

**Human Subjects Research Protocol:**

**Application for Expedited or Full Board Review**

* ***Please provide the information requested below.***
* ***Handwritten forms are not accepted – responses must be typed on the form.***
* ***All students, medical residents, and post-docs must list a research advisor.***

**Please check one of the options below:**

[ ]  Initial submission

[ ]  Revised application in response to reviewer requests

* *All revisions must be in UPPER CASE.*

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| **Principal Investigator:** |       |
| Telephone: |                          | E-mail Address: |       |
| Complete Mailing Address:  |       |
| School/College: |       | Department: |            |

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| **Research Advisor (if applicable):** |       |
| Telephone: |       | E-mail Address: |       |
| Address or Box #: |       |
| School/College: |       | Department: |       |

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| ***\*\*\* All IRB applications must include a*** [***Key Personnel Listing***](http://und.edu/research/resources/human-subjects/_files/docs/key-personnel-listing.xlsx)***.***  |

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| **Project Title:** |       |
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| **Proposed Project Dates:** Beginning Date: |       | Completion Date:  |       |
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**Funding agencies supporting this research:** |

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| (Including data analysis) |

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**Did the grant proposal with the funding entity go through UND Grants & Contracts Admin.?** [ ]  YES or [ ]  NO

Attach a copy of the grant proposal. Do not include any budgetary information. The IRB will not be able to review the study without a copy of the grant proposal submitted to the funding agency.

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| --- | --- | --- | --- |
|[ ]   YES or |  [ ]  |  NO | Does any researcher associated with this project have an economic interest in the research, or act as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research? If yes, submit on a separate piece of paper an additional explanation of the financial interest. The Principal Investigator and any researcher associated with this project should have a Financial Interests Disclosure Document on file with their department.  |

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|[ ]  YES or |[ ]  NO  | Will any research participants be obtained from another organization outside the University of North Dakota (e.g., hospitals, schools, public agencies, American Indian tribes/reservations)? |
|  |  |  |  |  |
|[ ]  YES or |[ ]  NO | Will any data be collected at or obtained from another organization outside the University of North Dakota? |
| If yes to either of the previous two questions, list all organizations:  |       |

**Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands its involvement and agrees to participate in the study. Letters must include the name and title of the individual signing the letter and should be printed on organizational letterhead.**

Does any external site where the research will be conducted have its own IRB? [ ]  YES [ ]  NO [ ]  N/A

If yes, does the external site plan to rely on UND’s IRB for approval of this study? [ ]  YES [ ]  NO [ ]  N/A

 (If yes, contact the UND IRB at 701 777-4279 for additional requirements)

If your project has been or will be submitted to other IRBs, list those Boards below, along with the status of each proposal.

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|        | Date submitted: |       | Status: |[ ]  Approved |[ ]  Pending |
|       | Date submitted: |       | Status: |[ ]  Approved |[ ]  Pending |

(include the name and address of the IRB, contact person at the IRB, and a phone number for that person)

**Type of Project:**Check “Yes” or “No” for each of the following.

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| --- | --- | --- | --- | --- |
|[ ]  YES or |[ ]  NO New Project |  |[ ]  YES or |[ ]  NO Dissertation/Thesis/Independent Study |
|[ ]  YES or |[ ]  NO Continuation/Renewal |  |[ ]  YES or |[ ]  NO Student Research Project |
|[ ]  YES or |[ ]  NO  | Is this a Protocol Change for previously approved project? If yes, submit a signed Protocol Change Form, along with a signed copy of this form with the changes bolded or highlighted.  |
|[ ]  YES or |[ ]  NO | Does your project involve abstracting medical record information? If yes, complete the HIPAA Compliance Application and submit it with this form. |
|[ ]  YES or |[ ]  NO  | Does your project include Genetic Research?  |

**Subject Classification**: Check all that apply, or check here if **N/A** [ ]

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|[ ]  Children (< 18 years) |  |[ ]  UND Students |
|[ ]  Prisoners |  |[ ]  Pregnant Women/Fetuses |
|[ ]  Cognitively impaired persons or persons unable to consent |
|[ ]  Other |       |

**This study will involve:** Check all that apply, or check here if **N/A** [ ]

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|[ ]  Deception (Attach Waiver or Alteration of Informed  Consent Requirements) |  |[ ]  Stem Cells |
|[ ]  Radiation |  |[ ]  Discarded Tissue |
|[ ]  New Drugs (IND) IND #       Attach Approval  |  |[ ]  Fetal Tissue |
|[ ]  Investigational Device Exemption (IDE) #       Attach Approval  |  |[ ]  Human Blood or Fluids |
|[ ]  Non-approved Use of Drug(s) |  |[ ]  Other       |
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**I. Project Overview**

Please provide a brief explanation (limit to 200 words or less) of the rationale and purpose of the study, introduction of any sponsor(s) of the study, and justification for use of human subjects and/or special populations (e.g., vulnerable populations such as children, prisoners, pregnant women/fetuses).

