuals who require special consideration or extra protection
    - Children and minorities
    - Prisoners
    - Cognitively impaired or physically ill
  - Consider the consenting and assenting procedures
  - Be aware that local sites can take up to 3 months for review and approval so please be sure to include this in your timeline
HELPFUL TIPS: CITI CERTIFICATION

- CITI certification is required for ALL students conducting research at NSU.
- CITI certification is valid for 3 years, after which you must complete the refresher course.
- The CITI certificate must be valid for the length of the student’s study.
- If your CITI certification is set to expire within 3 months you MUST go ahead and complete the refresher course before your IRB documents can be reviewed.
- CITI Homepage
  http://www.citiprogram.org
- CITI Assistance
  http://www.nova.edu/irb/training.html
HELPFUL TIPS: SITE APPROVAL

- For the IRB submission, the student must upload a signed administrative letter giving permission to conduct their study at the study site
  - If the site requires our IRB approval first, documentation must be uploaded to support this (e.g., email, letter, or application stating as such)!
  - Please note that NSU IRB approval does not guarantee approval from your study site!

- Please contact one of the FCE IRB Representatives with ANY questions or concerns!!! Please do not contact main campus as we have slightly different procedures.
HELPFUL TIPS: CONSENT FORMS

- Specific forms for specific situations:
  - Archival, de-identified data (ONLY) – no consent form needed
  - Anonymous survey (ONLY) – Participation Letter
  - Adults actively involved in research – consent form
  - Children actively involved in research – parent consent form AND child assent form
    - Parental consent MUST be secured FIRST and parent must be given at least 24 hours to decide
    - Student is consented 2nd, but student still has right to decline

- At all times, participation in a research study is VOLUNTARY!!!
  - Participants can withdraw from the study AT ANY TIME!

- Students should NOT approach any participants until they have IRB approval!!

- You are the principal investigator. Your dissertation chair is your co-investigator
HELPFUL TIPS: NEW IRB SUBMISSIONS

ADRIANA
- FCE’s dissertation tracking system

IRB Manager
- NSU’s electronic IRB submission system
- All IRB documents are submitted through IRB Manager with the exception of the Proposal
  - Note: Spanish-speaking students will continue to submit “paper” submissions via ADRIANA
- IRB Manager: https://nova.my.irbmanager.com/
- IRB Manager Instructions: http://www.nova.edu/irb/irbmanager/index.html
HELPFUL TIPS: IRB MANAGER

- Be sure to complete the Researchers Qualification Form before beginning a New Protocol Submission xForm.

- Student MUST add the chair as a collaborator who can EDIT the IRB Manager form.

- Chair is the co-investigator of the study AND the faculty advisor (but they only need to be added once as the faculty advisor)

- Be sure to upload scripts for any recruitment letters, emails, reminder emails, phone calls, etc.

- Be sure the information is consistent throughout IRB Manager and all documentation!
IRB DISSECTMENT CAFÉ

• Every Tuesday 7-10pm EST
• Ashley Russom (or another IRB Rep) is available for individual questions and assistance!
• You are welcome to attend alone or WITH your dissertation chair!
• Come with questions or log in and work on your IRB documents while someone is there to assist with any questions or concerns

• Join from PC, Mac, Linux, iOS or Android:
  https://zoom.us/j/884830929
STEPS FOR THE PRINCIPAL INVESTIGATOR (PI)

1. Student PIs:
   b. Obtain approval from Faculty Advisor prior to beginning IRB Process (if research is unrelated to thesis/dissertation).

2. Complete the required CITI Human Subjects Training course.

3. Create an IRBManager account.

4. Complete the Researchers Qualification xForm in IRBManager.

5. Complete the New Submission xForm in IRBManager.

6. Upon receiving IRB approval, begin their research study.

7. If any modifications to an approved study are necessary, file an Amendment xForm prior to implementing changes.

8. Once a year, file Continuing Review xForm if the study is still collecting or analyzing data.

9. Submit a Closing Report xForm upon completion of all data related activities, including data analysis.
BEFORE STARTING NEW PROTOCOL SUBMISSION XFORM:

1. Complete the required CITI Human Subjects Training course. Instructions for registering and completing this training can be found on our website on the CITI Training page at: http://www.nova.edu/irb/training.html

2. Create an IRBManager account. Instructions for registering can be found on our website on the IRBManager page at: http://www.nova.edu/irb/irbmanager/index.html

3. Complete the Researcher Qualification xForm. Instructions for completing this form can be found on our website on the IRBManager page at: http://www.nova.edu/irb/irbmanager/index.html

4. Make sure all study team members have:
   a. Completed the required CITI Human Subjects Training course.
   b. Created an IRBManager account.
   c. Completed and submitted the Researcher Qualification xForm.
Your IRBManager account

- http://www.nova.edu/irb/irbmanager/index.html
Log into your IRBManager account

- Enter User Name and password to log into your IRBManager account

**NOTE:** You must 1st create an IRBManager account. This is not an NSU system so your NSU login information/password will not work. If you have not created an account, please see our [Creating an IRBManager Account](#) Guide for instructions.

- If you have forgotten your password, click ‘Forgot Password?’ and follow instructions to be sent an email to reset your password.
Home Features

- Links you to the CITI training website.
- Ability to see all protocols linked to your account.
- Review status of your IRB application.
- On the Home screen under Actions (left-side tool bar) select ‘2. Click Here to New IRB Submission’
- This will open the New Protocol Submission xForm
Adding a Collaborator

- 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 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.

**NOTE:** The Principal Investigator will be required to approval all submissions entered by collaborators.
USEFUL FEATURES (1 OF 2)

‘Drop-down Menu’

At the top of each page in the xForm:

- 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.

At the bottom of each page in the xForm:

- Click ‘Previous’ or ‘Next’ to move to the previous/next page in the xForm. Information within each page is saved as you click ‘Previous’ or ‘Next’.
- Some pages allow you to “repeat” the page for additional groups. Select ‘Repeat’ to duplicate a page.
- To save all pages including the page currently being worked on, select ‘Save for Later’.
- To view only questions with note comments made by reviewers, select ‘View Questions with Notes’.
- To download a PDF of this application, select ‘PDF’.
USEFUL FEATURES (2 OF 2)

- Instructions can be found at the top of each page and at the beginning of each question.

