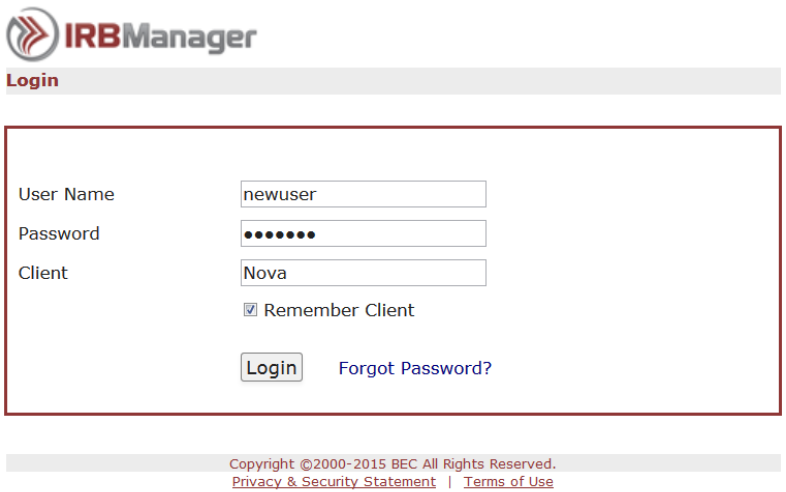
IRB Manager for New Users: Training manual

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)

New User: Login



* IRBManager access link: https://nova.my.irbmanager.com/Login.aspx
* New Users:
  * Username: newuser (all lowercase)
  * Password: newuser (all lowercase)
  * Client: Nova

IRBManager Dashboard

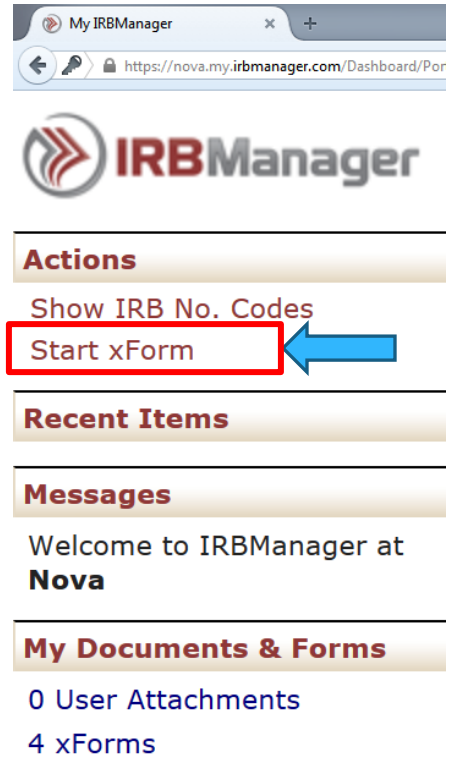
Dashboard Features:

* 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

Starting 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

Starting a New Protocol Submission Form

Action	Form (Click to start)	Description
	New Protocol Submission	Instructions: Use this form to submit a new study to the Nova Southeastern University IRB.

- 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

New Protocol Submission -- General Information

***Instructions*: In order to comply with federal regulations and with Nova Southeastern University's IRB policies, the Principal Investigator (PI) is required to complete this New Protocol Submission. If your study qualifies for an exemption under federal regulations and NSU policy, the Center Representative will provide you with a memorandum to that regard, and electronically-stamped documents as applicable. If your study appears to qualify for expedited or full board review, the Center Representative will make that determination and this protocol will be electronically forwarded to the NSU IRB office.** Add Note

For information on the levels of review, please see this decision tree from the Office of Human Research Protection: Human Subject Regulations Decision Charts

1.A. Please choose the appropriate Center Representative for your College/Center. *(Required)* Add Note

Please find your Center Representative here.

