NDMU IRB New Application — Preview & Planning Worksheet (Not For Submission)

This fillable PDF is a **preview and planning tool** for the NDMU IRB New Application. It is intended to help investigators (and student researchers with faculty advisors/committees) **draft and refine** their responses before completing the official online submission.

Use this Worksheet to:

- **Preview the full IRB application** in one place before you begin the online form.
- **Draft responses** (especially for longer narrative sections) that you can **copy/paste into the online form** to save time.
- **Review and revise with a faculty advisor/committee** before submitting to the IRB—especially helpful for student projects.
- **Check completeness** by gathering required documents ahead of time.

Important limitations (please read):

- This PDF is **not** the official IRB application and **cannot be submitted** to the IRB.
- The IRB will **not** review or accept this PDF in place of the online application.
- Because this is a fillable PDF, it may **not behave perfectly** across devices or PDF viewers (fields may shift, text may display oddly, or formatting may vary). It is still useful as a drafting and teaching tool.

Official submission link (required):

To submit a New IRB Application, you must use the online form:
www.bit.ly/ndmuirbapplication

Tips for using this worksheet effectively

- Draft longer sections in a separate document if preferred, then copy/paste here (and later into the online form).
- Keep entries concise and specific—assume an IRB reviewer is reading quickly and needs clarity.
- Save a copy for your records and for discussion with your faculty advisor/committee (students).

Need Help? Questions?

IRB website (information, policies, templates, forms): www.bit.ly/ndmuirb
IRB new application site: www.bit.ly/irbapplication : www.bit.ly/ndmuirbapplication
Email: irb@ndm.edu
IRB Chair: tbloom@ndm.edu | 443-808-1654

Document Prep Checklist (Gather Before You Start the Online Form)

Have ready to attach with your online IRB application:

Training documentation(CITI)

- ☐ **Faculty advisor / PI CITI completion documentation**
- ☐ **Student researcher CITI completion documentation** (if applicable)
- ☐ **Co-investigator CITI completion documentation** (if applicable)

Recruitment materials (if recruiting participants)

- ☐ Recruitment flyer(s) / posting(s)
- ☐ Recruitment email text
- ☐ Phone script / voicemail script (if calling)
- ☐ Social media post text (if applicable)
- ☐ Any screening questions or eligibility scripts (if applicable)

Study instruments /materials

- ☐ **Measures/instruments** (surveys, interview guides, focus group guides, observation checklists)
- ☐ Any stimulus materials (prompts, images, educational materials) participants will see

Informed consent materials

- ☐ **Informed Consent Form** using the required template, found at **www.bit.ly/ndmuirb**

External sites/permissions (if applicable)

- ☐ **Letters of support/permission** from external sites such as schools, clinics, agencies, community partners where the study will be advertised and/or data will be collected, if applicable (if already obtained)
- ☐ **External IRB approvals or determination letters** (if already obtained/required)
- ☐ Data use agreements or permission to access records/data (if applicable)

Student projects

- ☐ **Proof of faculty approval** (screenshot of email or a signed statement) indicating the faculty advisor has reviewed and approves the planned submission – your application will not be accepted for review without this

NDMU Initial Application for Research With Human Subjects

1. NDMU IRB Initial Application for Research With Human Subjects

Are you a Notre Dame of Maryland University faculty, staff, or student planning research involving human subjects? This is the initial application for Institutional Review Board (IRB) review of new projects.

The form requires detailed project information and may take several hours to complete (like doing your taxes). Before starting, visit the NDMU IRB webpage to download a preview of this form, required consent form templates, and find other IRB information.

You can save progress and edit responses until you click “DONE” to submit. To resume later, enable cookies and use the same device/browser. We recommend using Chrome, Firefox, or Edge. The option to save progress and edit responses later may not work in Safari or Duck Duck Go browsers, or any browser where "incognito mode" is turned on.

Applications are reviewed only after submission.