- Help Text appears in red to the right of questions in the xForm to provide further clarification.

- The ‘Add Note’ feature can be used by reviewers to request revisions or by the PI to provide clarification in response to reviewers comments.
1. **GENERAL INFORMATION (1 OF 3)**

- 1.A. Select your College that you are enrolled or affiliated with.
- 1.B. This field is automatically generated by IRBManager system and cannot be changed in the form.
- 1.C. Enter a unique study title that is different from any previously submitted IRB studies.
  - Do not include your name, credentials, or NSU N# as part of title.
1. Enter the email address for the Principal Investigator
   - Click TAB key to populate information.
   - In order to add Principal Investigator, they must have an IRBManager account.

2. Information regarding this question is presented on the next slide.

3. Select funding status of study.
1. **GENERAL INFORMATION**  (3 OF 3)

<table>
<thead>
<tr>
<th>1.F. What is the Principal Investigator’s relationship to Nova Southeastern University? (Required)</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Checkbox options: Student, Faculty, Staff]</td>
</tr>
<tr>
<td>![Input fields: Do you have an approved thesis/dissertation proposal?, Date of Thesis/Dissertation Approval]</td>
</tr>
</tbody>
</table>

- 1.F. Select whether the PI will be performing the study as a Student, Faculty, or Staff at NSU (Select all that apply)

- If you select ‘Student’, you will be asked for information regarding your thesis/dissertation proposal (if applicable).
2. Student researchers must enter their Faculty Advisor or Thesis/Dissertation Chair's NSU email address *(Required)*

- Enter their email address
- Click TAB key

2.A. and 2.B. Adding Co-Investigators and Research Assistants

- Select ‘Add Contact’ to search for a contact using their email address.
- For multiple investigators, continue to add their names using the ‘Add Contact’ feature.

**NOTE:** If person is not identified by the system, they must create an account and complete the Researcher Qualification xForm in IRBManager before a New Protocol Submission xForm can be submitted for review.
QUALIFICATIONS CHECK PAGE

- This page will display researcher qualifications as they were entered on the Researcher Qualification xForm for each member of the research team. This form must be completed prior to beginning the New Submission Form.

- You cannot alter the information in this Section.
  - IRBManager automatically generates this information from your completed and submitted Researcher Qualification xForm.

- If information does not appear in this section for a research team member, they must complete and submit the Researcher Qualification xForm before you can submit your study for review. Exit the New Protocol Submission xForm, and complete and submit the Researcher Qualification xForm before continuing.

- If a research team member completed the Researcher Qualification xForm after you started the New Protocol Submission xForm, the information will not appear until you submit xForm for review.
CITI CHECK FOR RESEARCH STAFF

- CITI Check for Research Staff page will display the CITI expiration dates for each member of the research team.

- **You cannot alter information in this Section.**
  - IRBManager automatically generates this information from your completed and submitted *Researcher Qualification xForm*.

- If information does not appear in this section for a research team member, they must complete and submit the *Researcher Qualification xForm*. Exit the *New Protocol Submission xForm*, and complete and submit the *Researcher Qualification xForm* before continuing.

- If your CITI has expired, the IRB Office will contact you.

- If a research team member completed the *Researcher Qualification xForm* after you started the *New Protocol Submission xForm*, the information will not appear until you submit xForm for review.
### Funding Information (1 of 2)

- This page only appears if the researcher selects ‘Funded’ or ‘Funding Applied For’ in the General Information Page. This is the first “Smart Form” page.
- This page asks for information regarding the type of funding for the study.
- Please use the Repeat feature to add multiple grants/sources of funding.

<table>
<thead>
<tr>
<th>Column</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J.A. Name of Sponsor</td>
<td>Add Note</td>
</tr>
<tr>
<td>J.B. Source of Funding (if known)</td>
<td>Add Note</td>
</tr>
<tr>
<td>Internal or Internal Funding</td>
<td>Add Note</td>
</tr>
<tr>
<td>J.C. Funded Project Title (if different from section 1.C.)</td>
<td>Add Note</td>
</tr>
<tr>
<td>J.D. Enter the name of the principal investigator if different from principal investigator on this study</td>
<td>Add Note</td>
</tr>
<tr>
<td>J.E. Type of Funding</td>
<td>Add Note</td>
</tr>
<tr>
<td></td>
<td>Grant</td>
</tr>
<tr>
<td></td>
<td>Contract</td>
</tr>
<tr>
<td></td>
<td>Sub-Award</td>
</tr>
<tr>
<td></td>
<td>Cooperative Agreement</td>
</tr>
<tr>
<td></td>
<td>Fellowship</td>
</tr>
<tr>
<td></td>
<td>Gift</td>
</tr>
<tr>
<td></td>
<td>Other</td>
</tr>
<tr>
<td>J.F. Select the NSU Department that is administering the funding</td>
<td>Add Note</td>
</tr>
<tr>
<td></td>
<td>Office of Clinical Research (OCR)</td>
</tr>
<tr>
<td></td>
<td>Office of Sponsored Programs (OSP)</td>
</tr>
<tr>
<td></td>
<td>HPD Grant</td>
</tr>
<tr>
<td></td>
<td>PFRO/WQI Grant</td>
</tr>
<tr>
<td></td>
<td>Other</td>
</tr>
<tr>
<td>J.G. Award amount (if known)</td>
<td>Add Note</td>
</tr>
<tr>
<td>J.H. Insert your index number (if known)</td>
<td>Add Note</td>
</tr>
</tbody>
</table>

For studies involving multiple sources of funding, please click the ‘Repeat’ button.
3. **Funding Information (2 of 2)**

- Your study is not considered a “funded” study if money comes from your personal funds.