1.B. Submitter (person who initiates submission form) Add Note View Audit

Denis, Randy BS, RN

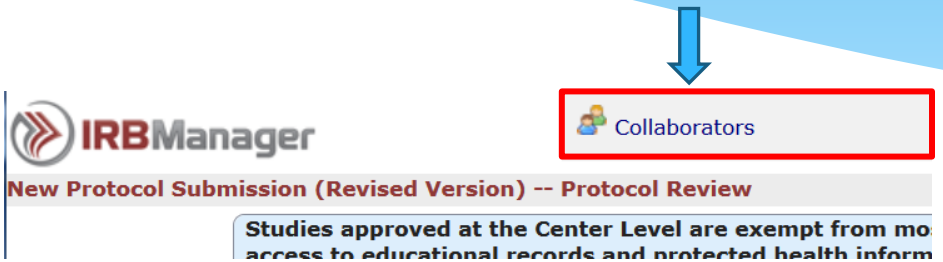
Email:	rdenis@nova.edu	**Specialty:**	
Relationship to NSU:	Staff	**CITI Training Date:**	
Qualifications:			
Contact Roles	IRB Member, Investigator, Faculty Advisor, Research Assistant		

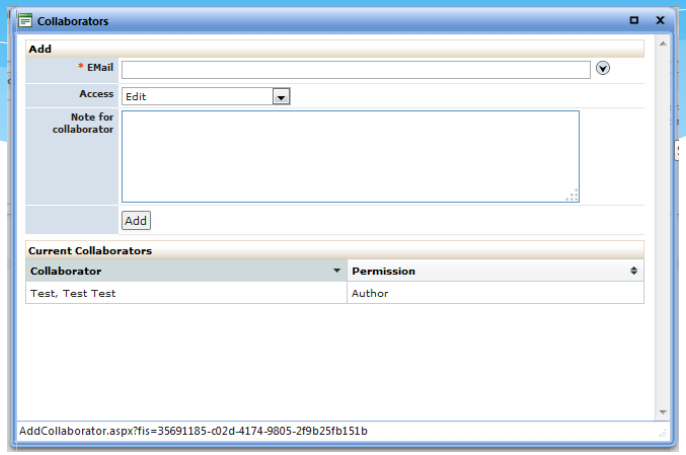
1.C. Research Project Title *(Required)* Add Note

Please use a study title unique from any previously submitted IRB studies

- 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.

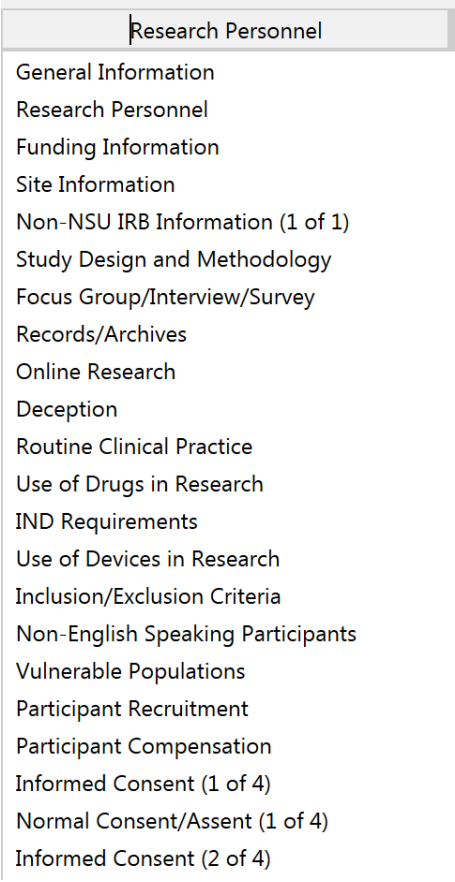
Collaborator Feature

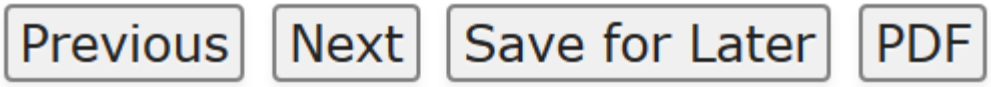




* Located at the TOP LEFT of the screen:
  * Allows the PI the option to add individuals to the development of the document. This feature is helpful when various researchers are working on the IRB application.
* You determine the access level for each individual:
  * ***Edit*** (the person added will 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.

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’.

