New Protocol Submission Form

DISCLAIMER:

These questions have been edited for brevity, have had Help Text and instructions removed for length, and have generally been altered. This document is not intended to be a reproduction of the submission form; this document is intended to be a guide for the general type of questions you will possibly encounter.

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New Protocol Submission Data Entry Questions

General Information

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

1.B. Submitter (person who initiates submission form)

1.C. Research Project Title (Required)

1.D. Principal Investigator (Required)
   - Please enter the NSU email address for the Principal Investigator.
   - In order to add a Principal Investigator, they must have an IRBManager profile.

1.E. Please briefly describe the Principal Investigator's applicable professional, educational, employment, licensure, and research experience. (Required)

1.F. What is the Principal Investigator's relationship to Nova Southeastern University? (Required)

1.G. Funding Status (Required)

Research Personnel

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

2.B. Please click "Add Contact" and enter the email address for each of the research assistants.

2.C. For student researchers, please enter the NSU email address for the faculty adviser.
   - Please briefly describe the faculty adviser's applicable professional, educational, employment, licensure, and research experience. (Required)

Funding Information

3.A. Name of Sponsor (Required)

3.B. Source of Funding (if known)
• External or Internal Funding Source? (Required)

3.C. Funded Project Title (if different from section 1.C.).

3.D. Please enter the name of the principal investigator if different from principal investigator on this study.

3.E Type of Funding (Required)

• Please explain "Other." (Required)

3.F. Please select the department that is administering the funding. (Required)

3.G. Please specify the department administering the funding. (Required)

3.G. Award amount (if known)

3.H. Please insert your index number (if known)

**Site Information**

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

• Please list the location within NSU, i.e., department or clinic name.

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

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

4.D. Will the study be conducted at a non-NSU location? (Required)

4.E. Please enter name, address, and contact information for each site.

4.F. Please attach documentation of approval to conduct your study from the non-NSU sites previously listed.

**Non-NSU IRB Information**

5.A. Name of other institution where you will conduct the study. (Required)

5.B. Please select this study's status with the other IRB. (Required)
• Attach Approval Letter (Required)

5.C. Level of review (if IRB reviewed) (Required)

5.D. Please provide the contact information for the cooperating institution (if known).

**Study Design and Methodology**

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

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)

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)

6.D. Is this a multi-part study involving the administration of instruments/interventions that have yet to be developed? (Required)

• Please identity the steps in the research process that have yet to be developed. Prior to the implementation of the new instruments/interventions, please complete an Amendment Form. Please note that these changes may affect the review status of the study.

6.E. Please select all of the following procedures which apply to this study protocol. (Required)

**Focus Group/Interview/Survey**

Please see Appendix A: General Methodology Questions

**Records/Achives**

Please see Appendix A: General Methodology Questions

**Online Research**

Please see Appendix A: General Methodology Questions


**Deception**

Please see Appendix A: General Methodology Questions

**Routine Clinical Practice**

Please see Appendix B: Biomedical Questions

**Use of Drugs in Research**

Please see Appendix B: Biomedical Questions

**IND Requirements**

Please see Appendix B: Biomedical Questions

**Use of Devices in Research**

Please see Appendix B: Biomedical Questions

**Device Exemptions**

Please see Appendix B: Biomedical Questions

**Devices Abbreviated IDE**

Please see Appendix B: Biomedical Questions

**Devices Full IDE**

Please see Appendix B: Biomedical Questions

**Inclusion/Exclusion Criteria**

18.A. Describe the inclusion criteria for proposed participants. If there are multiple groups of potential participants, please list the inclusion criteria separately. (Required)

18.B. Describe the exclusion criteria for proposed participants. If there are multiple groups of potential participants, please list the inclusion criteria separately.

18.C. Please indicate the approximate number of participants in this study. If there are multiple groups, please list the approximate number separately. (Required)
18.D. Does the study involve the exclusion of, or the limitation to, enrollment of based on gender, race, or ethnicity. (Required)

- Provide a justification for the exclusion of these potential participants. (Required)

18.E. Will the study involve non-English speaking participants? (Required)

- Please attach any prescreening tools (optional).

**Non-English Speaking Participants**

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.

- Please attach the translated documents

**Vulnerable Populations**

20.A. Please select all of the following groups of participants that apply to your study: (Required)

- If you chose other, please specify.

