

Institutional Review Board Review Process Policy

Overview

As part of its overall commitment to protecting individuals as subjects of research activities, including their well-being, privacy, and other rights, the Minnesota Department of Human Services (DHS) has established an Institutional Review Board (DHS IRB). This Board operates in compliance with [Title 45, part 46 of the Code of Federal Regulations](#) and applicable state laws. It provides the necessary review and approval process for department-sponsored research. It also reviews and approves certain types of program evaluation. The Minnesota Department of Human Services, because of its unique capacities, supports research activities which contributes to a better understanding of DHS programs, the people participating in them, and their wellbeing. DHS is guided by the ethical principles regarding research involving humans as subjects defined in the [Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research](#).

Description:

This policy explains the types of research and evaluation projects that need to be approved by the IRB and the process required to propose projects to the DHS Institutional Review Board. The purpose of this policy is to support consistent application of IRB review across DHS, and to help ensure appropriate protections are provided for human subjects and their personal data in all applicable research and evaluation projects at DHS.

Applicability:

This policy and its procedures apply to all DHS employees who are conducting research or evaluation studies or are sponsoring research or evaluation by an external partner.

Failure to Comply:

Failure to comply with this policy and its procedures may result in disciplinary actions or termination. Permission to conduct a research or evaluation project may be denied or withdrawn at any time for violation of DHS IRB procedures.

Allegations of research misconduct (defined per federal rule [42 CFR 93.103](#) as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results”) are brought to and reviewed by the DHS IRB. A violation of data privacy regulations regarding client information may subject the researcher to civil or criminal liability.

- Any report of noncompliance will result in the immediate suspension of research and an investigation by the DHS IRB. Upon completing the investigation, the DHS IRB will report its findings and vote to dismiss

the allegation, reinstate the research with additional protections/supervision, require correctional measures, or terminate the research.

- If a researcher is found to be in noncompliance after data collection is complete, the DHS IRB reserves the right to restrict the release of research results.

Policy:

The DHS Institutional Review Board (IRB) has the authority to review and approve specific program evaluation activities and all research projects occurring under DHS auspices which either include contact with people receiving DHS services, or which use DHS data. The IRB is responsible for ensuring that human subjects participating in the studies are protected, that private data is safeguarded, and that private data is released only when authorized. The DHS IRB has a formal process whereby it reviews proposals for research and evaluation projects, and authorizes those which meet human subjects and data privacy protections in accordance with state and federal law.

Research and evaluation studies subject to IRB review

Research and evaluation studies which include any of the following elements may need to submit a proposal to the DHS IRB:

- There is contact with DHS program participants or their representatives for the purpose of research or program evaluation. The contact can be anything from a mailed questionnaire to participation in an interventional experimental program.
- The findings will be generalized to populations other than the one studied.
- Individual-level data on DHS participants is shared outside of DHS. Data is individual-level if each participant's information can be linked together (even if the participant cannot be identified). If DHS is sharing data with a vendor and the vendor will collect or analyze data solely for DHS or other state government purposes, and the above two conditions do not apply, this does not require IRB review.

If a research or evaluation study meets one or more of the above criteria, the DHS employee must refer to Which Projects Require IRB Review to determine if the project requires IRB review. Research and program evaluation studies requiring IRB review cannot begin without DHS IRB approval. Research and evaluation studies being conducted by anyone outside of DHS must have a DHS project sponsor and follow the criteria listed in the roles and responsibilities section below.

Roles and responsibilities

Common roles and responsibilities involved with preparing and approving a study before it is reviewed by the IRB board include:

- **Principal investigator(s):** The person or people conducting the study. The principal investigator completes and submits the IRB application. Once a project is approved, it is their responsibility to

provide the DHS IRB with written updates on their project as described on the IRB page on the DHS public website.

- If the principal investigator(s) are not DHS employees they must update the DHS project sponsor and the IRB regularly as to progress and any difficulties encountered.
- Provide the DHS sponsor and the IRB with all reports or articles before they are shared outside of their organization or submitted for publication, to ensure that research subjects cannot be identified.
- **Site, program or division director:** Must approve all IRB proposals for their business area and assure that research and evaluation projects have sponsorship continuity in the event of changes in staffing.
- **DHS Project sponsor:** DHS employee who is sponsoring research or evaluation being proposed by an external party. The project sponsor should be located in the division that administers the services that are being studied or evaluated or oversees the population that is to be included as research subjects. The project sponsor must be in a position where they can use the findings from the study to benefit recipients or other DHS stakeholders.
- **Academic advisor or committee chair:** Academic staff who signs the application for studies being conducted as partial fulfillment of a degree.
- **MSOP Research Committee:** Reviews all research proposals before they go before the DHS IRB.

Procedure(s):

- The Principal Investigator determines if the research or evaluation project meets the criteria listed under section I research and evaluation studies subject to IRB review:
 - If no, the project does not require IRB approval.
 - If yes, then refer to [Which Projects Require IRB Review](#) to determine if the project meets all criteria for review and what type of review is required.
 - If the project meets the criteria, complete an IRB application. Refer to the [IRB page](#).
 - Ensure that the application has all the required signatures.
 - When applicable, complete a Data Use Agreement. These can be found under Forms/Legal/Contracts Manual Forms.
- The IRB will review the application as part of an expedited or full board review process.
- No data collection can begin until the researchers have received a letter of approval from the DHS IRB.
- Once the project has been approved with an expedited or full IRB review, provide DHS with annual updates and a final report documenting progress, staffing changes, and problems encountered and how they were resolved.

- Notify the IRB administrator if the study departs from your approved application. That person will help to determine if there is the need to submit a new proposal or request a revision to your existing proposal.
- If there are adverse events associated with the project, notify the administrator immediately.

Form(s) that Apply:

[Application for expedited or Full IRB Review](#) (PDF)

Please refer to the [DHS IRB webpages](#) for additional materials that may be required of your project.

Related Policies and Reference(s):

- [Policy on DHS Business Surveys](#)

Legal Authority:

- [Title 45, part 46 of the Code of Federal Regulations](#)
- Definition of research misconduct: [Rule 42 CFR 93.103](#)
- [Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research](#)

Definition(s):

Definition of research misconduct: [Rule 42 CFR 93.103](#)

Policy Contact(s):

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This policy and its procedures remain in effect until rescinded or updated.