- Funding Administration refers to the department at NSU that is administering your funds.
  - Office of Clinical Research
  - Office of Sponsored Programs
  - HPD Grant
  - PFRDG/QOL Grant
  - Other
### 4. Site Information

<table>
<thead>
<tr>
<th>4.A. Will the study be conducted at an NSU location? (Required)</th>
<th>Add Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td>HELP TEXT: This does not include online research.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4.B. Will any research activities be conducted via the Internet or a web-based platform? (Required)</th>
<th>Add Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4.C. Does this research involve review and approval by non-NSU Institutional Review Boards (&quot;cooperative research&quot;)? (Required)</th>
<th>Add Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4.D. Will any part of the study be conducted at a non-NSU location? (Required)</th>
<th>Add Note</th>
</tr>
</thead>
</table>
| [ ]   HELP TEXT: Physical locations only, exclude Internet and web-based platforms.  
Please see the suggested NSU Template [here](#), under Site Approval Letter. |          |

Click the NEXT BUTTON to continue

- This page gathers information about where the study will occur
- 4.B. For studies that will not have a physical location because they are partly or entirely conducted via online platform, telephone, web/mobile apps, etc.
- 4.C. For studies being reviewed by IRBs other than NSU’s (“Collaborative Research”), additional pages will request information about the status of that application.
- 4.D. If you select ‘Yes’, you will be asked to provide name, address, and contact information for each site. You will also be asked to attach approval/permission letters for studies occurring at a non-NSU location.
- **CEME – Contact the IRB Office if you require clarification regarding study site location.**
5. NON-NSU IRB INFORMATION

- For studies involving “Collaborate Research”, this page will collect information about the other non-NSU IRB.
- Use the ‘Repeat’ option to add multiple Institutional Review Board pages.
6. STUDY DESIGN AND METHODOLOGY (1 OF 3)

- On this page, provide:
  - A 1-2 sentence description of your study’s purpose.
  - A brief literature review that outlines the justification for this study.
  - An outline of the steps of the research study.

- Below 6.C., you can use the “Add Attachment” button to add only graphics and/or pictures that are referenced in protocol steps. DO NOT attach other forms or documents here.
6. STUDY DESIGN AND METHODOLOGY (2 OF 3)

<table>
<thead>
<tr>
<th>6.D. Is this a multi-part study involving the administration of instruments/interventions that are being developed? (Required) Add Note</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>6.E. Select all of the following procedures which apply to this study. (Required) Add Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Case Study (HPD only)</td>
</tr>
<tr>
<td>[ ] Deception</td>
</tr>
<tr>
<td>[ ] Drug</td>
</tr>
<tr>
<td>[ ] Focus Group</td>
</tr>
<tr>
<td>[ ] Medical/Dental Procedures</td>
</tr>
<tr>
<td>[ ] Online/Internet Research</td>
</tr>
<tr>
<td>[ ] Social/Behavioral Intervention</td>
</tr>
<tr>
<td>[ ] Case Study (non-HPD)</td>
</tr>
<tr>
<td>[ ] Device</td>
</tr>
<tr>
<td>[ ] Educational Intervention</td>
</tr>
<tr>
<td>[ ] Interview</td>
</tr>
<tr>
<td>[ ] Observation</td>
</tr>
<tr>
<td>[ ] Records/Archives</td>
</tr>
<tr>
<td>[ ] Survey/Assessments</td>
</tr>
</tbody>
</table>

HELP TEXT:
Click here for explanations of these procedures.

- **6.D.** Will this study develop research instruments or interventions during first phase of multi-part study, that will be used in later phases?
  - If “Yes”, you will be asked to identify the steps in the research process that have yet to be developed.
  - Prior to the implementation of the new instruments/interventions, an Amendment Form must be completed, detailing these new instruments/interventions.

- **6.E.** Select **all** the different types of research methodology being used for this study.
  - A description of each type of research methodology can be found on the next slide.
6. STUDY DESIGN AND METHODOLOGY (3 of 3)

- **Deception**: Research involving providing false information to or withholding information from participants about the research study.
- **Device**: Research involving the use of instrument, apparatuses, implants, or similar articles that are used to diagnose, prevent, or treat diseases or other conditions.
- **Drug**: Research involving the administration of prescription and/or over-the-counter (OTC) medication intended to diagnose, cure, mitigate, treat, or prevent diseases or other conditions.
- **Educational Intervention**: Research involving the testing of standard or novel methods of teaching instruction.
- **Focus Group**: Research involving group interviews or discussions.
- **Interview**: Research involving individual interviews.
- **Observation**: Research involving observations of participant(s) either in a natural/unaltered environment or an environment altered by the researcher but without direct intervention between the researcher and participant.
- **Online/Internet Research**: Research involving the use of electronic means (i.e., computers, telephone, and websites) to interact and/or collect information from research participants.
- **Records/Archives**: Research involving the use of records or specimens (i.e., medical records, student records, organizational records, clinically-discarded tissues, etc.) that are either previously-collected or will be collected for non-research purposes.
- **Medical/Dental Procedures**: Research involving standard medical practices, the collection of biological specimens, routine diagnostic and laboratory testing, and/or evaluation of novel clinical procedures.
- **Social/Behavioral Intervention**: Research involving direct interaction between the researcher(s) and participant to create, measure, and evaluate the effect(s) of the interaction.
- **Survey**: Research involving the administration of questionnaires, tests, surveys, or other similar instruments.
7. FOCUS GROUP/INTERVIEW/SURVEY

- 7.A. For studies involving focus groups/interviews/surveys, list all the instruments and/or interview guides that will be used as part of the research procedures.

- 7.B. Attach copies of all questionnaires, tests, surveys, and other instruments.

- 7.C. For studies using email to survey an NSU population, if “Yes” is selected, a link to the [NSU Survey Policy](#) will be provided.
8. Records/Archives (1 of 2)

- 8.A. & 8.B. For studies involving the collection of data from records/archives, this page requests information regarding:
  - Records that are being used
  - Location of records (virtual and/or physical)
  - Who provides the researcher access to records
  - How the researcher will be provided the records
  - Exact variables collected from these records

NOTE: If Protected Health Information (PHI) for HIPAA purposes will be used, another section will ask about the collection of PHI.
8. RECORDS/ARCHIVES (2 OF 2)

8.C. Will educational/academic records will be accessed and how is that data is being collected?