- If you chose other, please describe proposed safeguards to protect these vulnerable participants.

20.B. Please justify your rationale for including these vulnerable participants in your study. (Required)

20.C. Please describe any other researcher qualifications for working vulnerable participants not previously described.

**Student/Employee**

Please see Appendix C: Vulnerable Populations Questions

**Patients of the Investigator(s)**

Please see Appendix C: Vulnerable Populations Questions

**Children**

Please see Appendix C: Vulnerable Populations Questions
**Wards of the State**

Please see Appendix C: Vulnerable Populations Questions

**Cognitively Impaired Participants**

Please see Appendix C: Vulnerable Populations Questions

**Prisoners**

Please see Appendix C: Vulnerable Populations Questions

**Participant Recruitment**

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

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

27.C. Will your participants receive any payments, incentives, or gifts? (Required)

**Participant Compensation**

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

28.B Please provide details about what actual expenses are eligible to be reimbursed. Please be sure to include any ceiling/maximums for total reimbursement. (Required)

28.C Please indicate the types of compensation. (Required)

- Describe the "other" type of compensation.

28.D Describe the compensation offered, who is eligible to receive compensation, the compensation amount, and the timing of payment(s) including any prorated payments. (Required)

28.E Discuss how students/employees can receive equivalent compensation by alternative means other than by participating in the research study. (Required)

**Informed Consent Process**

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.)
29.B. Name of Group (Required)

29.C. Please describe the group of participants affected by this particular consent process. (Required)

29.D Type of Consent Process (Required)

**Normal Consent/Assent Process**

30.A. Please provide an overview of the steps in the consent process in your research study for this group. (Required)

30.B. Do you plan to use phone, internet, email, etc. in the consent process for this group? (Required)

Please review your consent process for the following potential issues:

1. Participants have read the consent form and understand the nature of the study.
2. Participants have a reasonable opportunity to ask questions.
3. Participants have sufficient time to make a voluntary decision to participate.

**Waiver of Consent Process**

31.A. Provide a brief justification for why "The research involves no more than minimal risk to the subjects." (Required)

31.B. Provide a brief justification for why "The waiver or alteration will not adversely affect the rights and welfare of the subjects." (Required)

31.C. Provide a brief justification for why "The research could not practicably be carried out without the waiver or alteration." (Required)

31.D. Provide a brief justification for why "Whenever appropriate, the subjects will be provided with additional pertinent information after participation." (Required)

**Waiver of Documentation**

32.A. Select which of the following best explains the rationale for your request of a waiver of documentation of Informed Consent: (Required)

- Discuss the justification for the waiver of documentation request (Required)

32.B. Do you plan to use phone, internet, email, etc. in the consent process for this group? (Required)

- Please review your consent process for the following potential issues:

  1. Participants have read the consent form and understand the nature of the study.
2. Participants have a reasonable opportunity to ask questions.
3. Participants have sufficient time to make a voluntary decision to participate.

- Please provide an overview of the steps in the consent process in your research study for this group. (Required)

**Alteration of Consent**

33.A. Explain how you are going to alter the normal consent process and/or forms. (Required)

33.B. Provide a brief justification for why "The research involves no more than minimal risk to the subjects." (Required)

33.C. Provide a brief justification for why "The waiver or alteration will not adversely affect the rights and welfare of the subjects" (Required)

33.D. Provide a brief justification for why "The research could not practicably be carried out without the waiver or alteration." (Required)

33.E. Describe briefly if and how this statement applies: "Whenever appropriate, the subjects will be provided with additional pertinent information after participation." (Required)

- Please provide an overview of the steps in the consent process in your research study for this group. (Required)

**Protected Health Information**

Please see Appendix B: Biomedical Questions

**HIPAA Procedures**

Please see Appendix B: Biomedical Questions

**HIPAA Authorization Forms**

Please see Appendix B: Biomedical Questions

**Loss of Confidentiality**

37.A. Is this study recording data that can be linked to particular participants? (Required)

- Please explain how data will be recorded so that individual participants are not linked to their data. (Required)
37.B. What is the likelihood of this risk occurring? (Required)

37.C. How severe is the harm to potential participants? (Required)
   • Briefly discuss the severity of the risk (Required)

37.D. Describe the procedures undertaken to mitigate or prevent this risk. (Required)

37.E. Are you asking questions about sensitive issues, such that disclosure could put the participant at risk of criminal or civil liability or anything else that, if made public, could jeopardize a person’s financial standing, employability, safety, reputation or quality of life? (Required)
   • Please describe the sensitive information that will be collected.

