

HUMAN SUBJECTS REVIEW

Direct Care and Treatment

Issue Date: December 1, 2015 Effective Date: January 5, 2016 DCT Policy Number: 140-1000

POLICY:

This policy establishes the Direct Care and Treatment (DCT) system for conducting human subjects review through a program proposal process and appropriate connection to the Minnesota Department of Human Services (MDHS) Institutional Review Board (IRB) for final review.

AUTHORITY:

C.F.R. 45 Part 46 (Protection of Human Subjects)
Minn. Stat. § 144.651 Subd. 13 (Experimental Research)
MDHS Human Subjects Review Manual (2008) DHS-5473-ENG
DHS Information Policy on Surveys
Patients and Residents of Health Care Facilities Bill of Rights

APPLICABILITY:

DCT

PURPOSE:

To establish a policy and instruction system compliant with Federal and State Human Subject Research review standards in order to identify benefits and minimize risks to participants and to ensure their safety, privacy, and protection.

DEFINITIONS:

Exempt Research – Some research that involves human subjects is exempt from the regulations requiring MDHS IRB review. For example, educational testing and survey procedures where no identifying information will be recorded that can link subjects to the data. This also means that disclosure of the data could not reasonably place the subject at risk of civil or criminal liability or be damaging to the subject's financial standing, employability, or reputation. Research that involves the use of existing data, documents, or specimens, where no identifying information will be recorded that can link subjects to the data is also exempt.

Human Subjects – living individual(s) about whom an investigator conducting research obtains (1) data through interventions or interactions with the individual, or (2) identifiable private information and deceased individuals about whom an investigator conducting research obtains identifiable private information.

Institutional Review Board (IRB) – the Minnesota DHS committee, registered with the Office of Human Research Protections, that reviews all research proposals submitted by state agencies, including DCT

Investigator(s) – the person(s) authoring the research proposal and who are responsible for the completion of the research.

Legally Authorized Representative – an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Minimal Risk – means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

Research categories that involve minimal risk are those in categories two (2) through seven (7). Research in these categories are exempt from comprehensive IRB review and eligible for an Expedited Review by the MDHS IRB (include categories in appendix).

Performance Measurement and Improvement - a continuous function to ensure that the organization designs processes well and systematically monitors, analyzes and improves its performance to improve patient outcomes.

Program – DCT programs or mobile services provided at one or more sites

Program Director – The executive manager with responsibility for oversight of a DCT program

Program Evaluation Data – data collected which is intended to evaluate a program that involves survey or interview procedures is not considered research, and is exempt from this policy, unless all of the following conditions are met:

1. Subjects can be identified
2. If the subjects' responses became known outside the data collection process area, it would place them at risk for civil or criminal liability.
3. Data collection activities deal with sensitive aspects of the subject's own behavior.

Program Research Committee (PRC) – the DCT designated program staff responsible for performing human subjects review within the DCT program in which the proposed research will be conducted. The primary objective of the PRC is to ensure that all requirements are met before granting research approval to the investigator(s) for submission of the proposal and the MDHS IRB. Membership is comprised of at least three members, one of which is designated as the PRC Chair, who serves in a capacity similar to Research and Evaluation Director or Performance Management Director in coordination and oversight of the PRC process. No PRC may have a member participate in the PRC's review of any project in which the member has a conflicting interest, except to provide information requested by the PRC.

Research – a systematic investigation designed to develop or contribute to generalized knowledge. It does not include information gathered and provided in a summary format to administration at DCT used in reporting to stakeholders, information provided for data requests, nor that information gathered for routine program evaluations.

Research Involving Human Subjects – intended to cover the full range of activities involving the collection of data through: examination of individual human beings and their biological specimens, observation or performance and activities by individual human beings or groups of human beings; observation of physical or psychological reactions of individuals human beings or groups of human beings to stimuli; observation or evaluation of the products of individual performance of tasks or individuals reactions to stimuli; and examination and analysis of data derived from the types of examinations listed above.

Research involving human subjects is not limited to deliberate experimentation with human beings. It includes, as well, the performance of any procedures which are not performed solely for the benefit of the human involved and

any procedures where either a primary or secondary purpose or objective is the collection of data for research analysis.

Research involving human subjects is not intended to cover data obtained as part of the teaching or training of individuals, the performance of therapeutic procedures for the direct and sole benefit of the person involved, or any area of investigation of individuals as part of the performance of professional services.