- Access to data from participant's academic records falls under the Family Educational Rights and Privacy Act (FERPA).
- These are the **ONLY** three options regarding FERPA and the use of participant's academic records.
- For more information regarding the Family Educational Rights and Privacy Act (FERPA) visit the [FERPA website](#).
9. ONLINE RESEARCH

Online research occurs when the researcher and participants interact through electronic means. Particular concerns include loss of confidentiality, privacy/anonymity, and the lack of direct communication between parties.

9.A. Does this research involve the use of any online websites (e.g., SurveyMonkey, Redcap, Gizmo, etc.)? (Required)

9.B. Does this research involve the use of apps/programs to collect or interact with participants (e.g., iPhone/iPad chat, Skype, etc.)? (Required)

9.C. Does this research involve potential access to IP addresses, email addresses, unique user profiles, or other information that can be traced back to a particular person? (Required)

Click the NEXT BUTTON to continue

- 9.A., 9.B., & 9.C. For studies involving the collection of data using electronic means (i.e., online survey, questionnaires, etc.), this section requests information regarding the website/apps being used in addition to the protection of confidentiality.
10. DECEPTION

For studies involving deceptive procedures, this page provides basic guidance regarding the Deception Policy.

- Deception in research involves providing false information to or withholding information from participants about the research study. The IRB policy on Deception in Research is found on our website at [NSU IRB Policies & Procedures page](#).

10.A. & 10.B. request information regarding the nature of the deception, justification for the use of deception.

10.C. requests information about the debriefing procedures. The debriefing material can be uploaded into this page using the “Add Attachment” button.
### 11. MEDICAL/DENTAL PROCEDURES

<table>
<thead>
<tr>
<th>Question</th>
<th>Required?</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.A. Does the study involve the collection of biological specimens?</td>
<td>Yes</td>
</tr>
<tr>
<td>11.B. Does the study involve any diagnostic examinations/tests or clinical treatments?</td>
<td>Yes</td>
</tr>
<tr>
<td>11.C. Does this study involve the evaluation of current clinical best practice(s)?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

- **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

- Based on your response, you may be asked to provide further information.
12. USE OF DRUGS IN RESEARCH

- For studies involving the administration of medications, this section will ask questions to determine the name of medications and collects other necessary information.

- All studies involving FDA-approved drugs for the use of the approved indication will complete this page.

- For studies involving non-FDA approved drugs, or using an approved drug outside of the approved indication, future pages will collect additional information.

- Based on your response, you may be asked to provide further information.
13. IND REQUIREMENTS

- This page will collect additional information if the study involves the use of a drug in a manner not approved by the FDA.

- An Investigational New Drug (IND) application may be required unless it meets an exemption based on specific criteria or direct correspondence from the FDA.

- Based on your response, you may be asked to provide further information.

- If you are unsure or need assistance in acquiring an IND from the FDA, please contact the NSU IRB Office office.
### 14. Use of Devices in Research

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer Options</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>14.A. Will this study involve the use of any FDA-approved/cleared device(s) for the approved indication(s)?</strong> <em>(Required)</em></td>
<td>Yes, No</td>
</tr>
<tr>
<td><strong>14.B. Will this study involve the use of any FDA-approved/cleared device(s) for indication(s) not approved by the FDA?</strong> <em>(Required)</em></td>
<td>Yes, No</td>
</tr>
<tr>
<td><strong>14.C. Will this study involve the use of any device(s) not approved by the FDA?</strong> <em>(Required)</em></td>
<td>Yes, No</td>
</tr>
</tbody>
</table>

Click the **NEXT BUTTON** to continue.

- For studies involving the use of medical devices, this section asks questions regarding the level of approval received.
- All studies involving FDA-approved drugs for the use of the approved indication will complete this page.
- Studies involving non-FDA approved devices, or using an approved device outside of the approved indication, future pages will collect additional information.
- Based on your responses, you may be asked to provide further information.
15. DEVICE EXEMPTIONS
16. DEVICES ABBREVIATED IDE
17. DEVICES FULL IDE

- These pages ask for information regarding an Investigational Device Exemption (IDE).
- If you are unsure or need assistance in acquiring an IDE from the FDA, contact the NSU IRB Office.
18. INCLUSION/EXCLUSION CRITERIA (1 OF 2)

- 18.A., 18.B. and 18.C. asks questions about inclusion, exclusion criteria, and approximate number of participants in the study.
  - **Inclusion criteria** are characteristics that the prospective subjects must have if they are to be included in the study.
  - **Exclusion criteria** are any characteristics that would prohibit a potential participant who meets all inclusion criteria from participating in the study.
18. INCLUSION/EXCLUSION CRITERIA (2 OF 2)

- 18.D. Will study prevent enrollment based on gender, race, or ethnicity?
  - If “Yes” you will be asked to provide further information.

- 18.E. If the study involves the recruitment of non-English speaking participants, the next page will ask further information.

- 18.F. Attach any pre-screening tools (optional).
19. NON-ENGLISH SPEAKING PARTICIPANTS

Review NSU IRB Forms for specific forms regarding translations of study documents. The NSU IRB recommends the following procedures for studies using translated documents:

1. Do not translate the consent or assent documents until the English version has been approved by the IRB; this is to ensure that no time or money is wasted having to redo translations. Submit the translations after approval, using the Amendment Form.

2. For studies that are reviewed at the College Level or by Expedited Review, the IRB allows the use of non-certified translators but will require the translator to fill out the Verification of Translation Form.

3. For studies that are reviewed by the full IRB, a certified translation will be required after approval, using the Amendment Form.

4. Do not use Google Translate or any other translation program.

<table>
<thead>
<tr>
<th>19.A. List the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td>i. The language(s) involved in the study,</td>
</tr>
<tr>
<td>ii. The people using those language(s),</td>
</tr>
<tr>
<td>iii. The relevant document(s) to be translated.</td>
</tr>
</tbody>
</table>

Submit Translated Documents after Approval, using the Amendment Form.

Click the NEXT BUTTON to continue

- For studies involving non-English speaking participants, recommendations are and a link to the online Verification of Translation Form are provided.

- This page requests a list of languages being used, the people using those languages, and a list of the documents that will be translated upon approval.