Deadlines & Review:

- **Submission deadline: First Friday of the month**
- **IRB meetings: 3rd week of the month (academic year only)**
- **For urgent cases or questions, contact us (irb@ndm.edu)**

NDMU Initial Application for Research With Human Subjects

2. SECTION 1: PROJECT OVERVIEW AND INVESTIGATORS

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

* 2. **Project Dates (Required)** (*for components involving human participants, including participant recruitment and data collection. You must have IRB approval BEFORE you begin research with human participants.)*

Start Date

Date
MM/DD/YYYY

End Date

Date
MM/DD/YYYY

3. **Sponsored Project? (Required)** *(means 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) (Required)**

Every NDMU IRB-reviewed study requires an NDMU faculty/staff member as the principal investigator. ***For student projects, the faculty advisor serves in this role, and students must upload evidence of faculty advisor's approval of the project on the following screen.***

6. **Primary Principal Investigator Contact Information**

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

* 7. **CITI Certification for PI (Required)**

All investigators must provide proof of current CITI training for human research, including the expiration date. Students must submit their own certification and that of their faculty supervisor.

CITI training is free at www.citiprogram.org; create an account and affiliate with NDMU. The required courses are Social-Behavioral Research or Biomedical Foundations; other listed courses are generally optional.

Certification must be renewed:

Take Refresher 1 course 3 years after initial training;
Take Refresher 2 course 6 years after initial training.

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* 8. **Department Contact (Required)***(Principal investigator's supervisor; usually a chair or dean)*

Supervisor Name	
Supervisor Email	

* 9. **Is This a Student Research Project? (Required)**
(*i.e., dissertation, class project etc.*)

- ◯ Yes
- ◯ No

NDMU Initial Application for Research With Human Subjects

3. Student Investigator Information

10. **Student Investigator (Name) (Required)**

11. **Student Investigator Contact Information (Required)**

Department and School

Email Address

12. **Confirm Faculty Approval: (Required)**

*Is this a student project? If yes, upload a PDF of the Principal Investigator's approval (letter or email screenshot). Your application **will not be reviewed** without this documentation.*

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13. Upload student's CITI certificate here (Required)

All investigators must provide proof of current CITI training for human research, including the expiration date. Students must submit their own certification and that of their faculty supervisor. CITI training is free at www.citiprogram.org; create an account and affiliate with NDMU. The required courses are Social-Behavioral Research or Biomedical Foundations; other listed courses are generally optional.

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4. Additional Student Investigator Information

14. **Additional Student Investigators: (Required).** Are additional student investigators involved? *(Only report students interacting with research participants, collecting or accessing identifiable data, or obtaining consent.)*

- ◯ Yes
- ◯ No

15. **Additional Student Investigators: (Required).** *Please list all other student investigators and their email addresses in the space provided below. (If this question is not applicable, type N/A. You are not required to list student investigators who are not interacting with research participants, collecting or accessing identifiable data, or obtaining consent.)* ***You must upload current CITI certificates for all student investigators below.***

16. Upload student CITI certificate here

Choose File | Choose File | No file chosen

17. Upload student CITI certificate here

Choose File | Choose File | No file chosen

18. Upload student CITI certificate here

Choose File | Choose File | No file chosen

If you have additional student CITI certificates, you may email them to the IRB at irb@ndm.edu .

NDMU Initial Application for Research With Human Subjects

5. Other Investigators

* 19. **Co-investigators: (Required).** *Are there any other investigators on this project participating in the research? (Only report those interacting with research participants, collecting or accessing identifiable data, or obtaining consent.)*

- ◯ Yes
- ◯ No

* 20. **List Co-Investigators: (Required)**.*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. You are not required to list co-investigators who are not interacting with research participants, collecting or accessing identifiable data, or obtaining consent.)* ***You must also upload current CITI certificates for all Co-Investigators below.***

21. Upload co-investigator's CITI certificate here

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22. Upload co-investigator's CITI certificate here

Choose File | Choose File | No file chosen

If you have additional co-investigator CITI certificates, you may email them to the IRB at irb@ndm.edu .

6. Type of Review

Your answers in this section help the IRB determine the review type (exempt, expedited, or full board). If unsure, do your best—the IRB makes the final decision.

* 23. **Minimal risk: (Required).** Is defined as: "*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*."