Research Personnel

New Protocol Submission -- Research Personnel

To add study team members, they must have created an IRBManager profile. NSU faculty, students, and staff must to use their NSU email address to create an IRBManager profile. If a team member is not affiliated with NSU, please contact the Nova Southeastern University IRB Office for assistance. Add Note

Investigator is defined as "an individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB." Please see OHRP's definition here for more information.

2.A. Please click "Add Contact" and enter the email address for each of the co-investigators. Add Note

Add Contact

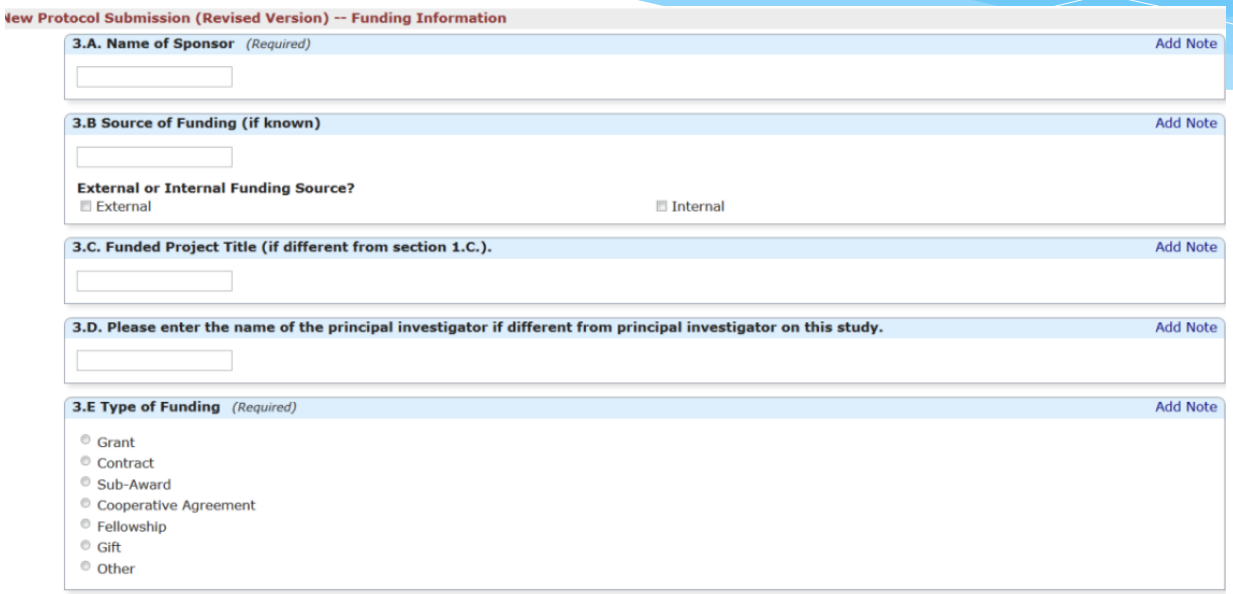
No answer provided.

Please use the table below to briefly the qualifications of each co-investigator. Enter their email address, then enter their qualifications, and click 'Add' under Action to complete the entry.

Co-Investigator's email*	Please briefly describe the co-investigator(s) applicable professional, educational, employment, licensure, and research experience. *	Action
		Add

* 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.

Funding Information



* 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.

Site Information

New Protocol Submission (Revised Version) -- Site Information

4.A. Will the study be conducted at an NSU location? *(Required)* Add Note

This does not include online research.

4.B. Will any research activities be conducted on the Internet or any web-based platform? *(Required)* Add Note

Cooperative research studies involve non-NSU Institutional Review Boards (IRBs). Typically, this is because the research takes place at more than one institution(s) or when an investigator is employed at or is an agent of a non-NSU institution. The Institutional Review Boards at those institutions(s) are required to review and approve the research. Add Note

If you have further questions, please contact the Nova Southeastern University Institutional Review Board office.

4.C. Does this research involve review and approval by non-NSU Institutional Review Boards ("cooperative research")?

* 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

5.A. Name of other institution where you will conduct the study. *(Required)* Add Note View Audit

5.B. Please select this study's status with the other IRB. *(Required)* Add Note View Audit

- Approved
- Not yet submitted
- Submitted (not yet approved)

5.C. Level of review (if IRB reviewed) *(Required)* Add Note View Audit

- Exempt
- Expedited
- Full
- Not yet reviewed

* For studies involving "Collaborate Research", this page will collect this information.
* Use the 'Repeat' option to add multiple Institutional Review Board pages.