- All translated documents are to be submitted to the IRB Office using the Amendment xForm once final approval of the New Protocol Submission xForm has been received.
20 Vulnerable Populations (1 of 2)

  - For studies not involving any of these vulnerable populations, select ‘None of the Above’.
  - Explanation of vulnerable populations can be found on the next slide.

- For studies involving vulnerable populations, supplementary pages will be added for each vulnerable group requesting additional information.
These groups of potential participants may be vulnerable to undue influence or coercion that would undermine true voluntary informed consent.

- **Students or employees of the investigator(s):** Research involving persons under the direct supervision of any researchers. “Students” only applies when a researcher has specific academic authority over the potential participant (i.e. students in the investigator’s class or student-employees).

- **Students in their educational setting (in class or at school):** Research involving persons recruited or participating as part of non-research academic activities or settings. This group is distinct from the “Students or employees of the investigators” because they might not have academic authority over participants. However, both categories are possible for the same group.
  - This refers to students recruited in class or by their teacher where there may be a perceived authority, grade pressure, and/or inability of the students to not participate in the research study.

- **Patients of the investigator(s):** Research involving the recruitment of patients from an investigator’s clinical practice.

- **Children/Minors (under the age of 18):** Research involving persons under the age of eighteen who are not emancipated.

- **Cognitively impaired, or otherwise unable to consent for themselves:** Research involving persons with temporary or permanent condition(s) that affects their mental or physical ability to provide informed consent.

- **Wards of the State:** Research involving children/minors who are under the custody of government departments, which act as their legal guardians (i.e., foster care).

- **Prisoners:** Research involving persons involuntarily confined or detained in a penal institution.

- **Women of child-bearing potential (are/may become pregnant and selected for that reason):** Research involving persons who are or may become pregnant, and whose inclusion in the study is based upon this criteria.

- **Others vulnerable to coercion:** Research involving other groups that may have particular characteristics that may make them vulnerable to coercion (i.e., terminally ill patients, persons of disadvantaged socioeconomic status, persons with limited literacy, etc.).
21. STUDENTS/EMPLOYEES

Researchers who checked-off 'Students/Employees' in the Vulnerable Population Page will be asked to complete this page.

This section asks questions regarding the relationship between researcher and participants, action plan to mitigate coercion, and how participant can feel free to decline participation.
Researchers who checked-off ‘Patients of the Investigator’ in the Vulnerable Population Page will be asked to complete this page.

This section asks questions regarding the relationship between researcher and participants, how to prevent “therapeutic misconception”, and how to prevent participants from mistaking a provider’s recommendation of a research study for a clinical recommendation.
23. CHILDREN

- Researchers who checked-off ‘Children’ in the Vulnerable Population Page will be asked to complete this page.

- This section asks questions regarding the level of risk associated with the study, if one or both parents whose permission will be asked, number of child participants who will complete assent, and the extent of child involvement in the decision-making process.

- Based on your response, you may be asked to provide further information.
24. WARDS OF THE STATE

Researchers who checked-off ‘Wards of the State’ in the Vulnerable Population Page will be asked to complete this page.

This section asks questions regarding the level of risk associated with the study along with other information about working with this vulnerable population.

Based on your response, you may be asked to provide further information.
25. COGNITIVELY IMPAIRED PARTICIPANTS

- Researchers who checked-off ‘Cognitive Impairments’ in the Vulnerable Population Page will be asked to complete this page.

- In this page, describe:
  A. the type of impairment
  B. how competency will be determined
  C. the potential need for Legally Authorized Representative
  D. how competency will be continually assessed throughout the study
  E. how cognitively impaired participants will be involved in decision making process
The instructions on this page provide 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 here.

Based on your response, you may be asked to provide further information.
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 along with participant compensation.

Based on your response, you may be asked to provide further information and/or to attach recruitment materials (may attach more...
27. PARTICIPANT RECRUITMENT (2 OF 2)

Recruitment materials must include **ALL** required elements.

**Required Elements***

- All flyers must have **1.25-inch blank/light colored space** in the top right-hand corner to allow for electronic approval stamping.
- Study title.
- The word "research." Make it clear that this is a research study.
- "Nova Southeastern University"
- The PI's name.
- A contact name with either a phone number or e-mail address.
- Eligibility criteria, if applicable, should be noted briefly. Especially if payment depends on meeting these criteria. For example, "*English speaking only*," "*Women only,*" etc.
- State whether participants will be paid for their time and effort. The amount of payment may be included, but should not be the most prominent element on the page and should not seem excessive considering the nature of the project.

**Recommended Elements**

- Purpose of the study.
- What is expected of the participant.
- The time commitment.
- The location where the research will take place.

*If your Recruitment Flyer does not meet these requirements, it will be sent back to you for revision.
## 28. Participant Compensation (1 of 2)

### Select 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 (i.e. mileage, lodging, etc.).
- For some studies, both compensation and reimbursement may apply.
- Based on your response, you may be asked to provide further information.

### 28.A. Which type(s) of payment will be offered to participants? (Required)

- Compensation
- Reimbursement

### 28.B. Provide details about what expenses are eligible for reimbursement, including any maximum dollar amounts. (Required)

#### HELP TEXT:
Compensation is general payment for inconvenience or an incentive to participate. For example, a $30 gift card to Target.

Reimbursement is repayment for direct and actual expenses. For example, a $12.68 check after being given a receipt for $12.68 in gasoline costs.

### 28.C. Indicate the types of compensation. (Required)

- Cash/Checks/Gift Cards
- Gifts/Items
- Lottery/Raffle
- Extra Credit (students)
- Other incentives

#### HELP TEXT:
Please Note: It is the responsibility of the Principal Investigator to contact University General Counsel, Joel Berman, JD, at jberman@nova.edu, prior to implementing study, to ensure they are in compliance with state regulations regarding the use of incentives or raffles.