In your opinion, based on this definition does your planned study present ***more than minimal risk?*

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

Other (please specify)

NDMU Initial Application for Research With Human Subjects

7. Type of Review

* 24. **(Required)** Does your research include any of the following: Children under age 18, prisoners, pregnant women/fetuses, people with impaired decision-making capacity, research procedures that might cause physical harm or serious psychological/emotional distress, or collecting information about highly sensitive, embarrassing, or stigmatized topics, illegal behavior, or other data that could seriously harm the participant legally, socially, financially etc. if their study information was revealed?
Check ALL that apply:

- [ ] Research with children under the age of 18
- [ ] Research with prisoners
- [ ] Research with pregnant women or fetuses
- [ ] Research with persons with impaired decision-making capacity
- [ ] Research procedures that might cause physical harm or significant psychological/emotional distress
- [ ] Research including collection of information about highly sensitive, embarrassing, or stigmatized topics, illegal behavior, or other data that could seriously harm the participant legally, socially, financially etc. if their study information was revealed
- [ ] **None of the above**

NDMU Initial Application for Research With Human Subjects

8. Other IRBs

* 25. **Other IRB oversight: (Required)** Have you, or will you, submit this application to an IRB at another institution?

- ◯ Yes
- ◯ No

9. Other IRBs - details

26. **Other IRB Details: (Required)** Please describe the involvement of other institutional IRBs in your study, if applicable.

27. **Other IRB documentation**

If applicable, upload documentation relevant to other IRB approvals here (e.g., other institutions' IRB approval letter), if you already have such documentation. Combine documents and upload as one pdf file.

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NDMU Initial Application for Research With Human Subjects

10. SECTION 3: RESEARCH DETAILS
Abstract and Sample

* 28. **Project Abstract (≤500 words). (Required)** Use clear, lay-friendly language.

Your abstract must address all the following:

- Significance & Purpose – Why is this research important?
- Aims/Research Question – What are you investigating?
- Sample – Who are the participants? Where are they recruited from? How many participants do you need?
- Design – How is the study structured?
- Methods – How will data be collected and analyzed?

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* 29. **Inclusion Criteria: (Required)** the specific, pre-defined characteristics participants must have to be eligible to enroll in your study (for example, adults ages 18–40; diagnosed with type 2 diabetes for at least 6 months; able to read and speak English; received care at Clinic X within the past 12 months).

* 30. **Exclusion Criteria: (Required)** the specific, pre-defined characteristics that disqualify otherwise eligible individuals from enrolling in your study (for example: unable to provide informed consent; currently pregnant; diagnosed with a severe cognitive impairment that would prevent completing study procedures; currently enrolled in another intervention study that could affect outcomes).

* 31. **Sample Size: (Required)** Specify the maximum expected participants. (*If obtaining consent, you must also include this number in the consent form, per federal requirements.*)

* 32. **How was the sample size determined? (Required)** (Provide a scientific reason, e.g., convenience sample/representing a cohort, power analysis, or data saturation.)

NDMU Initial Application for Research With Human Subjects

11. Setting

* 33. **Research Site: (Required)** Where will the study be conducted? (Location for study visits, sessions, or data collection, e.g., online survey, classroom, public areas on campus, etc..)

* 34. **Offsite Data Collection. (Required)** "*Offsite*" *means you are planning to* ***recruit participants and/or collect data*** *through any* ***external organization/institution/school*** *besides NDMU. (e.g., sending study invitations to school parents, students, or staff, posting recruitment flyers in a clinic, collecting data in a class or a clinic).*

Mark one answer below:

- [ ] I'm collecting data offsite, and I already have permission to conduct the study from that organization/institution/school. *(You'll upload documentation of permission later in this application).*
- [ ] I'm collecting data offsite and I am still needing some or all permission to conduct the study (*but will obtain it and submit documentation to NDMU IRB for final approval before I begin my study*).
- [ ] I'm not collecting data offsite and don't need permission to conduct the study from any external site.

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

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

NDMU Initial Application for Research With Human Subjects

12. Procedures

* 37. **Recruitment Process. (Required)**

Describe all the elements below:

- Where and how study information will be advertised.
- How interested individuals will contact investigators or find study details.
- How participants will be enrolled.
- What identifying information will be collected during the enrollment process and where it will be stored.

38. **Recruitment Materials. (Required)** If applicable, upload any advertisements (flyers, etc.) or other solicitations (emails) that you will use to invite people to take part in your study, as one pdf file.

