Note: This is a preview document for the NDMU IRB application, which can be found online at bit.ly/ndmuirbapplication

NDMU Initial Application for Research With Human Subjects

NDMU IRB Initial Application for Research With Human Subjects

Hello! Are you a Notre Dame of Maryland University faculty, staff, or student planning a research project involving human subjects? This is the form for the initial application for Institutional Review Board review.

The application asks for extensive information about your project design and human subjects procedures. It can take several hours to complete.

To see the information required in the application ahead of time (*recommended*), download the required templates for the informed consent forms, and view the NDMU IRB policy manual, click here: NDMU IRB webpage

- **When you have finished adding all your information in the application, at the end of the application click "DONE" to submit.**
- **You can change your answers on any page until you click "DONE" to submit.**
- **You can return to the application at a later time to pick up where you left off and/or edit your previous responses until you click "DONE" to submit. (To be able to return to the application, you must have cookies enabled and use the same device and web browser you used to start the application on -- because a cookie is stored in your browser that remembers your responses.)**
- **Applications started but not submitted within 30 days will be automatically deleted.**

Need help? If you have any problems or questions, contact the IRB at irb@ndm.edu

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SECTION 1: PROJECT OVERVIEW AND INVESTIGATORS

1. **Project Title**
if study is funded, this should match the title on the grant/contract.

2. **Project Dates** (*for components involving human participants, including participant recruitment and data collection*)

Start Date

Date
MM/DD/YYYY

End Date

Date
MM/DD/YYYY

3. **Sponsored Project?** *(funded)*

- ◯ Yes
- ◯ No

4. **Funding Agency** (*if none, please type "N/A*")

Key Personnel: *All investigators engaged in the research (defined as interacting or intervening with participants for the purposes of conducting research, collecting or accessing identifiable data, OR consenting subjects) should be included in the IRB application.*

5. **Primary Principal Investigator (Name)**

Every research study reviewed by the NDMU IRB requires an NDMU faculty/staff member as the principal investigator, who maintains project oversight and ultimate responsibility. For student projects (including dissertations, class projects, etc.) the faculty advisor serves as the principal investigator.

6. **Primary Principal Investigator Contact Information**

Department and School	
Work Address	
Address 2	
City/Town	
State/Province	
ZIP/Postal Code	
Email Address	
Phone Number	

7. **Department Contact (Supervisor)**

The NDMU IRB no longer requires supervisor (e.g., chair, dean) signatures on IRB applications, but will include supervisors in email communications to notify them when research protocols are approved.

Supervisor Name	
Supervisor Email	

8. **Is This a Student Research Project?** ***(skip pattern here)***

(*i.e., dissertation, class project etc.*)

- ◯ Yes
- ◯ No

Note: This page will be skipped if the answer to Question 8 = no)

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Student Investigator Information

9. **Student Investigator (Name)**

10. **Student Investigator Contact Information**

Department and School

Email Address

11. **Confirm Faculty Approval:**

Upload confirmation of Principal Investigator's approval of student project here (letter of support or a screenshot of an email confirming support).

Choose File Choose File No file chosen

Note: This page will be skipped if the answer to Question 8 = no)

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Additional Student Investigator Information

12. **Additional Student Investigators:** *Are there additional student investigators for this project who will be involved with the research (defined as interacting or intervening with participants for the purposes of conducting research, collecting or accessing identifiable data, OR consenting subjects)?*

- ◯ Yes
- ◯ No

13. **Additional Student Investigators:** *Please list all other student investigators and their email addresses in the space provided below. (If this question is not applicable, type N/A).*

Note:
You'll be required to upload proof of human subjects training in the "documents" section of this application for all listed co-investigators. You are not required to list co-investigators who do not fit the definition of "participating in research" above.

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Other Investigators

14. **Co-investigators:** *Are there any other investigators on this project participating in the research (defined as interacting or intervening with participants for the purposes of conducting research, collecting or accessing identifiable data, OR consenting subjects)?*

- ◯ Yes
- ◯ No

15. **List Co-Investigators:** *if yes, please list all other investigators, their titles and affiliations , and their email addresses in the space provided below. (If this question is not applicable, type N/A).*

Note:
You'll be required to upload proof of human subjects training in the "documents" section of this application for all listed co-investigators. You are not required to list co-investigators who do not fit the definition of "participating in research" above.