### 28.D. Describe:

1. The compensation offered
2. Who is eligible to receive compensation
3. The compensation amount
4. The timing of payment(s), including any prorated payments (Required)

#### HELP TEXT:
The IRB reviews compensation for “undue influence”: inducement to act differently than normal in order to obtain possible payment. Sources of undue influence include large payment amounts, completion bonuses, and the participant’s socioeconomic status.
IMPORTANT NOTE REGARDING THE USE OF LOTTERIES AS COMPENSATION:

It is the responsibility of the Principal Investigator to contact the University General Counsel, prior to implementing the study, to ensure they are in compliance with state regulations regarding the use of lotteries or raffles.
29. CONSENT PROCESS (1 OF 3)

- This page will be completed by all researchers and collects information regarding:
  
  A. How many and the names of the groups you will consent.
     - Use the same name for each group as they will be identified during the research study.
  
  B. How you will consent participants for the research study.

- Based on how many “groups of participants” you will be consenting, additional pages will request information on each group’s consent process.

- Based on the type of consent process, additional pages will request information on those consent processes.

- Information regarding the consent process, can be found on the next slide.
29. CONSENT PROCESS - PROCESS (2 OF 3)

- Unless the IRB Office has approved a Waiver of Informed Consent, an investigator may not involve human participants in research unless the investigator has obtained informed consent from the participant or their legally authorized representative (LARS).

- **Informed Consent is a process, not a document and involves:**
  - Reviewing the IRB approved Informed Consent Form with participants.
  - Discussing the risks and benefits of an intervention with participants.
  - Answering any questions participants may have about participation in the research study.
  - Ensure the participant understands by asking them questions regarding the Informed Consent Form.
  - Participants signing the Informed Consent Form in order to participate in the study (unless a waiver of documentation has been obtained from the IRB Office).
Consent Process Types

- **Normal Consent Process**: Select this option as the default consent process, unless a waiver or alteration is more appropriate for the study. This process includes consenting adults, assenting children, and seeking parental permission. Both the consent form(s) and the consent process must include all of the essential elements required by federal regulations.

- **Waiver of Documentation of Consent**: Select this option for studies seeking to waive or alter the requirement that participants must sign the consent form. This waiver is most appropriate for online questionnaires/surveys, or where the researcher data involves the collection of sensitive information.

- **The IRB must determine either**: (1) the principal risk to participants is a potential loss of confidentiality and a signed consent form is the only record linking participants to the study, or (2) the study does not involve procedures that would require written consent outside of a research context (i.e. observation of public behavior).

- **Waiver of Informed Consent**: Select this option for studies seeking to waive the entire consent process, including the consent form. A Waiver of Informed Consent is most appropriate when there is no interaction with participants (i.e. retrospective chart review).
  - The IRB must determine that: (1) the study involves little to no risk to participants, (2) participants will not be adversely affected by the waiver, (3) study would be unfeasible without the waiver, and (4) if applicable, additional information will be provided to participants.

- **Alteration of Consent**: Select this option for studies involving a deviation to the normal consent form and/or process that does not involve either a Waiver of Documentation (signature) or a Waiver of Informed Consent (entire consent process).
  - Studies seeking to remove or change the basic elements of the informed consent document must seek approval through this process and provide justification for the alteration of the document and/or consent process (i.e., studies involving deception).
Based on how many "groups of participants" you will be consenting, additional pages like this one will request information on each of the different types of consent processes.

- Click ‘Repeat’ if you need to add additional “Normal Consent/Assent” groups.

- There are specific requirements regarding the Informed Consent Forms that will be discussed on the next slide.
30. NORMAL CONSENT/ASSENT (2 OF 3)

Informed Consent/Assent Form requirements *:

1. Must include **ALL** required elements of consent (see next slide).

2. Use the NSU IRB template: [Informed Consent Documents](#)

3. All forms must have **1.25-inch or greater margin** at the top of each page to allow for electronic approval stamping.

4. The first page of each consent form must be on the official Letterhead of your College or academic unit. Contact your [College Representative](#) to obtain a copy.

*If your Informed Consent Form does not meet these requirements, it will be sent back to you for revision.*
30. NORMAL CONSENT/ASSENT (3 OF 3)

Elements of Consent: The following eight items must be included in the consent form as documentation that the consent process covered these essential principles of Informed Consent:

1. A description of the research, including that the study is research, the purpose of the research, the duration and nature of the procedures associated with participation, and which, if any, procedures are experimental.
2. Reasonable foreseeable risks associated with participation.
3. A description of benefits to participants as a result of the research.
4. Appropriate alternative procedures or courses of treatment that may be deemed beneficial to the participant, as applicable.
5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.
6. If the study is greater than minimal risk, an explanation of possible compensation for injuries, availability of medical treatments and further information on obtaining such treatment.
7. Contact information for questions about the research, participants’ rights, and research-related injuries.
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

Additional Elements of Consent: The following six items must be included when appropriate, but are not required under federal regulations. The IRB may determine that some, or all, of these additional elements are required during the IRB review process:

1. A statement that a particular treatment or procedure involves unforeseeable risks to the participant (including embryos or fetuses, if the participant or their partner may become pregnant).
2. A description of when the researcher may terminate participation without the participant’s consent.
3. Any additional costs to the participant that may result from participation in the research.
4. A description of how a participant may withdraw from a study and in any potential consequences from early withdrawal.
5. A statement indicating how significant new findings, developed during the course of the research, will be communicated to participants.
6. The approximate number of participants involved in the study.

Elements Required by Other States or Federal Agencies:

1. For research involving FDA-regulated drugs or devices to be used in clinical trials, the following statement is required: “A description of this clinical trial will be available on http://clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”
2. Other statements required by state law and regulation, depending on where the study will be conducted.
3. Other statements required by non-NSU Institutional Review Boards that may be responsible for reviewing and approving the study.
4. Other statements required as required by sponsored, funding agencies, or other entities with authority over the conduct of the study.
This page was generated based on the type of consent process you selected in a previous question.

The consent process must still occur with all participants, but documentation of consent (signed consent form) is waived.

Click ‘Repeat’ button at the bottom of the page if you have additional “Waiver of Documentation of Informed Consent” groups.

There are specific requirements regarding the Waiver of Documentation of Informed Consent that will be discussed on the next slides.

*Example situations where Waiver of Documentation of Informed Consent apply:

- Anonymous, one-time surveys
- Studies of a sensitive nature, where a signed consent form could place participants in danger physically, financially, etc.
The consent process must still occur with all participants. A Participation Letter that participants do not sign is used in place of the Informed Consent Form during the Consent process.