Choose File | Choose File | No file chosen

* 39. **Procedures: (Required)** Include all the elements below:

- Describe what your participants will experience, including data collection processes, interventions, and follow-ups.
- Provide a step-by-step process with frequency, duration, and location.
- Specify how data will be collected and what tools (surveys, interviews, instruments) will be used.
- If participants complete surveys or instruments multiple times, state this.

Note: Ensure consistency with the "What will I be asked to do?" section in the informed consent document.

* 40. **Data Collection Instruments/Measures. (Required)** Upload all data collection instruments (e.g., screening questions, demographic questions, surveys, interview guides or questions, data collection forms, and/or questionnaires or measures) as one pdf file.

Choose File | Choose File | No file chosen

* 41. **Sensitive Questions: (Required)** Are you asking about or collecting data about any stigmatized, personal, embarrassing, or illegal topics? If a participants' responses were accidently disclosed outside the study, could they face embarrassment, legal issues, problems at work or with their boss, financial harm, safety issues, or reputation damage?

Yes

No

Comment (optional)

* 42. **Copyrights: (Required)** If applicable, have you obtained permission to use any copyrighted measures in your study?

- Yes
- No
- N/A -- I am not using copyrighted measures in my study

13. Burden, Risk, and Benefits of Your Study

* 43. **Estimated Participant Time Burden: (Required)**

Include all of the following:

- Number of required activities for participants (e.g., how many interviews, surveys, sessions).
- Estimated duration of each activity (e.g., 60-minute interview, 15-minute survey).
- Total time commitment for required activities over the time participants will take part in the study (activities × duration).
- Study duration if participants are followed over time (e.g., six weeks).

Note: Ensure the estimated time burden for participants is included in the informed consent document, in the "What will I be asked to do?" section.

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* 44. **Risks to Participants: (Required)**

- Describe all potential risks (physical, psychological, social, legal, financial, or privacy breaches).
- Explain precautions to minimize risks.

Note: Ensure consistency with the informed consent document.

* 45. **Benefits to Participants: (Required)**

- List direct benefits, if applicable (this is rare)
- If no direct benefits, state, "participants may not benefit directly from research participation"
- List indirect benefits if applicable (e.g., gaining insight).

Note: Ensure consistency with the informed consent document.

* 46. **Benefits to Others: (Required)** Describe potential benefits to the community or society, for example, the knowledge to be gained, processes that could be improved in the future.

Note: Ensure consistency with the informed consent document.

* 47. **Deception: (Required)** Does your study involve deception of the participants?

- ◯ Yes
- ◯ No

48. **(Required if applicable)** If yes, explain why you are using deception and how you will debrief your participants.

49. **Debriefing Statement. (Required if applicable)**. If you are using deception, upload your debriefing statement for participants as one pdf file.

Choose File | Choose File | No file chosen

14. Participant Compensation

* 50. **Participant Compensation: (Required)** Are participants being compensated in the form of pay (cash, gift cards), academic credit, including them in a lottery drawing for a prize/gift card etc., or other?

- [ ] Pay (cash, gift cards)
- [ ] Academic credit
- [ ] Including them in a lottery drawing for a prize/gift card etc.
- [ ] Other
- [ ] **None**

15. Participant Compensation - Details

51. **Participant Compensation: (Required if applicable)**

Describe all the elements below:

- Type and amount of compensation
- Timing of compensation
- Policy for participants who withdraw
- Details on lotteries/drawings (value, quantity)

Note: Ensure this information is included in the consent form.

52. **(Required if applicable) In your opinion,** will the participant be unduly influenced by the compensation offered?

- ◯ Yes
- ◯ No

53. **Academic Credit for Student Research Participation: (Required if applicable)**

Describe:

- What extra or course credit will be offered for research participation.
- What comparable alternative assignment will be offered for those who decline to participate in the research (required)
- How you will ensure students understand research participation is voluntary and non-research alternatives are available.
- How you will ensure students understand they will not be penalized for non-participation.

Note: If applicable, ensure this information is included in the informed consent document.