Note: Don't worry if you're not completely sure about the questions in this next section or the level of review!
It's our job to figure that out, but your input is helpful (and may help us do a quicker review).

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Type of Review

Your response to the following questions helps the IRB determine what type of review is appropriate for your protocol (*exempt, expedited, or full board*). (*For more detail, see the NDMU policy manual: NDMU IRB webpage*)

16. **Minimal risk:** Studies eligible for expedited review present no more than minimal risk to participants (meaning the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Does the proposed study present *more than minimal risk?*

- ◯ Yes, the study presents more than minimal risk
- ◯ No, this study presents NO MORE than minimal risk

17. **Exempt Review Criteria:** Please check whether your proposed research meets any of the following criteria for exemption (check ALL that apply)

- ☐ **A.** Research, conducted in educational settings, involving normal educational practices not likely to adversely impact students' opportunity to learn required content or educators' assessments. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. *(Exempt Category #1)*

- ☐ **B.** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least **one** of the following criteria is met:
  I. The data is recorded without any identifying information;
  II. Disclosing participants' responses outside the research would not reasonably place them at risk of criminal or civil liability or damage their financial standing, employability, educational advancement, or reputation; or
  III. You record data in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, but the IRB determines there are adequate provisions to protect the privacy and confidentiality of participants. *(Exempt Category #2)*

  NOTE: If you're conducting educational research with children, this exemption category is narrower: your research may only fall under this exemption if it involves educational tests or observation of public behavior where you do not participate in the activity being observed, and you must also either record your data without individual identifiers, or meet the condition that disclosure of the recorded responses would not place the children at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation. If you are using survey or interviews with children, or observing their public behavior where you participate in the activity being observed, it cannot be exempt.

☐ **C.** Research involving benign behavioral interventions and collecting data from adults, through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees [2] to the intervention and data collection and at least **one **of the following criteria is met:
I. You record your data in such a manner that participants' identity cannot readily be ascertained, either directly or through linked identifiers;
II. Any disclosure of their responses outside the research would not reasonably place them at risk of criminal or civil liability or damage their financial standing, employability, educational advancement, or reputation; or
III. You record your data in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, but the IRB determines there are adequate provisions to protect the privacy and confidentiality of participants. *(Exempt Category #3)*

☐ **D.** Secondary research uses of identifiable private information or identifiable biospecimens, <u>if at least **one** of the following criteria is met:</u>

I. The identifiable data is publicly available;
II. Information is recorded by you in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, you don't contact the subjects, and you don't re-identify subjects;
III. The research involves only information collection and analysis involving your use of identifiable health information regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b).
IV. The research is conducted by, or for, a Federal department/agency using government-generated or government-collected data obtained for nonresearch activities, if the research data is properly collected and stored under federal law. *(Exempt Category #4)*

☐ **E.** Research and demonstration projects conducted, supported, or approved by a Federal department or agency, or otherwise subject to the their approval) designed to study, evaluate, improve, or otherwise examine public benefit or service programs, procedures, changes in or alternatives to those programs or procedures, or possible changes in benefits or services under those programs. *(Exempt Category #5)*

☐ **F.** Taste and food quality evaluation and consumer acceptance studies *(Exempt Category #6)*

☐ **G.** Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research if there is broad consent from participants *(Exempt Category #7)*

☐ **H.** Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, <u>if all the following criteria are met:</u>

I. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained;
II. Documentation of informed consent or waiver of documentation of consent was obtained;
III. An IRB conducts a limited IRB review and determines that the research to be conducted is within the scope of the broad consent; and,
IV. you aren't planning to return individual research results to subjects as part of the study plan. *(Exempt Category #8)*

☐ **None of the above**

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Type of Review

18. **Expedited Review Criteria:** Please indicate whether your study involves ANY of the following? (Check all that apply)

