Application for Approval of Research with Human Subjects

Instructions

This Application for Approval of Research with Human Subjects must be completed, signed, and sent a minimum of two (2) weeks prior to the IRB meeting date to ensure review by the IRB. (IRB meetings are held the second Wednesday of every month.)

In addition to all sections of the application form, the Principal Investigator MUST fill out the Informed Consent checklist at the end of the application.

Email this application form and all supplementary materials to the IRB Coordinator, Robyn Hunter at robyn.hunter@state.mn.us. Please copy the co-PI and any others you wish to be included on correspondence with the IRB. Alternatively, you may mail your submission to Robyn Hunter, MDH Institutional Review Board, P.O. Box 64882, St. Paul, MN 55164-0882 (Interoffice address: Institutional Review Board, 300 GRB). Unsigned and incomplete applications will be returned to principal investigator for completion prior to any IRB review.

The Principal Investigator (PI) (or an alternate) may be expected to be at the meeting to present a brief overview of the project and answer questions. You will be notified if this is necessary.

For More Information

If you have questions about the MDH IRB review process or need technical assistance, please contact the IRB Administrator, Sharrilyn Evered, by writing to the address listed above, by telephone 651-201-5942, or by email sharrilyn.evered@state.mn.us.

More information on the MDH IRB may be found on the IRB website (http://www.health.state.mn.us/irb/index.html).

Links to training resources on the protection of human subjects in research can also be found on the IRB website (http://www.health.state.mn.us/irb/index.html).
Application for Approval of Research with Human Subjects

Title of Research:

Principal Investigator Information:
- Name: ____________________________
- Title: ____________________________
- Address: ____________________________
- City State Zip
- Email/Internet Address: ____________________________
- Phone Number: ____________________________
- Fax Number: ____________________________

Co-Principal Investigator Information:
- Name: ____________________________
- Title: ____________________________
- Address: ____________________________
- City State Zip
- Email/Internet Address: ____________________________
- Phone Number: ____________________________
- Fax Number: ____________________________

Funding Agency Information:
- Name: ____________________________
- Address: ____________________________
- City State Zip
- Email/Internet Address:
- Phone Number: ____________________________
- Fax Number: ____________________________

If known, Application or Proposal Identification Number: ____________________________

Proposed Project Dates: From: __________ To: __________
Month/Day/Year Month/Day/Year

Is this project being reviewed by any other IRB? □ Yes □ No

If yes, give name of IRB and name and phone number of IRB contact person:

Name of IRB: ____________________________
Name of Contact Person: ____________________________
Phone Number: ____________________________

Has this project been approved by another IRB? □ Yes □ No

If yes, give date of approval, name and phone number of IRB contact person:

Date of Approval: ____________________________

I CERTIFY THAT THE INFORMATION FURNISHED CONCERNING THE PROCEDURES TO BE TAKEN FOR THE PROTECTION OF HUMAN SUBJECTS IS CORRECT. I WILL SEEK AND OBTAIN PRIOR APPROVAL FROM THE IRB FOR ANY SUBSTANTIVE MODIFICATION IN THE PROPOSAL. I WILL PROMPTLY REPORT TO THE IRB ANY UNEXPECTED OR SIGNIFICANT ADVERSE EFFECTS (E.G., BREACHES OF CONFIDENTIALITY, BREACHES OF PROTOCOL, WITHDRAWAL OF STUDY SUBJECTS, AND COMPLAINTS ABOUT THE STUDY) IN THE COURSE OF THIS STUDY.

Signature of Principal Investigator: ____________________________
Date: ____________________________

IRB STAFF USE ONLY
ID #: ____________________________
I. PURPOSE OF THE STUDY, INCLUDING THE RESEARCH QUESTION (S).

II. RESEARCH METHODS - Include the following:

A. Description of the subject population - number of subjects, age range, how subjects will be identified and selected;

B. Explanation of subject involvement in the research (the who, what, when, and how of subject involvement);

C. Summary of data analysis or statistical methods to be used in the study;

D. Specification of any inducements or rewards to be given subjects for their participation;

E. Specification of any research-related expenses to be charged to the subject or their third party payor.
III. **RISKS** Describe any reasonably foreseeable risks or discomforts to participants, including physical, emotional, economic, cultural or social factors. Delineate any steps taken to minimize risks, as well as care of subjects in the event of an accident or complication.