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16. Confidentiality and Data Management

* 54. **Identifying Data Collection: (Required)**

- Will you collect any identifying information about people in your study at any point (for example, names, contact details, video images, student ID number)?
- Will it be collected and stored separately from research data or will it be included in survey/forms?
- Select all applicable options.

- [ ] NO, I'm not recording any identifying information about any participants (participation is anonymous/question does not apply)
- [ ] Yes, I'm planning to record identifying information about my participants directly within my research data (as part of my survey or interview, etc.)
- [ ] Yes, but I'm NOT recording identifying information directly within the data, and all identifying information will be collected and stored separately from my data (best practice)
- [ ] *Comment (optional)*

- [ ] N/A

* 55. **Identifying Information: (Required)** Select all identifying information you will collect from research participants (*Check ALL that apply*)

- [ ] Does not apply -- No identifying infromation collected in this study
- [ ] 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

* 56. **Data Management Plan: (Required)** Describe your data management plan. Specifically address the following points. (You may upload this as a separate document if you prefer).

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).

If your study does not collect any identifying data, enter N/A below.

59. Data management plan (if you prefer to upload it as a separate file)

Choose File | Choose File | No file chosen

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

yes no

58. ***(Required if applicable) If yes***, explain:

59. Data management plan (if you prefer to upload it as a separate file)

Choose File | Choose File | No file chosen

17. Data Collection with Technology

* 60. **Will any web or electronic applications** be used to recruit participants, complete questionnaires, or process data? **(Required)**

- [ ] Qualtrics
- [ ] Survey Monkey
- [ ] RedCap
- [ ] Google Forms
- [ ] Microsoft Forms
- [ ] Learning Management System survey
- [ ] Other
- [ ] None of these will be used

61. ***(Required if applicable) 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

* 62. **Recording: (Required)** Does the study involve audio recording, video recording, or photographing?

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

18. Confidentiality - Recordings and Images

63. ***(Required if applicable) If yes,*** will identifiable information be blocked out from audio/video recordings/photographs? (*Identifiable information means distinguishing characteristics that could make a person recognizable to someone outside the research team -- including voice patterns, accents, speech, mannerisms, tattos, scars, markings, etc.)*

- ○ Yes
- ◉ No

64. **(Required if applicable) 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.)*

19. SECTION 4: OBTAINING INFORMED CONSENT & RELATED ISSUES

* 65. **Type of Informed Consent Document: (Required)**

Most studies require an informed consent document. You must use the NDMU template form available at the IRB website for informed consent, and choose one of two types of informed consent:

- Standard form: **Written informed consent** -- All participants will sign a consent form and return to the investigator before taking part in the study.
- Alternative form: **Waiver of documentation of informed consent --** participants will not sign a consent form, but will provide verbal consent or "click to agree" on a web survey. Even in these cases, you must still submit an informed consent document using the required NDMU template with your application and you must provide this document to all participants who want a copy. Under federal regulations, the IRB may only approve this alternative form if **either of the below circumstances is true:**

Circumstance A)(Significant privacy concerns): You plan to collect data that includes stigmatizing or embarrassing or illegal information and a breach of confidentiality is the main risk to your participants; your data will not otherwise contain identifying information, and therefore the signed consent form may be the only record that links participants to study participation in the case of a breach of confidentiality (e.g., your study laptop was stolen); **OR**

Circumstance B)(Very low risk) Your study involves innocuous procedures and questions that are routine and would not normally require a written consent form outside of a research context.

Indicate below what type of informed consent document you will submit.

- ◯ I am requesting a waiver of documentation of informed consent because circumstance A (above) applies
- ◯ I am requesting a waiver of documentation of informed consent because circumstance B (above) applies
- ◯ I will have all my participants sign a written consent form.
- ◯ N/A
- ◯ Other (please specify)

* 66. **Informed Consent Process (Required):** If you are obtaining informed consent from participants (even if they are not signing a consent form) you must describe the process by which you will obtain informed consent and ensure participants understand the study.

Include the following elements:

- Describe who on the study team will obtain consent and answer questions
- Explain how and when you will approach participants and obtain participant consent (or parental permission/child assent), and whether email or other technologies will be used
- Describe how potential participants can ask questions
- Explain how participants will be provided a printed or downloadable copy of the informed consent form, if they wish to have one. (**This is required for all studies, even those using an unsigned consent form**).