Study design and methodology

New Protocol Submission -- Study Design and Methodology

6.A. Please briefly describe the purpose of your study. Limit your description to 1-2 sentences. *(Required)* Add Note View Audit

6.B. Please outline the main goals and justification for this study. Include a brief overview of prior research or literature that supports the need for this study. Other sections will be ask about procedures and instruments. *(Required)* Add Note View Audit

6.C. Please outline the steps of the research study. Provide specific details about the tests given and/or treatments used, when they will occur in chronological order, and their frequency. Indicate how long the participants spend completing the different steps/procedures. If different groups or particular participants receive different treatments/procedures, please provide a separate outline for those groups or participants. *(Required)* Add Note View Audit

* 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.

Study Design and Methodology

6.E. Please select all of the following procedures which apply to this study protocol. *(Required)* Add Note View Audit

- ☑ Deception
- ☑ Drug
- ☑ Focus Group
- ☑ Observation
- ☑ Records/Archives
- ☑ Social/Behavioral Intervention
- ☑ Device
- ☑ Educational Intervention
- ☑ Interview
- ☑ Online/Internet Research
- ☑ Routine Clinical Procedures
- ☑ Survey

...link to webpage for explanation of each...

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* 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.

Focus group/interview/survey

IRBManager | Collaborators | Focus Group/Interview/Survey | Page 7 of 27 | Next

New Protocol Submission -- Focus Group/Interview/Survey

7.A. List all questionnaires, tests, instruments, interview questions, or any other forms that will be used. *(Required)* Add Note View Audit

00000

7.B. Please attach all questionnaires, tests, instruments, or forms that will be used.

Add Attachment

7.C. Does this study involve giving surveys to NSU students, faculty, employees, and/or alumni. *(Required)* Add Note

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* 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.

Records/archives

New Protocol Submission -- Records/Archives

Research involves records or archives involves using data that has previously been collected for any purpose, or will be collected for non-research purposes (e.g. medical or academic records, non-research surveys, etc.). Add Note

8.A. Please identity the records being used in this research study. Please include where the records are kept, who will provide access to the records, and how the records will be provided to the researchers. *(Required)* Add Note View Audit

8.B. Specify the exact data to be gathered from these records, or provide a data collection form.

Attach data collection form (optional).

Add Attachment

* 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).

Online research

New Protocol Submission -- Online Research

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

9.A. Does this research involve the use of any online websites? *(Required)* Add Note

9.B. Does this research involve the use of apps/programs to collect or interact with participants? *(Required)* Add Note

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

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* 9.A., 9.B., & 9.C. 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.

Deception

New Protocol Submission -- Deception

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 here (weblink to be added). Please review the policy and note the following items of importance: Add Note

1. Deception in research requires an "Alteration of Informed Consent". Please request this alternation in the Consent Process section of this application.

2. Please review Part D of the policy for examples of specific risks to participants from the use of deception in research. Please include these risks and steps taken to minimize these risks in the "Risks, Discomforts & Inconveniences" section of this application.

3. The IRB requires debriefing of participants as soon as research procedures allow. If debriefing is not possible, please contact the IRB office.

10.A. Please describe the deception being used in the study. *(Required)* Add Note

Please review Part B of the policy for examples

- 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.

Routine clinical practices

New Protocol Submission -- Routine Clinical Practice

11.A. Does the study involve the collection of biological specimens (i.e., blood, sputum, saliva, etc.)? *(Required)* Add Note

11.B. Does the study involve clinical diagnostic procedures/tests? *(Required)* Add Note

11.C. Does this study involve the evaluation of current clinical best practice(s)? *(Required)* Add Note

...For instance, determining which accepted technique works best, if standard of care is supported by evidence, etc.....

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* 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.