- ☐ **A.** Collection of data from voice, video, digital, or image recordings made for research purposes
- ☐ **B.** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- ☐ **C.** Clinical studies of drugs and medical devices, but only when condition (a) or (b) is met.
  a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
  b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- ☐ **D.** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  a. From healthy, nonpregnant adults who weigh at least 110 pounds, and not more than 550 ml in 8 weeks and not more frequently than 2 times per week; or
  b. From other adults and children considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and not more frequently than 2 times per week.
- ☐ **E.** Prospective collection of biological specimens for research purposes by noninvasive means (like a cheek swab)
- ☐ **F.** Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves, general anesthesia or sedation
- ☐ **None of the above**

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Type of Review

19. **Full Review Criteria.** *Check ALL that apply:*

- [ ] Children under the age of 18
- [ ] Prisoners
- [ ] Pregnant women, fetuses, or neonates
- [ ] Persons with impaired decision-making capacity
- [ ] Economically or educationally disadvantaged persons
- [ ] Procedures that might cause physical harm
- [ ] Procedures that might cause significant psychological/emotional distress
- [ ] Collection of information about highly sensitive topics
- [ ] Collection of information about illegal behavior
- [ ] Collection of information that could seriously harm the participant legally, socially, financially etc. if other people could identify them
- [ ] **None of the above**

20. Based on the previous questions, what level of review do you believe is appropriate for your proposal? (*Note: the IRB makes the final determination on the level of review).*

- ◯ Exempt
- ◯ Expedited
- ◯ Full Board
- ◯ Not sure

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Other IRBs

21. **Other IRB oversight:** Have you, or will you, submit this application to an IRB at another institution? ***(skip pattern here)***

- ◯ Yes
- ◯ No

Note: This page will be skipped if the answer to Question 21 = no)

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Other IRBs - details

22. **Other IRB Details:** Please describe the involvement of other institutional IRBs in your study.

23. **Other IRB documentation**

Upload documentation relevant to other IRB approvals here (e.g., other institutions' IRB approval letter), as one pdf file.

Choose File Choose File No file chosen

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SECTION 3: RESEARCH DETAILS
Abstract and Sample

24. **Abstract.** Provide a brief abstract that describes the significance and purpose, aims/research question, sample, design, and methods of your project (500 words or less).

25. **Inclusion Criteria:** What are the eligibility criteria for participants in your study? (*who you will be targeting for recruitment, who is eligible to participate?)*

26. **Exclusion Criteria:** What are the exclusion criteria for participants in your study? (*who cannot participate in your study, who is ineligible to participate. Specify any exclusion criteria specific to gender, age, race/ethnicity, language, or other characteristics)*

27. **Sample Size:** How many people do you expect to complete the study?

28. **How was the needed sample size determined?** (*describe*)

29. **Recruitment Method:** Explain how you will have access to your study population. Describe the recruitment process from the participants' perspective. How will you identify, contact, recruit, and enroll participants? *(You'll upload any recruitment materials in the "documents" page at the end of the application.)*

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Setting

30. **Research Site:** Where will the research take place?
(*the location of study visits/sessions/data collection)*

31. **Permission to Conduct the Study**

- [ ] I'm collecting data at a location offsite from NDMU, and I attest that I already have permission to conduct the study at the location(s). *(You'll upload documentation of permission on the "documents" section of this IRB application form).*
- [ ] I'm collecting data offsite from NDMU and I am still needing some or all permission to conduct the study, but will secure permission prior to participant recruitment and submit to IRB as an amendment.
- [ ] I'm not collecting data at a location offsite from NDMU and don't need permission to conduct the study at an external site.

32. **Research Location Comments** (*optional; anything else you want the IRB to know*)

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Procedures

33. **Procedures:**
Describe in detail the research procedures in terms of what your participants will experience during their participation in the study.

Provide a step-by-step description of each procedure including the frequency, duration, and location of each procedure, and the measures you will use (surveys, questionnaires, interview guides, tools, instruments). (*You'll upload copies of measures at the end of the application, in the "documents" section*.)

If participants will complete surveys and/or other instruments on more than one occasion, state this here.

34. **Copyrights:** If you are using any copyrighted measures, have you obtained the necessary permission to use them in your study?

- ◯ Yes
- ◯ No
- ◯ N/A

35. **Participant Burden:** Estimate how long the participant will actively participate in the research. (*Actively participate includes the protocol-specific sessions that require their attendance and/or participation. Specify the number of sessions and estimate how long they will take, as well as the total time burden for participants).*

36. **Risks:** Describe all risks to subjects (physical, psychological, social, legal, and/or financial. Describe the precautions you have taken to minimize these risks. (*Please note all research involves some risk*).

