

# 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. The IRB meets the second Wednesday of every month. The Principal Investigator (PI) (or an alternate) may be asked to attend the IRB meeting to present a brief overview of the study and answer questions. You will be notified if this is necessary.

Email this application form and supplementary materials to health.irb.mdh@state.mn.us.

## More information

For technical assistance with this application, please contact the **IRB administrator**. You can find contact information for IRB staff at: [Institutional Review Board at the Minnesota Department of Health (https://www.health.state.mn.us/data/irb/index.html)](https://www.health.state.mn.us/data/irb/index.html).

For information on the MDH IRB, visit: [About the MDH IRB (https://www.health.state.mn.us/data/irb/about.html)](https://www.health.state.mn.us/data/irb/about.html).

For links to training resources on the protection of human subjects in research, visit: [Training, Tips, and Related Information (https://www.health.state.mn.us/data/irb/relatedinfo.html)](https://www.health.state.mn.us/data/irb/relatedinfo.html).

**The application begins on the following page.**

Minnesota Department of Health
Institutional Review Board
625 Roberts St N
PO Box 64975
St. Paul, MN 55164-0975
health.irb.mdh@state.mn.us
[www.health.state.mn.us/data/irb/](http://www.health.state.mn.us/data/irb/)

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*To obtain this information in a different format, call: 651-201-3880*

## Application

This form may be completed electronically. Click in the gray space to begin typing. You may use as much space as you like for each answer.

### Study information

Study Title:

### Proposed study dates (month/day/year)

From:

To:

### Principal investigator information

Name:

Title:

Organization:

Email:

Phone:

### Co-principal investigator information

Name:

Title:

Organization:

Email:

Phone:

### Additional people to CC on correspondence, if any (provide email addresses)

Email:

### Funding agency information

Organization:

Contact Person:

Email:

Phone:

### IRB review

1. Is this study being **reviewed** by any other IRB?

[ ]  No

[ ]  Yes

If yes, please provide the name of the IRB and the name and email of a contact person:

1. Has this study been **approved** by another IRB?

[ ]  No

[ ]  Yes

If yes, please provide a) the name of the IRB; b) the name and email of a contact person; and c) the approval date:

1. Do you request that the MDH IRB defer review of this study to another IRB?

[ ]  No

[ ]  Yes

If yes, please provide the name of the IRB and the name and email of a contact person:

If yes, has the research funder required use of a single IRB? [ ]  No [ ]  Yes

If yes, to your knowledge do federal regulations, state law, or some other policy require use of a specific IRB? [ ]  No [ ]  Yes

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[[1]](#footnote-1)**

**Date**

### Purpose of the study

Describe the purpose of the study, including the research questions.
How will you use the findings?

### Study methods

1. Describe the study population, include the number of subjects, age range, and how subjects will be identified and selected.

1. Explain how human subjects will be involved in the research (who, what, when, and how).

1. Summarize the data analysis or statistical methods to be used in the study.

1. Specify any inducements or rewards to be given to subjects for their participation.

1. Specify any research-related expenses to be charged to the subject or their third-party payer.

1. **Primary** **data** are information or specimens collected to answer a research question that you would not otherwise collect to do your regular work for MDH. **Secondary data** are existing data, collected for another purpose, that will be used to answer a research question. Studies can involve one or both types. Will this study use primary or secondary data? *(Check all that apply)*

[ ]  Primary data[[2]](#footnote-2)

[ ]  Secondary data

### Risks

Describe any reasonably foreseeable risks or discomforts to participants, including physical, emotional, economic, cultural, or social factors. Describe any steps taken to minimize risks, as well as care of subjects in the event of an accident or complication.

### Benefits

Describe all reasonably foreseeable direct benefits to subjects as well as potential benefits to their community or to society.

### Confidentiality and privacy of data

1. Describe 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.

1. If applicable, list the statute that requires the collection or analysis of the study data. Be sure to include classification of the study data under the Minnesota Government Data Practices Act, if specified by the statute.

1. Identify 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.

1. Will organizations or persons outside of MDH be given access to individually identifiable health information or any other nonpublic data?

[ ]  No

[ ]  Yes; please be sure they are identified in part “c” of this section, specify the organization they are affiliated with and that organization’s relationship to MDH (e.g., contractor).[[3]](#footnote-3)

1. Do you plan to publish the results of this study in a peer-reviewed journal?

[ ]  No

[ ]  Yes[[4]](#footnote-4)

### Training in human subjects protection

1. Provide documentation of the training in human subjects protection that the Principal Investigator(s) and all key personnel who will participate in the design or conduct of human subjects research has received. This includes all personnel who will be interacting with the human subject or that will be handling data (even if they do not interact with the human subjects). Identify the institution (e.g., University of Minnesota) or online 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 at: [Training, Tips, and Related Information (https://www.health.state.mn.us/data/irb/relatedinfo.html)](https://www.health.state.mn.us/data/irb/relatedinfo.html).
2. Describe procedures for documenting the training in human subjects protection received by any personnel added to the study in the future.