Use of drugs in research

New Protocol Submission -- Use of Drugs in Research

12.A. Will this study administer any FDA-approved drugs for their approved indication/usage? *(Required)* Add Note View Audit

12.B. Will this study administer any FDA-approved drugs for non-approved indication/usage? (e.g., new use, new combination of two or more drugs, altered dose, new route of administration, new participant population, etc). *(Required)* Add Note View Audit

12.C. Will this study administer any drugs not yet approved by the FDA? *(Required)* Add Note View Audit

12.D. Will marketed herbs, vitamins, minerals sold over-the-counter (OTC) be used for this study? *(Required)* Add Note View Audit

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- 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.

Use of devices in research

New Protocol Submission -- Use of Devices in Research

14.A. Does this study involve use any FDA-approved/cleared device(s) for the approved indication(s)? *(Required)* Add Note View Audit

No

14.B. Does this study involve use any FDA-approved/cleared device(s) for indication(s) not approved by the FDA? *(Required)* Add Note View Audit

No

14.C. Does this study involve use any device(s) not approved by the FDA? *(Required)* Add Note View Audit

No

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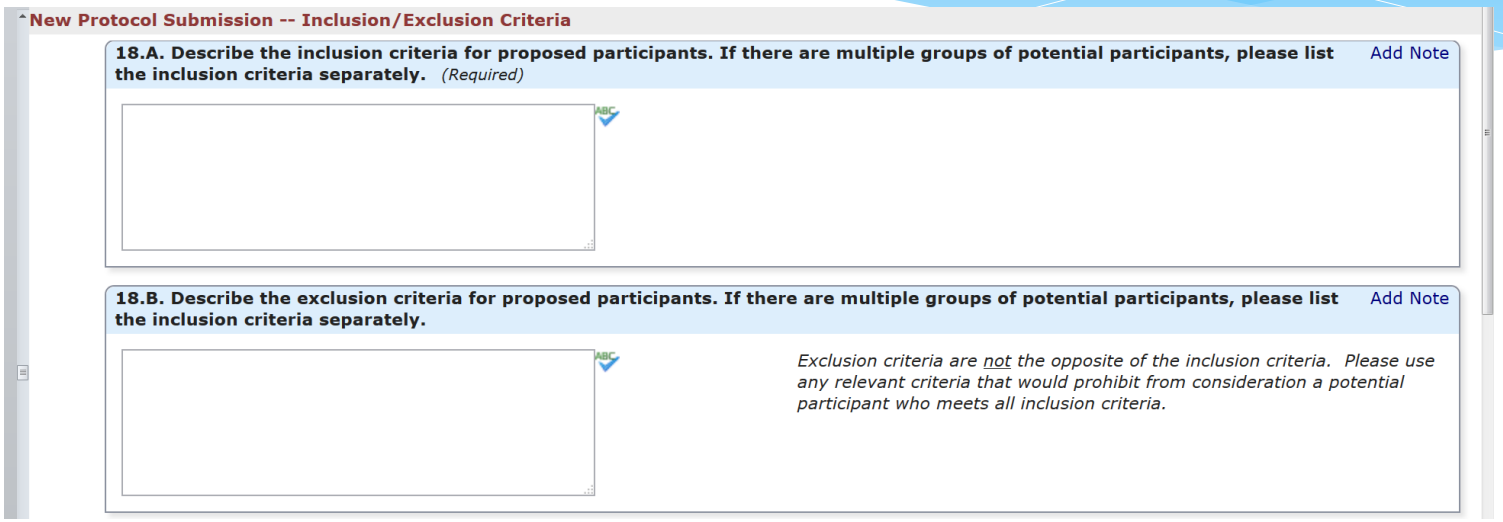
- For studies involving the use of medical devices, this section asks questions as to the level of approval received.
- FDA-approved devices for the use of the approved indication will only complete this page.
- Studies involving non-FDA approved devices, or using an approved device outside of the approved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

Inclusion/exclusion criteria



* 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.

Non-English speaking participants

New Protocol Submission -- Non-English Speaking Participants

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

1. Please do not translate the consent or assent documents until the English-version has been approved by the IRB; this is to insure that no time or money is wasted having to redo translations. Please submit the translations after approval using the Amendment Form.

2. For studies that may be reviewed at the Center Level or by Expedited Review, the IRB permits the use of non-certified translators but will require the translator to fill out the Verification of Translation Form. Back-translations by a second translator is recommended.