Participation Letter requirements *:

1. **Must include ALL** required elements of consent (see next slide).
   - **CEME** – Use the NSU IRB template unless your institution has a consent template they mandate.

2. **Use the NSU IRB template**: [Informed Consent Documents](#)

3. All forms must have **1.25-inch or greater margin** at the top of each page to allow for electronic approval stamping.

4. The first page of each consent form must be on the official Letterhead of your College or academic unit. Contact your [College Representative](#) to obtain a copy.
   - **CEME** – Use the NSU IRB College of Osteopathic Medicine letterhead unless your institution has a letterhead they mandate.

*If your Informed Consent Form does not meet these requirements, it will be sent back to you for revision.*
Elements of Consent: The following eight items must be included in the consent form as documentation that the consent process covered these essential principles of Informed Consent:

1. A description of the research, including that the study is research, the purpose of the research, the duration and nature of the procedures associated with participation, and which, if any, procedures are experimental.
2. Reasonable foreseeable risks associated with participation.
3. A description of benefits to participants as a result of the research.
4. Appropriate alternative procedures or courses of treatment that may be deemed beneficial to the participant, as applicable.
5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.
6. If the study is greater than minimal risk, an explanation of possible compensation for injuries, availability of medical treatments and further information on obtaining such treatment.
7. Contact information for questions about the research, participants’ rights, and research-related injuries.
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

Additional Elements of Consent: The following six items must be included when appropriate, but are not required under federal regulations. The IRB may determine that some, or all, of these additional elements are required during the IRB review process:

1. A statement that a particular treatment or procedure involves unforeseeable risks to the participant (including embryos or fetuses, if the participant or their partner may become pregnant)
2. A description of when the researcher may terminate participation without the participant’s consent
3. Any additional costs to the participant that may result from participation in the research
4. A description of how a participant may withdraw from a study and in any potential consequences from early withdrawal
5. A statement indicating how significant new findings, developed during the course of the research, will be communicated to participants.
6. The approximate number of participants involved in the study.

Elements Required by Other States or Federal Agencies:

1. For research involving FDA-regulated drugs or devices to be used in clinical trials, the following statement is required: “A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”
2. Other statements required by state law and regulation, depending on where the study will be conducted.
3. Other statements required by non-NSU Institutional Review Boards that may be responsible for reviewing and approving the study.
4. Other statements required as required by sponsored, funding agencies, or other entities with authority over the conduct of the study.
This page was generated based on the type of consent process you selected in a previous question.

The entire participant consent process is waived (i.e. there is no consent process).

Click ‘Repeat’ button at the bottom of the page if you have additional “Waiver of Documentation of Informed Consent” groups.

*A Waiver of Documentation of Informed Consent can be used when there is no contact/interaction between the research study team and the participants.*
This page was generated based on the type of consent process you selected in a previous question.

The participant consent process is altered in any manner.

For research involving Deception, the debriefing script is found in the Deception Policy.

Click ‘Repeat’ button at the bottom of the page if you have additional “Wavier of Documentation of Informed Consent” groups.
33. ALTERATION OF CONSENT/ASSENT (2 OF 3)

For research involving Deception, the debriefing script is found in the Deception Policy.

Informed Consent/Assent Form requirements *:

1. Use the NSU IRB template: Informed Consent Documents

2. All forms must have 1.25-inch or greater margin at the top of each page to allow for electronic approval stamping.

3. The first page of each consent form must be on the official Letterhead of your College or academic unit. Contact your College Representative to obtain a copy.

*If your Informed Consent Form does not meet these requirements, it will be sent back to you for revision.
33. ALTERATION OF CONSENT/ASSENT (3 of 3)

Elements of Consent: The following eight items must be included in the consent form as documentation that the consent process covered these essential principles of Informed Consent:

1. A description of the research, including that the study is research, the purpose of the research, the duration and nature of the procedures associated with participation, and which, if any, procedures are experimental.
2. Reasonable foreseeable risks associated with participation.
3. A description of benefits to participants as a result of the research.
4. Appropriate alternative procedures or courses of treatment that may be deemed beneficial to the participant, as applicable.
5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.
6. If the study is greater than minimal risk, an explanation of possible compensation for injuries, availability of medical treatments and further information on obtaining such treatment.
7. Contact information for questions about the research, participants’ rights, and research-related injuries.
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

Additional Elements of Consent: The following six items must be included when appropriate, but are not required under federal regulations. The IRB may determine that some, or all, of these additional elements are required during the IRB review process:

1. A statement that a particular treatment or procedure involves unforeseeable risks to the participant (including embryos or fetuses, if the participant or their partner may become pregnant)
2. A description of when the researcher may terminate participation without the participant’s consent
3. Any additional costs to the participant that may result from participation in the research
4. A description of how a participant may withdraw from a study and in any potential consequences from early withdrawal
5. A statement indicating how significant new findings, developed during the course of the research, will be communicated to participants.
6. The approximate number of participants involved in the study.

Elements Required by Other States or Federal Agencies:

1. For research involving FDA-regulated drugs or devices to be used in clinical trials, the following statement is required: “A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”
2. Other statements required by state law and regulation, depending on where the study will be conducted.
3. Other statements required by non-NSU Institutional Review Boards that may be responsible for reviewing and approving the study.
4. Other statements required as required by sponsored, funding agencies, or other entities with authority over the conduct of the study.
34. PROTECTED HEALTH INFORMATION

This page will appear for all researchers.

Information regarding HIPAA can be found in the NSU HIPAA Primer Guide.

Based on the answers to two questions in this section:
  - If HIPAA regulations apply, additional pages will be generated to ensure compliance with the protection of private health information.

NOTE: Research that does not occur at NSU may still be at a site that is covered under HIPAA, please check with those sites to verify if site is a covered entity under HIPAA. If they are, select ‘Other Covered Entity External to NSU’
35. **HIPAA PROCEDURES**

35. A. Select all that apply to this study.
   - If ‘Use of a de-identified data set’ is selected, a text box will be generated requesting further information.
   - If ‘Use of limited data set’ is selected, a field will be generated requesting what data is included in your limited data set.

