



Minnesota Department of Health  
Institutional Review Board (IRB)  
PO Box 64882  
St. Paul, MN 55164-0882

## Application for Approval of Research with Human Subjects INSTRUCTIONS

- The attached 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.)
  
- Three (3) **unbound, signed** copies of the application and all appropriate forms and instruments should be sent to: Ann Kowski, 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. They will be notified if this is necessary.
  
- If you have questions about the MDH IRB review process or need technical assistance, please contact Peter Rode by writing to the address listed above, by telephone 651.201-5942, or by e-mail [peter.rode@state.mn.us](mailto:peter.rode@state.mn.us).
  
- More information on the MDH IRB may be found at the following 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 web site: <http://www.health.state.mn.us/irb/index.html>
  
- In addition to all sections of the application form, the Principal Investigator **MUST** fill out the HIPAA checklist at the end of the application.

More information on HIPAA (Health Insurance Portability and Accountability Act) may be found at [www.hhs.gov/ocr/hipaa](http://www.hhs.gov/ocr/hipaa)



IRB Staff USE ONLY
ID #: \_\_\_\_\_

Application for Approval of Research with Human Subjects

Title of Research: \_\_\_\_\_

Principal Investigator Information:
Name: \_\_\_\_\_
Title: \_\_\_\_\_
Address: \_\_\_\_\_
City State Zip
E-Mail/Internet Address: \_\_\_\_\_
Phone Number: \_\_\_\_\_
Fax Number: \_\_\_\_\_
Co-Principal Investigator Information:
Name: \_\_\_\_\_
Title: \_\_\_\_\_
Address: \_\_\_\_\_
City State Zip
E-Mail/Internet Address: \_\_\_\_\_
Phone Number: \_\_\_\_\_
Fax Number: \_\_\_\_\_

Funding Agency Information:
Name: \_\_\_\_\_
Phone Number: \_\_\_\_\_
Fax Number: \_\_\_\_\_
Address: \_\_\_\_\_
City State Zip
E-Mail/Internet Address: \_\_\_\_\_

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

Name of IRB Name of Contact Person Phone Number

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

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**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.

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- 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.

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**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.)

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**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?   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| B. | Pregnant Women?                                      | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| C. | Children?  | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| D. | Cognitively Impaired Persons?                        | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| E. | Economically or Educationally Disadvantaged Persons? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| F. | Fetuses?   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| G. | Human In-Vitro Fertilization?                        | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| H. | HIV Antibody Testing?                                | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| I. | Non-English Speaking Participants?                   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| J. | Other Vulnerable Populations? Please specify*:       | <input type="checkbox"/> Yes | <input type="checkbox"/> 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**

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**Informed Consent Checklist**

/	<i>Elements</i>
	A statement that the study involves research.
	An explanation of the purposes of the research.
	The expected duration of the subject's participation.
	A description of the procedures to be followed.
	Identification of any procedures that are experimental.
	A description of any reasonably foreseeable risks or discomforts to the subject.
	A description of any benefits to the subject or to others which may reasonably be expected from the research.
	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
	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.
( ) Research Qs	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 Peter Rode, 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).
( ) Rights Qs	
( ) Injury Qs	
	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.

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**HIPAA Checklist**

<i>Y YES</i>	<i>Y NO</i>	<i>Elements</i>
		<p>1. Will any of the information for the study be “protected health information” (PHI) that the study obtains directly from a HIPAA “covered entity”? (Exact definitions of “covered entity” and “PHI” are available at <a href="http://www.hhs.gov/ocr/hipaa">www.hhs.gov/ocr/hipaa</a> For the most part, however, you can use the following definition):</p> <ul style="list-style-type: none"> <li>• A HIPAA “<b>covered entity</b>” includes providers (hospitals, clinics, doctors, etc.,) health plans (health insurers, HMOs), and health care clearinghouses (go-betweens for providers &amp; plans). <b>NOTE:</b> MDH is <b>not</b> a covered entity under HIPAA and any health information that MDH has collected or received for public health purposes is not PHI in MDH’s possession.</li> <li>• <b>PHI</b> is individually identifiable health information that is held by a covered entity and that relates to the health condition of an individual, the provision of health care to an individual or the payment for the provision of health care.</li> </ul> <p><i><b>If you answered no to this question you do not have to complete the rest of the checklist.</b></i></p>
		<p>2. Has the research been reviewed by a Privacy Board or another IRB for HIPAA purposes? If yes, specify which entity is doing this review and submit their review when available.</p> <p>_____</p>
		<p>If no, are you requesting this IRB to review HIPAA requirements? If yes, you will be contacted by MDH staff for further information.</p>