3. For studies that are reviewed by the full IRB, a certified translation will be required.

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

19.A. Please list the language(s) involved in the study, the persons using those language(s), and the relevant document(s) to be translated for those persons. Add Note

- 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.

Subject Vulnerability

New Protocol Submission -- Vulnerable Populations

20.A. Please indicate if your study will involve any of the following groups as participants. *(Requir*

- [x] Students or employees of the investigator(s)
- [x] Students in their educational setting, (in class or at school)
- [x] Patients of the investigator(s)
- [x] Children/Minors (under the age of 18)
- [x] Cognitively impaired, or otherwise unable to consent for themselves
- [x] Wards of the State (e.g., children in foster care)
- [x] Prisoners
- [x] Pregnant women & women of child-bearing potential (due to that status)
- [ ] Terminally Ill
- [x] Others vulnerable to coercion
- [ ] None of the above

If you chose other, please specify.

- 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.

Students/employees

New Protocol Submission -- Student/Employees

21.A. Please describe any real or perceived authority that the investigator(s) may have over potential participants? *(Required)* Add Note View Audit

21.B. Describe how you will mitigate any coercion over potential participants due to the real or perceived authority of the investigator(s) *(Required)* Add Note View Audit

* 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.

Patients of the investigator

New Protocol Submission -- Patients of the Investigator(s)

22.A. Please describe the relationship between the potential participants and the investigator(s). *(Required)* Add Note View Audit

22.B. Please describe how will you prevent "therapeutic misconception," which is the mistaken belief that research is equivalent to treatment. *(Required)* Add Note View Audit

* 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.

Children

Please select the risk level that you believe best characterizes this study: *(Required)* Add Note

- Minimal Risk to participants
- Greater Than Minimum Risk but with DIRECT benefit to the health or well-being of participants
- Greater Than Minimum Risk but only a minor increase over minimum risk AND likely to yield generalizable knowledge about the participants' disorders or conditions
- None of the above owing to increased risk BUT offers an opportunity to understand, alleviate or prevent a serious problem to children.

From how many parent(s)/guardian(s) will permission be obtained? *(Required)* Add Note

A parent must have legal responsibility for the care and custody of the child in order to give permission.

From how many children will you obtain assent? *(Required)* Add Note

To what extent will children be involved in the decision making process about participation in the research study? Add Note

Even if children do not assent, they may be required to cooperate with research. Discuss how researchers will obtain this cooperation. If cooperation is not needed, "N/A" will suffice.

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* 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.

Cognitive Impairments

New Protocol Submission -- Cognitively Impaired Participants

25.A. Discuss the type(s) of impairment(s) that you anticipate encountering among potential participants. Add Note View Audit
(Required)

- 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.

Prisoners

New Protocol Submission -- Prisoners

Add Note View Audit

26.A. All of the follow conditions must be met for studies involving prisoners. Provide a brief justification for each condition:

1) Advantages to the prisoner(s) are appropriately scaled for the prison environment;

2) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

3) Selection procedures are fair for all prisoners and without arbitrary interference from prison authorities or other prisoners. Control participants must be randomly selected from available prisoners who meet the inclusion/exclusion criteria unless there is a reasonable justification for another procedure;

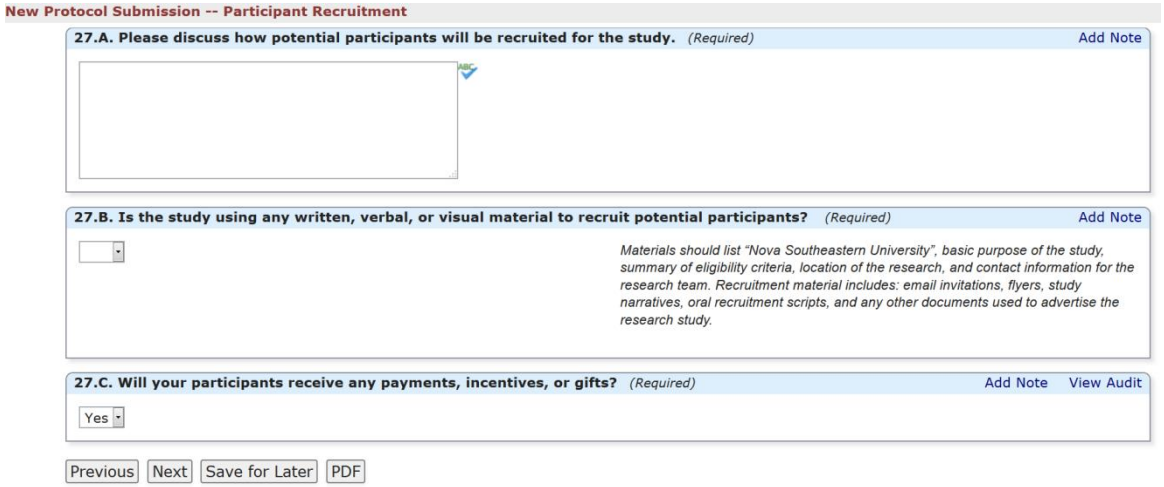
4) The information presented is understandable to the participant population;