37. **Benefits to Participants:** What are the potential direct benefits to the participant? (*it's possible the study has no potential for direct benefit. If this is the case, state this.)*

38. **Benefits to Others:** What are the potential benefits to the community and society?

39. **Deception:** Does your study involve deception of the participants?

- ◯ Yes
- ◯ No

40. If yes, explain why you are using deception and how you will debrief your participants. (*you'll upload your debriefing statement in the "documents" section at the end of the application.*)

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Participant Compensation

41. **Participant Compensation:** Are participants being compensated in the form of:

- [ ] Pay (cash, gift cards) *(skip pattern here)*
- [ ] Academic credit
- [ ] Inclusion in a lottery drawing for a prize
- [ ] Other
- [ ] They are not receiving compensation

Note: This page will be skipped if the answer to Question 41 = "they are not receiving compensation")

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Participant Compensation - Details

42. **Describe Compensation:** Describe the types and amount of compensation that will be available, and whether/how you will compensate participants who withdraw from the study.

43. **In your opinion,** will the participant be unduly influenced by the compensation offered?

- ◯ Yes
- ◯ No

44. **Academic credit:** If you are offering extra credit or course credit for student participation, describe the alternative assignment for students who may decline. The alternative assignment must be comparable in effort and time commitment.

Note: The federal Office for Human Research Protections (OHRP) regulations require that the investigator seek consent only under circumstances that minimize the possibility of coercion or undue influence (45 CFR 46.116). OHRP recommends that both students and faculty are aware that any participation of students in research must be voluntary. Reasonable levels of extra credit or rewards may be offered for participating in research. If extra credit or rewards are offered for participation, students must be provided with and informed of non-research alternatives involving comparable time and effort to obtain the extra credit in order for the possibility of undue influence to be minimized. However, if participation in research is a course requirement, students must be informed of non-research alternatives involving comparable time and effort to fulfill those requirements in order for the possibility of undue influence to be minimized. Moreover, students must not be penalized for refusing to participate in research (45 CFR 46.116(a)(8)).

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Confidentiality

45. **Identifying Information:** Select all identifying information that may be collected for the study. (*Check ALL that apply*)

- [ ] Name
- [ ] Date of birth
- [ ] Mailing address
- [ ] Email address
- [ ] Phone number
- [ ] Fax number
- [ ] Social security number
- [ ] Medical record number
- [ ] Health plan number
- [ ] Account number
- [ ] License or certificate number
- [ ] Student ID number
- [ ] Vehicle ID number
- [ ] IP address
- [ ] Facial photos or images
- [ ] Other (please specify)

- [ ] None of the above

46. **Data Management Plan:** Describe your data management plan. Address the following points:

1. Where any identifying information about participants will be collected, and where and how you will store identifying information, and whether it will be kept separate from data;
2. Whether data (*surveys, questionnaires, interviews, transcripts, etc*) will be de-identified, and how;
3. If you will retain identifiers within the data, what security measures will you take while the data is identifiable;
4. If data and identifying information are linked with a code/data key, explain when that data key will be destroyed;
5. How and where you will store your data during data collection and analysis;
6. How and where you will store your data after the study is complete;
7. Who will have access to raw data/identifying information;
8. The method and timing of destroying data (including, as applicable, any recordings).

47. **Dissemination of results:** Is there any way a participant's identity may be known from subsequent publications or presentations?

- ◯ Yes
- ◯ No

48. ***If yes***, explain:

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Data Collection with Technology

49. **Will any web or electronic applications** be used to recruit participants, complete questionnaires, or process data?

- [ ] Qualtrics
- [ ] Survey Monkey
- [ ] RedCap
- [ ] Other
- [ ] None of these will be used

50. ***If yes***, and you are administering an anonymous online survey, have you checked/will you check the appropriate boxes on the survey tool to ensure data collected will be anonymous?

- ◯ Yes
- ◯ No
- ◯ N/A

51. **Recording:** Does the study involve audio recording, video recording, or photographing?