### Informed consent

1. Describe procedures for obtaining consent. Include a copy of the proposed consent form(s). **NOTE**: You must submit a consent form or letter that contains all required elements of informed consent as outlined in the Informed Consent Checklist found near the end of this application. If requesting that informed consent is waived or altered, provide a justification.

1. Are you requesting that documentation of informed consent is waived for this study?

[ ]  No

[ ]  Yes

If yes, please provide a justification for waiving informed consent. You can find information on informed consent procedures at: [MDH IRB: Frequently Asked Questions (https://www.health.state.mn.us/data/irb/faq.html)](https://www.health.state.mn.us/data/irb/faq.html).

1. What is the reading level of your informed consent document? You may use Microsoft Word’s Readability statistics (i.e., Flesch-Kincaid grade level) or something similar to assess the reading level of your document. If it is higher than 8th grade, you must provide a justification for the higher level.

1. Describe your plans to translate the informed consent document, if any. For help, see [MDH Intranet: Language Access (Translation/Interpretation) (https://fyi.health.state.mn.us/translation/interpretation)](https://fyi.health.state.mn.us/translation/interpretation).

### Study instruments

Please attach copies of all instruments to be used (questionnaires, surveys, etc.) with this application.

### Vulnerable populations checklist

When subjects who are especially vulnerable to coercion and undue influence are targeted by research, investigators must incorporate additional safeguards in the research plan, and be certain to document fully their informed consent or the informed consent of their legal representatives.

1. Will your research intentionally involve any of the following?

[ ]  Prisoners

[ ]  Children

[ ]  Individuals with impaired decision-making capacity

[ ]  Economically or educationally disadvantaged persons

[ ]  Fetuses

[ ]  Human in-vitro fertilization

[ ]  HIV antibody testing

[ ]  Non-English speaking participants

[ ]  Other vulnerable populations, specify:

1. If you checked any of the listed vulnerable populations, describe additional safeguards you will use.

### Informed consent checklist

Informed consent documents should provide subjects with plainly stated information that a reasonable person would need to know to decide what best serves their interests. The information must be presented in sufficient detail and presented in a way that facilitates an understanding of why one might, or might not, want to participate. Informed consent should not merely be a list of isolated facts, but should help people process the complicated information they’re being given and make it easier for them to make an informed decision. In addition, if your informed consent document is long (25 pages or more), it must contain a key summary of the most important information at the beginning.

Does your informed consent document(s) contain each of the following **required** elements? Check all that apply.

[ ]  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.

[ ]  A statement that says that information or biospecimens collected for the study might be stripped of identifiers and used in other research in the future or that this will not happen.

[ ]  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.

[ ]  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.

An explanation of whom to contact for:

[ ]  Answers to pertinent questions about the research (research study contact name and phone number);

[ ]  Research subjects' rights (“For questions about your rights as a participant in this research, contact the administrator of the Minnesota Department of Health Institutional Review Board, [include the name and phone number for the current IRB administrator]”). See: [Institutional Review Board at the Minnesota Department of Health (https://www.health.state.mn.us/data/irb)](https://www.health.state.mn.us/data/irb/) for contact information.

[ ]  Who to contact in the event of a research‑related injury to the subject (**not** required if the research is minimal risk).

If any of the following apply to your study, it **must** be included in your informed consent document. To guide your decision on whether an element is appropriate, see Part III, Section C of the [FDA: Informed Consent: Guidance for IRBs, Clinical Investigators, and Sponsors (PDF) (https://www.fda.gov/media/88915/download)](https://www.fda.gov/media/88915/download)*.* Check the elements that apply and have been included in your informed consent document.

[ ]  A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.

[ ]  Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent.

[ ]  Any additional costs to the subject that may result from participation in the research.

[ ]  The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

[ ]  A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.

[ ]  The approximate number of subjects involved in the study.

[ ]  A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

[ ]  A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

[ ]  For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

1. The MDH IRB accepts the PI’s name typed in the form in lieu of signature if the PI emails this form from a work email account, as this authenticated email is considered their valid electronic signature. The PI’s inked signature is required on submissions that are emailed by persons other than the PI. [↑](#footnote-ref-1)
2. FYI: because you are collecting data from Minnesotans a Tennessen Warning Notice may apply to your study even if the IRB deems it nonresearch. For more information, visit:
[Minnesota Department of Administration: Tennessen Warning Notice (https://mn.gov/admin/data-practices/data/warnings/tennessen/)](https://mn.gov/admin/data-practices/data/warnings/tennessen/)
[MDH IRB Frequently Asked Questions (https://www.health.state.mn.us/data/irb/faq.html)](https://www.health.state.mn.us/data/irb/faq.html) [↑](#footnote-ref-2)
3. MDH staff should contact the General Counsel’s Office (GCO) if there are questions about MDH’s authority to share study data. [↑](#footnote-ref-3)
4. MDH researchers who plan to publish are encouraged to review MDH Procedure Number: PR205.01 which states the process for obtaining approval for “Publishing in Non-MDH Publications” posted in [Polices Plus (https://mn365.sharepoint.com/teams/MDH/permanent/pp/SitePages/Home.aspx)](https://mn365.sharepoint.com/teams/MDH/permanent/pp/SitePages/Home.aspx). [↑](#footnote-ref-4)