37.F. Does this study contain any additional risks to participants beyond potential loss of confidentiality? (Required)

**Risks, Discomforts & Inconveniences**

38.A. List one risk associated with the research study. Use the ‘Repeat’ feature located at the end of this section to add additional risks. (Required)

38.B. What is the likelihood of this risk occurring? (Required)

38.C. Describe the severity and potential duration of the risk (Required)

38.D. Describe the procedures undertaken to mitigate or prevent this risk. (Required)

**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)

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

39.C. Are there any direct benefits to the research participants? (Required)
   • List/describe each direct benefit. (Required)

39.D. Please briefly discuss how this study has a positive benefit-to-risk ratio? (Required)
**Data Storage and Destruction**

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)

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)

- Please list the person(s) or entities, their activities, and what specific study data they will have access to (Required)

40.C. Please indicate how and when you plan to destroy data that contains identifiable information, such as consent forms, data coding lists, or raw data containing participants names. (Required)

**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)

- If “Yes,” please describe the safety monitoring plans. Please specify if the study will be monitored by the investigators, sponsors (if applicable), or a Data Safety Monitoring Board (DSMB). Sponsored studies may reference an attached Investigator Brochure.

**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.

- Please review the list of attachments for this protocol and use the "Additional Attachments" question above to make add any relevant attachment not already included.
Appendix A: New Protocol Submission – General Methodology

Questions

Focus Group/Interview/Survey

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

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

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

Records/Archives

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)

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

- Attach data collection form (optional).

8.C. Are you obtaining any data from the participant’s academic records? (Required)

- Which procedure are you proposing to use? (Required)

Online Research

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

- Please list the name(s) and URL(s) of website(s). (Required)

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

- Please list the name of the app(s)/program(s) and any associated URL(s). (Required)

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)
- Please list the potential identifying information and discuss whether that information will be recorded. (Required)

**Deception**

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

10.B. Please provide a justification for the use of deception in this study, including why equally effective non-deceptive procedures are not feasible, examples of similar studies using deception, and the associated harms of such research. (Required)

10.C. Please describe the debriefing procedures used with research participants. Please include information about the method, timing, and how participants will be given the opportunity to remove their data from the study. (Required)
Appendix B: New Protocol Submission – Biomedical Questions

Routine Clinical Practice

11.A. Does the study involve the collection of biological specimens (i.e., blood, sputum, saliva, etc.)? (Required)
   • Please list the type of specimen(s), the amount collected, and the frequency of collection. (Required)

11.B. Does the study involve clinical diagnostic procedures/tests? (Required)
   • Please list the diagnostic procedures/tests? (Required)

11.C. Does this study involve the evaluation of current clinical best practice(s)? (Required)
   • Please discuss how participants' clinical care during the research study will differ from non-participants receiving equivalent care. (Required)

Use of Drugs in Research

12.A. Will this study administer any FDA-approved drugs for their approved indication/usage? (Required)
   • Please list the name of the FDA-approved drug(s) and relevant information about its administration.
   • Please attach the Package Insert (if any).

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)
   • Please list the name of the FDA-approved drug(s) and relevant information about its administration. (Required)
   • Please attach the Package Insert, Investigator's Brochure and study protocol (if any).

12.C. Will this study administer any drugs not yet approved by the FDA? (Required)
• Please list the name of the non-approved drugs and relevant information about its administration. (Required)

• Please attach the Investigator’s Brochure and study protocol (if any). (Required)

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

• List the name of the marketed herbs, vitamins, minerals.

• Attach a copy of the product label.