**II. Protocol Description**

Please provide a thorough description of the procedures to be used by addressing the instructions under each of the following categories.

**1. Subject Selection.**

a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will be recruited and for how long) and include copies of any advertisements, fliers, etc., that will be used to recruit subjects.

b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from any of the categories listed in the “Subject Classification” section above.

 c) Describe your exclusionary criteria and provide a rationale for excluding subject categories.

d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects.

e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method.

**2. Description of Methodology.**

a) Describe the procedures used to obtain informed consent.

b) Describe where the research will be conducted. Document the resources and facilities to be used to carry out the proposed research. Please note staffing, funding, and space available to conduct this research.

 c) Indicate who will carry out the research procedures.

 d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them.

e) Describe audio/visual procedures and proper disposal of tapes.

f) Describe the qualifications of the individuals conducting all procedures used in the study.

g) Describe compensation procedures (payment or class credit for the subjects, etc.).

Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal**.**

**3. Risk Identification.**

a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.

 b) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and if so, what the justification is for having that link.

 c) Provide a description of the data monitoring plan for all research that involves greater than minimal risk.

 d) If the PI will be the lead-investigator for a multi-center study, or if the PI’s organization will be the lead site in a multi-center study, include information about the management of information obtained in multi-site research that might be relevant to the protection of research participants, such as unanticipated problems involving risks to participants or others, interim results, or protocol modifications.

**4. Subject Protection.**

 a) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).

b) Describe procedures you will implement to protect confidentiality and privacy of participants (such as coding subject data, removing identifying information, reporting data in aggregate form, not violating a participants space, not intruding where one is not welcome or trusted, not observing or recording what people expect not to be public, etc.). If participants who are likely to be vulnerable to coercion and undue influence are to be included in the research, define provisions to protect the privacy and interests of these participants and additional safeguards implemented to protect the rights and welfare of these participants.

c) Indicate that the subject will be provided with a copy of the consent form and how this will be done.

d) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will both be retained in separate locked locations for a minimum of three years following the completion of the study.

 Describe: 1) the storage location of the research data (separate from consent forms and subject personal data)

 2) who will have access to the data

 3) how the data will be destroyed

 4) the storage location of consent forms and personal data (separate from research data)

 5) how the consent forms will be destroyed

e) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.).

f) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.

# III. Benefits of the Study

Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). **Please note:** extra credit and/or payment are not benefits and should be listed in the Protocol Description section under Methodology.

# IV. Consent Form

Clearly describe the consent process below and be sure to include the following information in your description (Note: Simply stating ‘see attached consent form’ is not sufficient. The items listed below must be addressed on this form.):

1. The person who will conduct the consent interview
2. The person who will provide consent or permission
3. Any waiting period between informing the prospective participant and obtaining consent
4. Steps taken to minimize the possibility of coercion or undue influence
5. The language (English, French, German, etc.) to be used by those obtaining consent
6. The language (English, French, German, etc.) understood by the prospective participant or the legally authorized representative
7. The information to be communicated to the prospective participant or the legally authorized representative

**A copy of the consent form must be attached to this proposal*.***

**Necessary attachments**:

 [ ]  Signed Student Consent to Release of Educational Record Form (below) (students only);

 [ ]  Investigator Letter of Assurance of Compliance (below) (all researchers)

 [ ]  [Consent form](http://und.edu/research/resources/human-subjects/_files/docs/sample-consent-form.doc), or [Waiver or Alteration of Informed Consent Requirements](http://und.edu/research/resources/_files/docs/application-for-waiver-alteration-of-informed-consent.doc)

 [ ]  [Key Personnel Listing](http://und.edu/research/resources/human-subjects/_files/docs/key-personnel-listing.xlsx)

 [ ]  Surveys, interview questions, assessments, etc. (if applicable);

 [ ]  Printed web screens (if survey is over the Internet); and

 [ ]  Advertisements (flyer, social media postings, email/letters, etc.).