(skip pattern here)

- [ ] Audio recording
- [ ] Video recording
- [ ] Photographing
- [ ] The study does not involve any of these

Note: This page will be skipped if you indicate in Question 51 that your study does not use audio/video recordings.

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Confidentiality - Recordings and Images

52. ***If yes,*** will audio/video recordings/photographs be identifiable? (*will they contain distinguishing characteristics that could make a person recognizable to someone outside the research team -- including voice patterns, accents, speech, mannerisms, tattos, scars, markings, etc. --if identifiable characteristics are blocked out, the information is not identifiable)*

- ◯ Yes
- ◯ No

53. **Describe** how audiorecording/videorecording/photographs will be kept confidential. *(note: information describing the use and confidentiality of audio/videorecordings and photographs must be disclosed in the consent document.)*

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SECTION 4: INFORMED CONSENT

54. **Informed Consent:** Describe the process for obtaining informed consent (or in the case of children under 18, parental permission and child assent), including the timing and who will obtain informed consent. (*you'll upload your informed consent documents in "documents" section of this application.)*

55. **WAIVER OF DOCUMENTATION OF INFORMED CONSENT.**

Are you requesting the IRB to approve *a waiver of documentation of informed consent*? *(i.e., the requirement for a signed consent form; for more information, see this OHRP page; scroll down to "When may the requirement for documentation of informed consent or parental permission be waived or altered?"***)**

- ◯ Yes, because the only record linking the participant and the research would be the signed consent document, and the principal risk in this study would be potential harm resulting from a breach of confidentiality;
- ◯ Yes, because the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (e.g., drawing a blood sample, or asking shoppers in a mall about the ambient lighting or temperature).
- ◯ No, I am not requesting a waiver of documentation of informed consent.

Note: see the NDMU IRB webpage for required templates for informed consent documents: www.bit.ly/ndmuirb

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SECTION 6. FERPA, HIPAA, AND CONFLICT OF INTEREST

56. **FERPA Compliance**: FERPA requires subjects' permission to access any of student records. Each and every record to be examined is required to be listed on the consent form. Subjects must be well aware and informed that their records are being accessed. Students' expressed and written consent is required. Researchers are required to explain what these records are being accessed. It must be clear to subjects that they can refuse access of their records at any time (before, during or after research). *Check below:*

- [ ] I am aware of the FERPA compliance requirements, and my study and consent procedures reflect this.
- [ ] FERPA compliance requirements do not apply for my study.

57. FERPA comment (optional)

58. **HIPAA Compliance:** State whether you are using HIPAA protected health information or "PHI".

- [ ] My study uses HIPAA protected PHI, and my study procedures and consent reflect this.
- [ ] My study does not use HIPAA protected PHI.

59. **Conflict of Interest:** Describe any potential conflict of interest on the part of investigators, including how such a conflict would affect the level of risk to the study participants. *If there is no conflict of interest, type N/A in this box.*

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SECTION 7. INTERNATIONAL RESEARCH AND RESEARCH WITH PRISONERS

International Research

60. Does your study involve research conducted outside of the United States? *(skip pattern here)*

- ◯ Yes
- ◯ No

Note: This section will be skipped if the answer to Question 60 = no)

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SUBPART SECTION A: INTERNATIONAL RESEARCH

Research Outside of the United States: Provide responses to the following questions. Separate responses are required for each country where the research will be conducted.

61. Did the investigator(s) previously conduct research in the country where the research will take place? Briefly describe the investigator's knowledge and experience working with the study population.

62. Are there any regulations, rules or policies for human subjects research in the country where the research will take place?

Note: The United States Department of Health and Human Services, Office for Human Research Protections (OHRP) has an International Compilation of Human Subject Research Protections with a listing of the laws, regulations and guidelines of over 50 countries. This compilation can be accessed on the OHRP website.

- ◯ Yes
- ◯ No

63. If yes, please describe and explain how you will comply with the local human subject protection requirements.

64. Do you anticipate any risks to the research participants in the country where the research will take place, taking into account the population involved, the geographic location, and the culture?

- ◯ Yes
- ◯ No

65. If yes, please describe, including any physical, psychological, social, legal and financial risks, and how these are managed.