**IND Requirements**

13.A. Does this study require/have an Investigational New Drug (IND)? (Required)

• Please list the name of each drug, with their respective Investigational New Drug (IND) number, and who is the IND sponsor. (Required)

• Please select the reason that you believe this study does not require an IND (Required)

• FDA Correspondence (Required)

• Please confirm if all of the follow criteria apply to this study. (Required)

**Use of Devices in Research**

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

• Please list the name of the device(s) and provide any relevant information. (Required)

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

• Please list the name of the device(s) and provide any relevant information. (Required)

• Please attach the manufacturer’s brochure and any other relevant documents. (Required)

14.C. Does this study involve use any device(s) not approved by the FDA? (Required)
• Please list the name of the device(s) and provide any relevant information. (Required)

• Please attach the manufacturer's brochure and any other relevant documents. (Required)

**Device Exemptions**

15.A. Does this device require/have an IDE? (Required)

• Please select the reason that you believe that this device is exempt from IDE requirements (Required)

• Please attach a 510(k) clearance letter (Required)

• Please attach FDA Correspondence (Required)

• Please select the following categories that apply to this device (Required)

• All of the following: (Required)

**Devices Abbreviated IDE**

16.A. Who is listed as the sponsor of the device? (Required)

• Please list the sponsor (Required)

16.B. Please determine if any of the following apply to the use of the device in this study (Required)

• This device appears to be "significant risk" device, please contact the IRB office about an IDE application and requirements

16.C. In order to qualify for an abbreviated IDE, the device must fulfill all of the following requirements (Required)

• Please attach sponsor determination and correspondence (Required)

• Please present an explanation of why the device does not pose a significant risk to participants. (Required)
**Devices Full IDE**

17.A. Please list the IDE number (Required)

17.B. What is the classification of the device?

17.C. What is the FDA category for the IDE? (Required)

17.D. Please attach all FDA correspondences, as applicable

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**Protected Health Information**

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

- Please list other covered entities (Required)

34.B. Please select whether any of the following applies to this study: (Required)

- Please explain the other situation (Required)

**HIPAA Procedures**

35.A. Which of the following applies to this study? (Required)

35.B. Please check only if the study is collecting any of the following:

35.C. Please check only if the study is collecting any of the following:

35.D. Please list of all variables being collected or attach a Data Collection Form

**HIPAA Authorization Forms**

36.A. Please attach NSU HIPAA Authorization Form

36.B. Please attach Non-NSU HIPAA Authorization Form

36.C. Please attach the NSU HIPAA Waiver of Authorization Form

36.D. Please attach Preparatory to Research Form

36.E. Please select if you are collecting information from any of the following (Required)
Appendix C: New Protocol Submission – Vulnerable Populations

**Student/Employees**

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

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

21.C. Describe how you will ensure that participants will feel free to decline participation without fear of reprisal. (Required)

**Patients of the Investigator(s)**

22.A. Please describe the relationship between the potential participants and the investigator(s). (Required)

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

22.C. Please describe how you will prevent potential participants from mistaking a provider's recommendation of a research study as a clinical recommendation. (Required)

**Children**

23.A. Please select the risk level that you believe best characterizes this study. The risk level is determined by the IRB and may be revised. (Required)

23.B. From how many of each child's parent(s)/guardian(s) will permission be obtained? (Required)

23.C. From how many children will you obtain assent? (Required)

23.D. To what extent will children be involved in the decision making process about participation in the research study? (Required)
**Wards of the State**

24.A. Please select the risk level that you best believe characterizes this study: (Required)

24.B. Please select which of the following applies to this research: (Required)

24.C. Please identify:
   1. Child Advocates who shall act as an additional guardian for the Wards of the State
   2. The scope of their advocacy (how many, any particular group, etc)
   3. Their background and expertise for acting in the best interest of children
   4. Any affiliations they may have with the research, investigators or guardian organizations

**Cognitively Impaired Participants**

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

25.B. Please describe how a potential participant's competency will be assessed, by whom it will be assessed, and how the person making that assessment is related to the potential participant and/or the study. (Required)

25.C. If a potential participant is not competent to consent for themselves, how will you determine who is their Legally Authorized Representative (LAR)? (Required)

25.D. Please describe how competency to consent will be monitored during the course of the study for situations when participants may gain or lose competency to consent for themselves. (Required)

25.E. Please describe how you will involve cognitively impaired participants in the decision-making process. (Required)

**Prisoners**

26.A. All of the following 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)

26.B. Is this study conducted or supported by the Department of Health and Human Services (DHHS)? (Required)

- Which category best describes the research involving prisoners? (Required)