

# Preliminary Review Application for MDH Institutional Review Board

## Instructions

Not sure if your study needs Institutional Review Board (IRB) review? To find out, submit this form for consultation with the MDH IRB before collecting data. The IRB will determine whether: a) the project meets the criteria for “human subjects research” and requires a full IRB application or b) the project can be categorized as “public health practice” and can continue without further review.

Email this completed application 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 Robert 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/)

Last updated December 21, 2023

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.

### Contact information

Name of person submitting request:

Email:

Phone:

Organization:

If the organization is not MDH, please provide the name of an MDH employee who is associated with this study:

### About the study

Please completely answer the questions below. In this application, “data” means information or specimens.

1. What is the study’s title?

1. Why do you need the data that will be gathered for this study? What questions are you trying to answer?

1. What data will you collect and from whom? Clearly identify *who* is doing *what*. For example, say “MDH staff will mail surveys to…” instead of “Surveys will collect information...”

1. For this study, will organizations or persons outside of MDH be given access to individually identifiable health information or any other nonpublic data?

[ ]  No

[ ]  Yes; pleasebe sure to **identify** them in question #3, and **specify** the organization they are affiliated with and that organization’s relationship to MDH (e.g., contractor or partner).[[1]](#footnote-1)

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 pre-existing data or specimens, collected for another purpose, that will be used to answer your 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

1. Are you gathering data from any of the following potentially vulnerable populations? Human fetuses and neonates, children, cognitively impaired persons, prisoners, students, employees, or economically or educationally disadvantaged individuals.

[ ]  No

[ ]  Yes; please specify:

1. Will study participants’ names (or other identifying data) be linked to their data?

[ ]  No

[ ]  Yes; if yes, how will you secure participants’ data to protect their privacy?

1. How do you plan to use the data you collect? Who will see the results or benefit from this study?

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

[ ]  No

### [ ]  Yes[[3]](#footnote-3)Studies that May be Classified as Public Health Surveillance

Please answer the questions below if you think your project may be classified as public health surveillance.

1. Is the purpose of the activity to directly inform the decisions or actions that must be made by a public health authority (e.g., MDH).

[ ]  No

[ ]  Yes; if yes, Please describe the direct link between this activity and decision making and action by a public health authority.

1. Are all components of the project limited to those necessary to allow MDH as the public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance?

[ ]  No; if no, Please describe.

[ ]  Yes

1. Are any components added with the specific purpose of developing or contributing to generalizable knowledge?

[ ]  No

[ ]  Yes; if yes, Please describe these components.

1. MDH staff should contact the General Counsel’s Office (GCO) if there are questions about MDH’s authority to share study data. [↑](#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 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). [↑](#footnote-ref-3)