5) That participation will not affect parole decisions and that each prisoner is clearly informed in advance;

6) Adequate provisions will be made for any follow-up exams or care of participants after the end of their participation, taking into account the various lengths of individual's sentences. This information will be provided to participants. *(Required)*

* 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.

Participant recruitment


New Protocol Submission -- Participant Recruitment

27.A. Please discuss how potential participants will be recruited for the study. *(Required)* Add Note

27.B. Is the study using any written, verbal, or visual material to recruit potential participants? *(Required)* Add Note

Materials should list "Nova Southeastern University", basic purpose of the study, summary of eligibility criteria, location of the research, and contact information for the research team. Recruitment material includes: email invitations, flyers, study narratives, oral recruitment scripts, and any other documents used to advertise the research study.

27.C. Will your participants receive any payments, incentives, or gifts? *(Required)* Add Note View Audit

Yes

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- 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.

Participant compensation

New Protocol Submission -- Participant Compensation

28.A. Which type(s) of payment will be offered to participants? *(Required)* Add Note View Audit

- ☐ Compensation
- ☐ Reimbursement

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.

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- 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.

Informed consent

New Protocol Submission -- Informed Consent

For each group of participants who have a separate and unique informed consent process, please complete this page plus a subsequent page for the details of the unique informed consent process. Add Note

29.A. Does this study intend to consent more than one group of participants? (i.e. children and their parents would be two groups, teachers and students two groups as well, etc.) *(Required)* Add Note

29.D. Type of Consent Process *(Required)* Add Note

- Normal Consent/Assent
- Waiver of Documentation of Consent
- Waiver of Informed Consent
- Alteration of Consent

For explanations of these processes, please click here.

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* 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

New Protocol Submission -- Protected Health Information

This page deals with the requirements set forth by the Health Information, Portability, and Accountability Act (HIPAA). These requirements do not apply to every study, and the questions on this page will assist in determining whether HIPAA applies to this study. Add Note

For further information, please see the NSU HIPAA Primer. If you have further questions, please contact the Nova Southeastern University Institutional Review Board office.

34.A. Please select if any of the following locations are involved in this study: *(Required)* Add Note View Audit

- [x] Not Applicable
- [ ] Nova Southeastern University, Health Care Centers
- [ ] Nova Southeastern University, Dental Clinics
- [ ] Nova Southeastern University, Clinics for Audiology
- [ ] Nova Southeastern University, The Eye Care Institute
- [ ] Nova Southeastern University, Psychological Services Center
- [ ] Nova Southeastern University, Comprehensive Outpatient Rehabilitation Facility
- [ ] Nova Southeastern University, Clinic Pharmacy
- [ ] Nova Southeastern University, Clinics for Speech-Language, and Communication
- [ ] Nova Southeastern University, Student Counseling Center
- [ ] Nova Southeastern University, Sport Psychology Program
- [ ] Nova Southeastern University, Center for Assessment and Intervention
- [ ] Other Covered Entity

* 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.