IV. **BENEFITS** Describe all reasonably foreseeable direct benefits to subjects as well as potential benefits to society.

V. **CONFIDENTIALITY AND PRIVACY OF DATA** Include the following:

A. An explanation of the procedures that will be implemented to safeguard data privacy, including how and where the data will be stored, in what form the data will be stored, how long the data will be stored, methods for destroying the data, and how the anonymity of the subjects will be insured. The classification of the data under the Minnesota Government Data Practices Act or other relevant statutes should also be submitted, as well as specific security measures to be used.

B. Identification of all persons who will have contact with private information, including research staff, clerical staff, network administrators, and computer staff. Describe how these persons will maintain confidentiality of the data.
VI. TRAINING IN HUMAN SUBJECTS PROTECTION

A. Please describe the training that the Principal Investigator has received about using human subjects in research. Identify the institution (e.g. University of Minnesota) or on-line course providing the training. Include date (year) training was received. [NOTE: Links to training resources on the protection of human subjects in research can be found on the IRB web site at http://www.health.state.mn.us/irb/index.html.]

B. Describe the training in human subjects protection and data confidentiality received by all persons identified in section V.(B) above who will have access to private information.

VII. INFORMED CONSENT

Please describe procedures for obtaining consent. Attach a copy of the proposed consent form(s).

NOTE: You must submit a consent form or letter that contains all of the elements of informed consent as outlined in the Informed Consent Checklist found near the end of this application.

VIII. RESEARCH INSTRUMENTS

Attach copies of all instruments to be used (questionnaires, surveys, etc.)
IX. VULNERABLE POPULATIONS CHECKLIST

Will your research involve any of the following? If yes, attach a list of additional safeguards you will use.

A. Prisoners? □ Yes □ No
B. Pregnant Women? □ Yes □ No
C. Children? □ Yes □ No
D. Cognitively Impaired Persons? □ Yes □ No
E. Economically or Educationally Disadvantaged Persons? □ Yes □ No
F. Fetuses? □ Yes □ No
G. Human In-Vitro Fertilization? □ Yes □ No
H. HIV Antibody Testing? □ Yes □ No
I. Non-English Speaking Participants? □ Yes □ No
J. Other Vulnerable Populations? Please specify*:
   □ Yes □ No
   __________________________________________
   __________________________________________
   __________________________________________

Additional Safeguards:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Attached additional sheets if necessary.

Since these subjects, and others like them are particularly vulnerable to coercion and undue influence, investigators must incorporate safeguards in the research plan, and be certain to document fully their informed consent or the informed consent of their legal representatives.

Please be sure to sign PAGE 2 of this application.
### Informed Consent Checklist

<table>
<thead>
<tr>
<th>/</th>
<th>Elements</th>
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<tbody>
<tr>
<td></td>
<td>A statement that the study involves research.</td>
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<td>An explanation of the purposes of the research.</td>
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<td>The expected duration of the subject's participation.</td>
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<td>A description of the procedures to be followed.</td>
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<td>Identification of any procedures that are experimental.</td>
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<td>A description of any reasonably foreseeable risks or discomforts to the subject.</td>
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<td>A description of any benefits to the subject or to others which may reasonably be expected from the research.</td>
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<td>A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.</td>
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<td>A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.</td>
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<tr>
<td>( ) Research Qs</td>
<td>For research involving more than minimal risk, an explanation as to whether any compensation will be offered, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained.</td>
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<tr>
<td>( ) Rights Qs</td>
<td>An explanation of whom to contact for answers to pertinent questions about the research (research study contact name and phone number) and research subjects' rights (“For questions about your rights as a participant in this research, contact Sharrilyn Evered, Administrator of the Minnesota Department of Health Institutional Review Board, at 651-201-5942.”) and whom to contact in the event of a research-related injury to the subject (if the research is more than minimal risk).</td>
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<td>( ) Injury Qs</td>
<td>A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is entitled.</td>
</tr>
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Minnesota Department of Health
PO Box 64882
St. Paul, MN 55164-0882
651-201-5942
www.health.state.mn.us/irb/

08/08/17

To obtain this information in a different format, call: 651-201-5942.