This is a Word version of the NDMU IRB Application form, which can be found at [www.bit.ly/ndmuirbapplication](http://www.bit.ly/ndmuirbapplication) .

1. NDMU IRB Initial Application for Research With Human Subjects

NDMU 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](https://www.ndm.edu/academic-affairs/research-development/institutional-review-board) 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. Applications are reviewed only after submission.

Deadlines & Review:

Submission deadline: First Friday of the month

IRB meetings: 3rd week of the month

For urgent cases or questions, contact us (irb@ndm.edu)

2. SECTION 1: PROJECT OVERVIEW AND INVESTIGATORS

NDMU Initial Application for Research With Human Subjects

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

End Date

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

 Yes  No

1. **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.*

# Primary Principal Investigator (Name)

*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.*

# Primary Principal Investigator Contact Information

**Department and School**

**Work Address**

**Address 2**

**City/Town**

**State/Province**

**ZIP/Postal Code**

**Email Address**

**Phone Number**

1. **CITI Certiﬁcation**

All investigators who have contact with participants or identified data 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;](http://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 periodically:

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

No ﬁle chosen

1. **Department Contact** *(PI supervisor; chair or dean)*

Supervisor Name

Supervisor Email

# Is This a Student Research Project?

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

 Yes No

(IF NOT A STUDENT RESEARCH PROJECT, SKIP TO PAGE 6)

3. Student Investigator Information

NDMU Initial Application for Research With Human Subjects

# Student Investigator (Name)

1. **Student Investigator Contact Information**

**Department and School**

**Email Address**

# Conﬁrm Faculty Approval:

*Is this a student project? If yes, upload a PDF of the Principal Investigator's approval (letter or email screenshot).*

No ﬁle chosen

1. Upload student's CITI certiﬁcate here

No ﬁle chosen

4. Additional Student Investigator Information

NDMU Initial Application for Research With Human Subjects

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

 Yes  No

1. **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. You are not required to list student investigators who are not interacting with research participants, collecting or accessing identiﬁable data, or obtaining consent.)*
2. Upload student CITI certiﬁcate here

No ﬁle chosen

1. Upload student CITI certiﬁcate here

No ﬁle chosen

1. Upload student CITI certiﬁcate here

No ﬁle chosen

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

5. Other Investigators

NDMU Initial Application for Research With Human Subjects

1. **Co-investigators:** *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

(IF NO Co-INVESTIGATORS PARTICIPATING IN THE RESEARCH AS DEFINED ABOVE, SKIP TO PAGE 8)

1. **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. You are not required to list co-investigators who are not interacting with research participants, collecting or accessing identiﬁable data, or obtaining consent.)*
2. Upload co-investigator's CITI certiﬁcate here

No ﬁle chosen

1. Upload co-investigator's CITI certiﬁcate here

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

NDMU Initial Application for Research With Human Subjects

# 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.

1. **Minimal risk:** 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)

7. Type of Review

NDMU Initial Application for Research With Human Subjects

1. Does your research include any of the following?

*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**

8. Other IRBs

NDMU Initial Application for Research With Human Subjects

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

 Yes No

9. Other IRBs - details

NDMU Initial Application for Research With Human Subjects

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

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

No ﬁle chosen

10. SECTION 3: RESEARCH DETAILS

Abstract and Sample

NDMU Initial Application for Research With Human Subjects

1. **Project Abstract (≤500 words).** Use clear, lay-friendly language. Include:
* 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?
1. **Inclusion Criteria:** Who is eligible to participate? Specify your target recruitment group.
2. **Exclusion Criteria:** Who is ineligible to participate? Specify any restrictions based on gender, age, race/ethnicity, language, or other factors.

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

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

11. Setting

NDMU Initial Application for Research With Human Subjects

1. **Research Site:** Where will the study be conducted? (Location for study visits, sessions, or data collection, e.g., online survey, classroom, public areas on campus, etc.)
2. **Oﬀsite Data Collection.** *"Oﬀsite" means you are planning to recruit and/or collect data from research participants 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).*

 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.

1. **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.

No ﬁle chosen

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

12. Procedures

NDMU Initial Application for Research With Human Subjects

1. **Recruitment Process.** Describe:

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.

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

No ﬁle chosen

# Procedures:

 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.*

1. **Data Collection Instruments/Measures.** 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.

No ﬁle chosen

1. **Sensitive Questions:** Are you asking about stigmatized, personal, embarrassing, or illegal topics? Could disclosure of responses outside the study risk embarrassment, legal issues, ﬁnancial harm, or reputation damage?

 Yes  No

*Comment (optional)*

1. **Copyrights:** Have you obtained permission to use any copyrighted measures in your study?

 Yes  No

 Not needed N/A

13. Burden, Risk, and Beneﬁts of Your Study

NDMU Initial Application for Research With Human Subjects

1. **Participant Time Burden:** Include:

 Number of required activities (e.g., interviews, surveys, sessions).

 Estimated duration of each activity (e.g., 60-minute interview, 15-minute survey).  Total time commitment (activities × duration).

 Study duration if participants are followed over time (e.g., six weeks).

*Note: Ensure this information is in the informed consent form.*

# Risks:

 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.*

# Participant Beneﬁts:

 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.*

1. **Beneﬁts to Others:** Describe potential beneﬁts to the community or society.