**V. Signatures:**

**Principal Investigator:**

**I certify that the information provided on this form is accurate and that this research will be conducted in accordance with the statements provided above. I understand that if I want to make changes to the research protocol after IRB approval, I must submit a protocol amendment to the IRB for review prior to implementing any changes.**

**I will fully comply and assume responsibility for the enforcement of compliance with all applicable federal regulations and University policies for the protection of the rights of human subjects engaged in research. I understand the failure to do so may result in the suspension or termination of proposed research and possible reporting to federal agencies.**

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| (Principal Investigator) | Date: |
| **Research Advisor:****As the advisor for this research, I understand that I am responsible for the ethical conduct of this research as described in the protocol. I will fully comply and assume responsibility for the enforcement of compliance with all applicable federal regulations and University policies for the protection of the rights of human subjects engaged in research. I understand the failure to do so may result in the suspension or termination of proposed research and possible reporting to federal agencies.** |
|  |       |
| (Research Advisor) | Date: |

**Requirements for submitting proposals:**

Additional information can be found on the IRB website at: <http://und.edu/research/resources/human-subjects/index.html>

Original, signed proposals and all attachments, along with the necessary number of copies (see below), should be submitted to: Institutional Review Board, 4201 James Ray Drive Stop 7134, Grand Forks, ND 58202-7134, or brought to the Tech Accelerator, Suite 2050.

Required Number of Copies:

* Expedited Review: Submit the signed original and 1 copy of the entire proposal.
* Full Board Review: Submit the signed original and 22 copies of the entire proposal by the deadline listed on the IRB website: <http://und.edu/research/resources/human-subjects/meeting-schedule.html>
* Clinical Medical Subcommittee and Full Board Review: Submit the signed original and 24 copies of the entire proposal by the deadline listed on the IRB website: <http://und.edu/research/resources/human-subjects/meeting-schedule.html>

Prior to receiving IRB approval, researchers must complete the required IRB human subjects’ education. Please go to: <http://und.edu/research/resources/human-subjects/human-subject-education.html>

The criteria for determining what category your proposal will be reviewed under is listed on page 3 of the IRB Checklist. Your reviewer will assign a review category to your proposal. Should your protocol require full Board review, you will need to provide additional copies. Further information can be found on the IRB website regarding required copies and IRB review categories, or you may call the IRB office at 701 777-4279.

In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 5 copies if the proposal is clinical-medical. If the proposed work is being conducted for a pharmaceutical company, 5 copies of the company’s protocol must be provided.

**INVESTIGATOR LETTER OF ASSURANCE OF COMPLIANCE**

**WITH ALL APPLICABLE FEDERAL REGULATIONS FOR THE**

**PROTECTION OF THE RIGHTS OF HUMAN SUBJECTS**

I \_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (Name of Investigator)

agree that, in conducting research under the approval of the University of North Dakota Institutional Review Board, I will fully comply and assume responsibility for the enforcement of compliance with all applicable federal regulations and University policies for the protection of the rights of human subjects engaged in research. Specific regulations include the Federal Common Rule for Protection of the Rights of Human Subjects 45 CFR 46. I will also assure compliance to the ethical principles set forth in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research document, The Belmont Report.

I understand the University’s policies concerning research involving human subjects and agree to the following:

 1. Should I wish to make changes in the approved protocol for this project, I will submit them for review PRIOR to initiating the changes. (A proposal may be changed without prior IRB approval where necessary to eliminate apparent immediate hazards to the subjects or others. However, the IRB must be notified in writing within 72 hours of any change, and IRB review is required at the next regularly scheduled meeting of the full IRB.)

 2. If any problems involving human subjects occur, I will immediately notify the Chair of the IRB, or the IRB Manager.

 3. I will cooperate with the UND IRB by submitting Research Project Review and Progress Reports in a timely manner.

I understand the failure to do so may result in the suspension or termination of proposed research and possible reporting to federal agencies.

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 Investigator Signature Date

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| **STUDENT RESEARCHERS:** As of June 4, 1997 (based on the recommendation of UND Legal Counsel) the University of North Dakota IRB is unable to approve your project unless the following "Student Consent to Release of Educational Record" is signed and included with your IRB application. |
| **STUDENT CONSENT TO RELEASE OF EDUCATIONAL RECORD1**Pursuant to the Family Educational Rights and Privacy Act of 1974, I hereby consent to the Institutional Review Board’s access to those portions of my educational record which involve research that I wish to conduct under the Board’s auspices. I understand that the Board may need to review my study data based on a question from a participant or under |
| a random audit. The title of the study to which this release pertains is |       |
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| I understand that such information concerning my educational record will not be released except on the condition that the Institutional Review Board will not permit any other party to have access to such information without my written consent. I also understand that this policy will be explained to those persons requesting any educational information and that this release will be kept with the study documentation. |
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| ID # |  | Printed Name |
|       |  |  |
| Date  |  | Signature of Student Researcher |
| 1Consent required by 20 U.S.C. 1232g.  |