The scope of research involving human subjects does not only involve physical, chemical, electrical, or psychological stimulation of responses within the human body, but also interviews, observation of behavior, administration of tests or other techniques of measurement for evaluation of individual humans.

Research Subjects – includes DCT employees or clients

- A. who are voluntarily participating as human subjects in a research project,
- B. who are voluntarily participating in a survey or interview conducted as a part of a research or program evaluation project, and/or
- C. whose protected information will be disclosed to and used by a researcher during a research or program evaluation project.

Sponsor - a DCT staff member familiar with the PRC process, resources and requirements for human subjects review and IRB application process, who can help inform and guide investigator(s) through the review process and serve as liaison to the PRC and MDHS IRB.

PROCEDURES:

- A. Research conducted within DCT shall meet all professional, data practices, and informed consent guidelines.
- B. Any DCT program staff or intern may submit a research proposal.
- C. Per MDHS IRB requirements, identification of this individual is required for research conducted by non DHS employees and DHS employees who undertake research for school credit. Sponsors must sign the MDHS IRB application form.
- D. Prior to implementation, all research proposals (including pilot studies) which involve patients, personnel, or property of DCT shall be approved by both the local PRC and MDHS IRB.
- E. Determining if a proposed data collection activity constitutes research requiring a full review.
 - 1. All proposals to collect data by non-employees of DCT require full review by the program's human subjects review committee and the MDH IRB.
 - 2. Any DCT employee proposing to conduct data collection will discuss his or her plans with the MDHS IRB to determine if their plans constitute research or performance measurement. If the proposal is deemed to constitute research, the researcher will submit a complete application which must move through all levels of PRC and MDHS IRB approval prior to beginning data collection.

3. No one may access a record for the purpose of doing research without the expressed written permission of the subject, unless a data sharing agreement with the department is in place; the department authorizes such research; and the MN DHS IRB approves the project.
 4. Employees proposing performance measurement will work with a staff member of the Office of Performance Improvement in conducting the project.
- F. Research proposals qualifying for an Expedited Review will be identified by the MDHS IRB and directed to follow the expedited process.
1. Federal criteria for risk assessment make some studies eligible for Expedited Review (see 45 CFR § 46.110 and 21 CFR § 56.110).
 2. Studies eligible for Expedited Review must meet the federal definition of minimal risk as defined above and found in Appendix A.
- G. Informed Consent
1. Except as provided, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.
 2. The MDHS IRB may approve a consent procedure which does not include, or which alters some or all of the elements of informed consent or waives the requirements to obtain informed consent provided the IRB finds and documents that:
 - a) The research involves no more than minimal risk to the subject;
 - b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - c) The research could not practically be carried out without the waiver or alteration; and
 - d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- H. Submission Criteria
1. Risks to participants must be minimized [relative to benefits]:
 - a) by using procedures that are consistent with sound research design, and that do not unnecessarily expose participants to risks, and
 - b) whenever appropriate, researchers are employing procedures that are already being performed on participants for prevention, diagnosis, or treatment purposes. Risks and benefits can be physical, psychological, social, or economic. An important consideration in assessing this criterion is whether the design of the research is adequate; an inadequate design will not yield benefits.

- c) When considering risks and benefits, consideration is made only for those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).

I. Submission and Review of Research Proposals

1. Any person planning a research project must contact the MDHS IRB to initiate a discussion regarding the nature of the proposed research to begin obtaining guidance on whether the proposal will constitute human subjects research.
2. Research proposals will include:
 - a) The MDHS IRB Application Packet (refer to DHS Policy DHS-5473-ENG for additional details), which includes:
 - i) Application for Approval of Research with Human Subjects;
 - ii) Evaluation Checklist;
 - iii) Agreement Relating to Private or Confidential Data Maintained by an Agency of the Statewide Welfare System in Order to Prepare Summary Data; and
 - iv) Academic Endorsement Form (if applicable)
 - b) The name of the sponsor who is responsible for meeting with the investigator to provide information related to the Program Review Committee (PRC), research policy, and the IRB.
 - c) The proposed research's monitoring/oversight plan that includes at minimum monthly meetings between the investigator and the sponsor to discuss the research's progress status and any difficulties and issues encountered. The sponsor will timely keep the IRB informed of any critical issues.
3. Before the proposal is introduced at the PRC meeting for review, the investigator(s) will identify resources needed from the respective program to conduct the research.
4. Completed applications must be submitted to the chair of the PRC.
5. The chair of the PRC will distribute completed applications to other members of the PRC for review. The chair of the PRC may invite other content experts to join the PRC as appropriate. Then:
 - a) Within thirty (30) days of the distribution, at least three (3) members of the committee will meet to discuss the proposal.
 - b) If any member of the committee is submitting a research proposal, the Clinical Director will appoint a temporary designee to the committee.