35. B. Select all that apply to this study.
   - Based on your response, additional pages will request information on records involving special protections.
36. HIPAA AUTHORIZATION FORMS

- 36. A. Attach NSU HIPAA Authorization Form
- 36.B. Attach non-NSU HIPAA Authorization Form

*Templates for this form can be found on our website on our [Form Templates](#) page under HIPAA Forms.
Answer the questions regarding PHI that will be collected:

A. What PHI is required
B. Why research cannot be carried out without the listed PHI
C. Reasons why research could not occur without a waiver of authorization
D. How you will protect PHI
E. Plan to destroy PHI
F. Will study use PHI of a deceased person

Certify and attest to Principal Investigator Responsibility
38. HIPAA WAIVER OF AUTHORIZATION DECEDENTS

This section is completed for Waivers of HIPAA Authorization for research involving deceased patients, if the patient has been dead for less than fifty (50) years.

38.A. Describe the reasons why it is not practical to obtain authorization from the personal representatives of the decedents in order to conduct the research. (Required)

I hereby certify and attest to the following:

- Principal Investigator Responsibility #1
  - The use or disclosure sought is solely for research on the protected health information of the decedent.

- Principal Investigator Responsibility #2
  - There is documentation of the death of the patients in question (researcher must provide documentation to NSU clinic if requested by clinic)

Click NEXT BUTTON to continue

- 38.A. Describe the reasons why it is not practical to obtain authorization from the personal representatives of the decedents in order to conduct the research.

- Certify and attest to Principal Investigator Responsibility #1 and #2.
39. ALCOHOL/SUBSTANCE ABUSE

This section must be completed by any researcher desiring to conduct a review preparatory to research involving alcohol or substance abuse records protected by 42 CFR Part 2.

39. Describe your qualifications for conducting research involving alcohol or substance abuse records. (required) Add Note View Audit

I hereby certify and attest to the following:

Principal Investigator Responsibility #1
☐ Protected Health Information necessary for conducting the review preparatory to research will be maintained in accordance with security protocols required under the Part 2 regulations.

Principal Investigator Responsibility #2
☐ I will not re-disclose, in any manner or form (e.g., verbal, electronic, written), any patient identifying information in the course of conducting the review preparatory to research.

Principal Investigator Responsibility #3
☐ I will only provide patient identifying information directly to the NSU clinic that maintains the information and I will not otherwise prepare research reports or other materials containing identifying information.

Principal Investigator Responsibility #4
☐ A group of 3 or more individuals who are independent of the research project have reviewed the protocol and determined that the rights of the patients will be adequately protected and that the risks involved of disclosing the information to me are outweighed by the potential benefits of the research.

Click NEXT BUTTON to continue Add Note

40.A. Describe the PI’s qualifications for conducting research involving alcohol or substance abuse records.

Certify and attest to Principal Investigator Responsibility #1, #2, #3, and #4.
40. HIV STATUS ADDENDUM

This section must be completed by any researcher desiring to conduct a review preparatory to research involving HIV records.

40. Describe your qualifications for conducting research involving HIV records.  (Required)

I hereby certify and attest to the following:  (Required)

☐ I will not re-disclose, in any manner or form (e.g., verbal, electronic, written), any patient identifying information in the course of conducting the review preparatory to research.

Click NEXT BUTTON to continue

41.A. Describe the PI’s qualifications for conducting research involving HIV status records.

Certify and attest to Principal Investigator Responsibility.
41. MENTAL HEALTH ADDENDUM

This section must be completed by any researcher desiring to conduct a review preparatory to research involving mental health records protected by Florida law.

41. Describe your qualifications for conducting research involving Mental Health Records. (Required)

I hereby certify and attest to the following: (Required)

- I will not re-disclose, in any manner or form (e.g., verbal, electronic, written), any patient identifying information in the course of conducting the review preparatory to research.

Click NEXT BUTTON to continue

42.A. Describe the PI’s qualifications for conducting research involving mental health records.

Certify and attest to Principal Investigator Responsibility.
42. LOSS OF CONFIDENTIALITY

This page will be completed by all researchers.

This page asks the researcher questions about confidentiality and may generate additional pages.

Based on your response, you may be asked to provide further information regarding:

- The likelihood of the risk
- the severity
- procedures that will be used to mitigate the risks

HELP TEXT:

"Risks" may include possible dangers to participants as part or resulting from the research (i.e. physical, economic/financial, legal, psychological, social harm, etc.)

Please note that time spent and inconvenience are not risks of participation.
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.

Please use your best judgement to assess the risk, likelihood, severity, etc.

Click ‘Repeat’ if you need to add additional risks.
44. BENEFITS TO PARTICIPANTS

- This page will be completed by all researchers.
- 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.
45. DATA STORAGE AND DESTRUCTION

- 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.

NOTE: All data must be kept for a **minimum of 36 months** after all study related
46. SAFETY MONITORING PLANS

- All researchers will be asked whether or not they have Safety Monitoring Plans. These plans are usually created for high-risk clinical trials.
47.  OTHER INFORMATION

This page will be completed by all researchers and provides:

- a place to attach additional documents that were not previously attached in the other sections
- a listing of all attachments in the submission for the PI to review for accuracy
- a text box for additional statements or information not captured in earlier questions.
The principal investigator is asked to review the various responsibilities and check off that they are in accord with each statement.

The Principal Investigator is then asked to enter their password to electronically sign as the Principal Investigator of this study.

After this section, click ‘Next’ and the the Check & Submit page will appear if there are no pages with unanswered required questions.
You can do one of three things:

a) Save *New Submission Form* for a later date.

b) Print a copy of the *New Submission Form*

c) Submit the *New Submission Form* for review. The review process is as follows:

1. Review by faculty advisor/dissertation chair (students)
2. Review by College Representative
3. Review by the IRB Office
4. Review by the IRB Chair

Once you have submitted the xForm for review, it is locked and no further edits may occur until it has been sent back to you for revisions.

**NOTE:** At any stage in the review process, a submission may be sent back to the PI for revisions.
For questions, please contact your Faculty Advisor/Dissertation Chair or your IRB College Representative, Dr. Ashley Russom at russom@nova.edu.