66. Do you anticipate that subjects who participate in this research will be placed at risk of criminal or civil liability?

- ◯ Yes
- ◯ No

67. If yes, please describe.

68. (*optional*) Is there anything else you would like the IRB to know regarding the international context of your study?

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Research with Prisoners

69. Does your study involve research with prisoners? *(skip pattern here)*

- ◯ Yes
- ◯ No

Note: This section will be skipped if the answer to Question 69 = no)

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SUBPART SECTION B: RESEARCH WITH PRISONERS

Provide responses to the following additional IRB criteria for research involving prisoners.

70. I attest that the research under review represents one of the categories of research permissible described below:

- [ ] It is a study of the possible causes, effects, and processes of incarceration, and of criminal behavior, which presents no more than minimal risk and no more than inconvenience to the subjects
- [ ] It is a study of prisons as institutional structures or of prisoners as incarcerated persons, which presents no more than minimal risk and no more than inconvenience to the subjects
- [ ] It represents research on condition(s) particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults); or
- [ ] It represents research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well- being of the subject.

71. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.

- ◯ Yes
- ◯ No

72. The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers.

- ◯ Yes
- ◯ No

73. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.

Unless the investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.

- ◯ Yes
- ◯ No

74. If no, please explain:

75. The information is presented in language which is understandable to the subject population.

- ◯ Yes
- ◯ No

76. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole (*this must be included in your informed conset document and process*).

- ◯ Yes
- ◯ No

77. If there is a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

- ◯ Yes
- ◯ No

78. (*Optional*) any additional information you would like the IRB to know about your study's protections of prisoners?

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SECTION 8: DOCUMENT UPLOAD

All supporting documents should be in pdf format.

79. **Recruitment Materials.** If applicable, upload any advertisements (flyers, etc.) or other solicitations (emails) that you will use in participant recruitment, as one pdf file.

Choose File Choose File No file chosen

80. **Informed Consent.** Upload informed consent document(s) or parental permission/child assent documents, if applicable. These must be written using the NDMU IRB informed consent template. Combine all consent forms into one pdf file.

Choose File Choose File No file chosen

81. **Data Collection Instruments.** Upload data collection instruments (e.g., surveys, interview guide/questions, and/or questionnaires) as one pdf file. The IRB generally reviews a complete copy of all materials participants will view.

Choose File Choose File No file chosen

82. **Debriefing Statement.** If applicable (if you are using deception) upload your debriefing statement as one pdf file.

Choose File Choose File No file chosen

83. **Data Management Plan.** If applicable, upload any documents relevant to your data management plan, as one pdf file.

Choose File Choose File No file chosen

84. **Letters of Support and/or Permission.** If applicable (if you are collecting data at an offsite location), upload letters of support and/or permission or MOUs here. Combine these into one pdf file.

Choose File Choose File No file chosen

85. **CITI Certification.** All investigators who are participating in the research must provide proof of current CITI training for research involving human participants (*required; Responsible Conduct of Research, basic course*). CITI training can be accessed at www.citiprogram.org. NDMU investigators register and affiliate with Notre Dame of Maryland University (NDMU is a CITI subscriber organization). Download copies of CITI certification for all investigators and assemble into one pdf file.

Choose File Choose File No file chosen

NOTRE DAME OF MARYLAND UNIVERSITY

NDMU Initial Application for Research With Human Subjects

SUBMIT IRB APPLICATION

86. **Investigator Certification:** I certify that the statements made in this IRB application are accurate and complete.

I have double-checked my submission details, answered all relevant questions in this form, and uploaded all applicable documents.

I agree not to begin the proposed research until final approval has been issued by the NDMU IRB.

I agree to inform the NDMU IRB of any emergent problems, significant procedural or protocol changes, or adverse events, and I agree to discontinue the research until such problems have been resolved or the IRB has reviewed and approved the changes.

- ◯ I agree
- ◯ I disagree

87. Any questions for the IRB? Anything else you want us to know?

88. Any feedback on the application form/suggestions for improvements?

89. Please type your name as an electronic endorsement of this application form.

90. Please enter today's date

Date / Time

Date

MM/DD/YYYY

Note: Once you click "Done" at the bottom, your application will be submitted, and you should see a confirmation page.