* 67. **Understandability and readability: (Required)** All study materials (informed consent forms, recruitment materials, data collection tools) seen by participants must be succinct, clear, well-organized, and at a reading level appropriate for the intended participants. Please indicate how you have addressed this requirement:

- [ ] Checked readability (e.g., using an appropriate online tool) and revised as needed
- [ ] Used an AI program such as ChatGPT to reduce reading level/format documents for clarity
- [ ] Used best practices (e.g., substituted plain language for complex terms, minimized wordiness and complex clauses, used bullet points, etc.)
- [ ] Pilot-tested study documents with the target population and obtained feedback on understandability and clarity
- [ ] Obtained feedback on study documents' understandability and clarity from experts, peers, etc.
- [ ] N/A
- [ ] Comments or questions:

- [ ] None of the above

20.

68. **Informed Consent Forms. (Required)** Whether you intend to use a signed or unsigned consent form, you must submit the informed consent template for NDMU available at the IRB website.

Upload all informed consent forms here. If you are also using parental permission/child assent documents, upload these here as well. Combine all consent forms into one pdf file.

Choose File Choose File No file chosen

21. SECTION 6. FERPA, HIPAA, AND CONFLICT OF INTEREST

* 69. **FERPA Compliance**: **(Required)** FERPA applies to student educational records accessed for research studies. FERPA protects student educational records used in research, even if accessing them is otherwise a normal part of your job. If your study involves FERPA-protected data, you must:

A) Obtain written consent from students (or parents, if applicable), listing all records accessed and explaining why. Participants must be informed they can refuse or revoke access at any time.

B) Use de-identified data provided by someone with legal FERPA access (other than you).

Document your FERPA procedures in your protocol (Section 3) and consent form. Check below:

- ◯ I am aware of the FERPA compliance requirements, and my study and consent procedures reflect this; I will obtain a signed, authenticated FERPA release from all student research participants (or their parents, if applicable).
- ◯ I am aware of the FERPA compliance requirements, and my study and consent procedures reflect this; de-identified student data will be provided by a person who has FERPA-authorized access to this data.
- ◯ FERPA compliance requirements do not apply for my study -- I am not accessing FERPA-protected data.

70. FERPA comment (optional)

* 71. **HIPAA Compliance: (Required)** 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.

* 72. **Conflict of Interest: (Required)** 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.*

22. SECTION 7. INTERNATIONAL RESEARCH AND RESEARCH WITH PRISONERS

International Research

* 73. Does your study involve research conducted outside of the United States? **(Required)**

- ◯ Yes
- ◯ No

23. SUBPART SECTION A: INTERNATIONAL RESEARCH

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

74. 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.

75. 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

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

77. 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

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

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

- ◯ Yes
- ◯ No

80. If yes, please describe.

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

24. Research with Prisoners

* 82. Does your study involve research with prisoners? **(Required)**

- ○ Yes
- ○ No

25. SUBPART SECTION B: RESEARCH WITH PRISONERS

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

83. **(Required if applicable).**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.

84. 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

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

- (●) Yes
- (●) No

86. 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

87. If no, please explain:

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

- ◯ Yes
- ◯ No

89. 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

90. 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

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

26. SECTION 8: ADDITIONAL DOCUMENT UPLOAD

All supporting documents should be in pdf format.

92. **Additional Uploads.** If you have any other files or documents for the IRB to review, you may upload them on this page.

Choose File Choose File No file chosen

93. Upload additional documentation here, if needed

Choose File Choose File No file chosen

94. Upload additional documentation here, if needed

Choose File Choose File No file chosen

NDMU Initial Application for Research With Human Subjects

27. SUBMIT IRB APPLICATION

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

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

* 97. **Investigator Certification: ((Required).** 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, and that doing so may be a violation of institutional policy and federal regulations, and an instance of serious research misconduct. I understand that human subjects research cannot be approved retrospectively.

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

98. **(Required):** Please type your name as an electronic endorsement of this application form.

* 99. **(Required):** Please **enter today's date and click the forward button** to submit your application. Your application is not submitted and will not be reviewed until you complete this final step.

Date / Time

Date

MM/DD/YYYY