Loss of confidentiality

New Protocol Submission -- Loss of Confidentiality

Loss of confidentiality is a risk associated with all studies involving human participants because their participation and resulting data are not intended to be public knowledge. Therefore, all studies need to discuss "Loss of Confidentiality" as potential risk, including: Add Note

1. **Likelihood: How likely is it that this risk will occur?**
2. **Magnitude: If a loss of confidentiality occurs, how severe is the harm to potential participants?**
3. **Risk Minimization: What procedures will be undertaken to prevent or mitigate this risk?**

37.A. What is the likelihood of this risk occurring? *(Required)* Add Note

- Minimal
- Moderate
- High

Please provide the best approximation based on personal judgement.

37.B. How severe is the harm to potential participants? *(Required)* Add Note

- Minimal
- Moderate
- High

Briefly discuss the severity of the risk

- 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.

Risks, discomforts, and inconveniences

ission -- Loss of Confidentiality

Loss of confidentiality is a risk associated with all studies involving human participants because their participation and resulting data are not intended to be public knowledge. Therefore, all studies need to discuss "Loss of Confidentiality" as potential risk, including: Add Note

1. **Likelihood: How likely is it that this risk will occur?**
2. **Magnitude: If a loss of confidentiality occurs, how severe is the harm to potential participants?**
3. **Risk Minimization: What procedures will be undertaken to prevent or mitigate this risk?**

37.A. Is this study recording data that can be linked to particular participants? *(Required)* Add Note View Audit

Yes

If "Yes", then the confidentiality of that data is a risk associated with participation.

37.B. What is the likelihood of this risk occurring? *(Required)* Add Note View Audit

- (●) Minimal
- ( ) Moderate
- ( ) High

Please provide the best approximation based on personal judgement.

* 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

New Protocol Submission -- Benefits to Participants

39.A. Please briefly describe proposed data analysis procedures. Analysis of study data should be reasonable, given the type(s) and quantity of data collected, and should generate generalizable information. *(Required)* Add Note

39.B. Briefly describe how this study will enhance scientific understanding, improves societal welfare, or provides long-term indirect benefit(s) to society. *(Required)* Add Note

39.C. Are there any direct benefits to the research participants? *(Required)* Add Note

- There are no direct benefits to study participants
- This study provides direct benefit to study participants

Direct benefits are limited to diagnostic or therapeutic improvement 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.

Data storage and destruction

New Protocol Submission -- Data Storage and Destruction

NSU IRB policy and federal regulations require adequate storage of identifiable information, a reasonable plan to remove identifiers upon completion of the study and retention of key study documents for a predetermined period of time. Please note that NSU IRB policy requires that all data be kept for a minimum of 36 months after completion of the study. Add Note

40.A. Please describe how you will store study data and who will have access to it. Discuss how you will protect participants' confidentiality through procedures to prevent disclosure of identifiable information, such as, consent forms, audio-recordings, etc. *(Required)* Add Note

40.B. Will any person or entity that is not a member of the study team have access to study data? This includes translations/interpretations/transcriptions, commercial testing, etc. *(Required)* Add Note

- 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.

Safety monitoring plan

New Protocol Submission -- Safety Monitoring Plans

41.A. Studies that entail significant risk to subjects, such as randomized controlled drug trials, may warrant safety monitoring by an independent safety board. Does your study utilize a Data Safety Monitoring plan or similar entity? *(Required)*

Add Note

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

Other information

New Protocol Submission -- Other Information

42.A. If there is other information about this study that is required in order for those reviewing the study to fully understand the study, its risks and benefits, please describe below. Add Note View Audit

IRB Research on Decedents Add Note View Audit

Add Attachment

Additional Attachments Add Note View Audit

Add Attachment

* 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.

Assurances and Obligations

New Protocol Submission -- Principal Investigator Assurance and Obligations

I certify that all information provided in this submission (including any supporting documents) is a complete and accurate description of the proposed study. I agree to the following attestations: Add Note

Principal Investigator Responsibility #1
- I will conduct this study in the manner described in this submission.

Principal Investigator Responsibility #2
- I will not implement this study until ALL applicable IRBs have granted approval to conduct the research

Principal Investigator Responsibility #3
- I will not implement changes to this study until an Amendment Form has been submitted to and approved by the IRB.

Principal Investigator Responsibility #4
- I will submit for continuing review, as required by IRB policies and procedures.

* 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.

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 our website for updates:

http://nova.edu/irb/updates.html