- c) The PRC chair will record the committee's recommendation on the PRC Proposal Review Form (102.110B, attached) for notification of the investigator(s).
6. The PRC will:
- a) Ensure that MDHS IRB is completed
 - b) Review the merits of research proposals and consider whether sufficient resources exist to complete requested research; if, in the opinion of the PRC, sufficient resources are not available to fulfill a research request, the PRC will include this as part of any recommendation;
 - c) Review each proposal utilizing the PRC Proposal Review Form; each member of the committee who is present during the presentation of the proposed research will complete the form to establish a consistent review of the research project;
 - d) Assign proposals one (1) of four (4) designations:
 - i) Approval
 - A. No changes are recommended; there is an acceptable risk/benefit ratio; and the protocol is acceptable.
 - B. The committee approves moving the proposal forward to the DHS Institutional Review Board.
 - ii) Conditional Approval
 - A. Minor changes are needed in the informed consent document, protocol, or other study materials. Once the changes are provided to the PRC chair, the proposal is approved to move forward the MDHS IRB.
 - B. Minor clarification regarding a specific aspect of the study or additional information is requested from the primary investigator. Once the clarification or information is provided to the Research and Evaluation Director, the proposal is approved to move forward to the MDHS IRB.
 - C. No additional PRC meeting is needed.
 - iii) Deferral
 - A. There is an unacceptable risk/benefit ratio because:
 - 1. the protocol is poorly written, lacking significant amounts of information regarding scientific justification, study procedures, risk reduction, etc.; the proposal needs to come back before the PRC before moving ahead to the DHS IRB;
 - 2. it is possible that a response from the investigator could alter the risk/benefit ratio; the proposal needs to come back before the PRC

before moving ahead to the MDHS IRB; and/or

3. there are ethical concerns, which can be addressed by obtaining more information or requiring changes in the study design and procedures; the proposal needs to come back before the PRC before moving ahead to the MDHS IRB.

iv) Disapproval

- A. The risks significantly outweigh the benefit or value of the knowledge to be gained.
- B. There are significant ethical concerns or questions that deem the study unacceptable.

7. The PRC will provide its determination, including the designation assigned, to the research proposal's investigator within ten business days of the determination.
8. If a proposal receives IRB approval, the investigator(s) will coordinate with the PRC chair how and where data will be stored. The investigators will provide a copy of the IRB approval, the submitted research proposal, and any following renewals for storage with the data and research proposal.
9. Any research conducted by department staff on department time or using department resources is the intellectual property of DCT.
10. Permission to conduct a research project may be denied or withdrawn at any time for violation of the above procedures or any conditions set by the PRC or DHS IRB. A violation of data privacy regulations regarding client information may subject the researcher to civil or criminal liability.
 - a) Any report of noncompliance will result in the immediate suspension of research and a review by the PRC. Upon completing a review, the PRC will report its findings and vote to dismiss the allegation, reinstate the research with additional protections/supervision, require correctional measures, or terminate the research.
 - b) If a researcher is found to be in noncompliance after data collection is complete, the PRC reserves the right to restrict the release of research results.
11. Applications must be approved by the DHS IRB prior to starting the project and before any data is provided to the researcher.
12. Any deviation from the original research proposal must be submitted in writing to the IRB for approval prior to resuming research activities.

G. Data Management

1. Human Subjects data forms (interview questionnaires, observation forms etc.) will be coded to protect the privacy and safety of participants.

2. Consent forms containing private information are stored separately.
3. Records retention periods vary depending on the type of record and should be followed based on the program's records retention schedule policy.

REFERENCES:

FS Procedure 10001, "Performance Measurement and Improvement"

ATTACHMENTS:

Research Decision Tree DCT-140-1000a

Research Categories DCT-140-1000b

MDHS IRB Application DCT-140-1000c

Expedited Review Categories DCT-140-1000d

MSOP Research Proposal Form DCT 140-1000e

MRC Proposal Review Form DCT-140-1000f

SUPERSESSSION:

MSOP Policy 102.110, "Research with Human Subjects"

/s/

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