*Note: Ensure consistency with the informed consent document.*

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

 Yes  No

1. If yes, explain why you are using deception and how you will debrief your participants.
2. **Debrieﬁng Statement.** If applicable (if you are using deception) upload your debrieﬁng statement as one pdf ﬁle.

No ﬁle chosen

14. Participant Compensation

NDMU Initial Application for Research With Human Subjects

1. **Participant Compensation:** 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.

 Other

**None**

15. Participant Compensation - Details

NDMU Initial Application for Research With Human Subjects

1. **Participant Compensation:** Describe:

 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.*

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

 Yes  No

# Academic Credit for Student Research Participation: 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: Include this information in consent form as well.*

16. Conﬁdentiality and Data Management

NDMU Initial Application for Research With Human Subjects

# Identifying Data Collection:

Will you collect any identifying information about your participants (e.g., their names, contact details, student ID number)?

Will it be stored separately from research data or included in survey/forms? Select all applicable options.

NO, I'm not recording any identifying information about any participants (participation is anonymous)

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

1. **Identifying Information:** Select all identifying information you will collect from research participants (*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

1. **Data Management Plan:** 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).
2. **Dissemination of results:** Is there any way a participant’s identity may be known from subsequent publications or presentations?

 Yes  No

1. ***If yes***, explain:

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

No ﬁle chosen

17. Data Collection with Technology

NDMU Initial Application for Research With Human Subjects

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

 Qualtrics

 Survey Monkey  RedCap

 Learning Management System survey

 Other

 None of these will be used

1. ***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

1. **Recording:** 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

NDMU Initial Application for Research With Human Subjects

1. ***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

1. **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

NDMU Initial Application for Research With Human Subjects

# Type of Informed Consent Document:

Most studies require an informed consent document.

 This is usually a document that participants must sign and return to the investigator before taking part in the study.

 In some cases, the IRB can waive the signature requirement on the document. This is called a *waiver of documentation of informed consent,* also known as "verbal consent" or "clicking to agree" in web surveys. The IRB may waive the signature requirement on the form to protect privacy or simplify data collection if **either of the below circumstances is true:**

**Circumstance A)** 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)** Your study involves innocuous procedures 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)

1. **Informed Consent Process.** The IRB cannot approve most research studies without a description of the informed consent process.

Explain how and when you will obtain participant consent (or parental permission/child assent).

Describe how potential participants can ask questions Describe who on the study team will obtain consent

Explain how participants will be provided a 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**).

1. **Understandability and readability:** All study materials 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](https://www.wordcalc.com/readability/)) 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

NDMU Initial Application for Research With Human Subjects

1. **Informed Consent Forms.** Whether you intend to use a signed or unsigned consent [form, your form must use the appropriate informed consent template for NDMU available at the IRB website.](http://www.bit.ly/ndmuirb)

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.](https://acrobat.adobe.com/link/acrobat/combine-pdf?x_api_client_id=adobe_com&x_api_client_location=combine_pdf) These answers have logic applied

No ﬁle chosen

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

NDMU Initial Application for Research With Human Subjects

1. **FERPA Compliance**: 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:
2. 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.
3. 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.

1. FERPA comment (optional)
2. **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.

1. **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.*

22. SECTION 7. INTERNATIONAL RESEARCH AND RESEARCH WITH

PRISONERS

NDMU Initial Application for Research With Human Subjects

# International Research

1. Does your study involve research conducted outside of the United States?

 Yes No

IF NO, SKIP TO PAGE 36

23. SUBPART SECTION A: INTERNATIONAL RESEARCH

NDMU Initial Application for Research With Human Subjects

# 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.

1. 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.
2. 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.*](http://www.hhs.gov/ohrp/international/)

 Yes  No

1. If yes, please describe and explain how you will comply with the local human subject protection requirements.
2. 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

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

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

 Yes  No

1. If yes, please describe.
2. (*optional*) Is there anything else you would like the IRB to know regarding the international context of your study?

24. Research with Prisoners

NDMU Initial Application for Research With Human Subjects

1. Does your study involve research with prisoners?

 Yes No

IF NO, SKIP TO PAGE 39

25. SUBPART SECTION B: RESEARCH WITH PRISONERS

NDMU Initial Application for Research With Human Subjects

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

1. 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.

1. 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

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

 Yes  No

1. 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

1. If no, please explain:
2. The information is presented in language which is understandable to the subject population.

 Yes  No

1. 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

1. 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

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

26. SECTION 8: ADDITIONAL DOCUMENT UPLOAD

NDMU Initial Application for Research With Human Subjects

# All supporting documents should be in pdf format.

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

No ﬁle chosen

1. Upload additional documentation here, if needed These answers have logic applied

No ﬁle chosen

1. Upload additional documentation here, if needed These answers have logic applied

No ﬁle chosen

27. SUBMIT IRB APPLICATION

NDMU Initial Application for Research With Human Subjects

1. Any questions for the IRB? Anything else you want us to know?
2. Any feedback on the application form/suggestions for improvements?
3. **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

1. Please type your name as an electronic endorsement of this application form.
2. Please enter today's date and click forward to submit your application.

Date