



MONTANA STATE HOSPITAL POLICY AND PROCEDURE

INSTITUTIONAL REVIEW BOARD

Effective Date: June 12, 2020

Policy: TX-24

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- I. PURPOSE:** To provide a framework for an Institutional Review Board (IRB) to review and approve research activities at Montana State Hospital (MSH) in the event research is proposed which would involve or affect hospital patients.
- II. POLICY:** All research activities involving or affecting hospital patients must be approved by the MSH IRB. The Board will convene on an “as needed” basis. The committee will be guided by ethical principals involving human subjects which include¹:
- A. *Respect for Persons.* Individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.
 - B. *Beneficence.* Persons are treated in an ethical manner not only by respecting their decision and protecting them from harm, but also by making efforts to secure their wellbeing. The two general rules formulated, as complementary expressions are (1) do not harm, and (2) maximize possible benefits and minimize possible harms.
 - C. *Justice.* The selection of subjects for research should be equitable and the fruits of the research should be distributed equitably.

MSH acknowledges and accepts responsibilities for protecting the rights and welfare of patients involved in research activities and will ensure all proposed projects comply with Federal and State regulations.

MSH recognizes proper consideration must be given to:

- A. The potential risk to the subject(s);
- B. The anticipated benefits to the subject(s) and others;
- C. The importance of the knowledge which may be reasonably expected to result;
and
- D. The informed consent process to be employed.

III. DEFINITIONS:

- A. **Institutional Review Board:** An administrative committee designated to ensure protection of MSH patients who are the subject of research studies.
- B. **Research:** A structured scholarly or scientific inquiry to discover or check facts. Research differs from treatment in that the inquiry is carried out in accordance with experimental design principles and the outcome is uncertain.

¹ Adopted from the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, “*The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research.*”

IV. RESPONSIBILITIES:

- A. **Medical Director:** To convene the committee and chair IRB meetings.
- B. **DPHHS HIPAA Attorney:** Available for review/questions.

V. PROCEDURE:

- A. The IRB will be comprised of the following members:
 - 1. Medical Director (chair);
 - 2. Hospital Administrator;
 - 3. MSH Psychologist;
 - 4. Director, Quality Improvement;
 - 5. Attorney, Mental Disabilities Board of Visitors;
 - 6. One Additional Physician or Licensed Psychologist appointed by the Medical Director.

In the event any person in the above positions is unavailable or the position is unfilled, the Medical Director may designate a replacement from within the appropriate discipline.

- B. Research proposals involving MSH patients will be reviewed by the Medical Director who will determine whether to convene an IRB meeting to review and approve the research proposal. The Medical Director will also determine whether the principle investigator or associate needs to appear before the committee to answer questions or explain the proposal. The IRB may convene as often as necessary to approve proposals and oversee projects. The IRB will meet at the conclusion of any project to review findings and adherence to all requirements.
- C. Approval will be granted by the committee reaching agreement (consensus) by all members that the proposal has merit and any concerns have been appropriately addressed. Any member of the committee may veto the proposal.
- D. The Committee must review procedures to ensure Health Insurance Portability and Accountability Act (HIPAA) compliant consent by the research subjects or guardians for participation in the project and must be satisfied the process protects individual rights and allows for full and appropriate disclosure.
- E. Minutes of all meetings will be maintained and will include actions taken by the committee in response to proposals.
- F. This process does not replace or substitute for the responsibilities of the Mental Disabilities Board of Visitors (MDBOV) to review all plans for experimental research involving persons admitted to a mental health facility (53-21-104, M.C.A.). The MDBOV is responsible for establishing their own review process and communicating approval or non-approval to the Hospital.
- G. Use of patient medical records in research activities will conform to requirements of the Montana Uniform Health Care Information Act (50-16-501 through 553, M.C.A.).

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In accordance with Montana statute, records may only be disclosed after the IRB has determined the research project:

1. Is of sufficient importance to outweigh the intrusion into the privacy of the patient which would result from the disclosure;
2. Is impracticable without the use or disclosure of the health care information in individually identifiable form;
3. Contains reasonable safeguards to protect information from improper disclosure;
4. Contains reasonable safeguards to protect against directly or indirectly identifying any patient in any report of the research project; and
5. Contains procedures to remove or destroy at the opportunity, consistent with the purposes of the project, information which would enable the patient to be identified unless the IRB authorizes retention of identifying information for purposes of another research project.

VI. REFERENCES:

- A. Montana Uniform Health Care Information Act (M.C.A.50-16-501 through 553)
- B. M.C.A. 53-21-104(2) – Powers and duties of mental disabilities board of visitors.
- C. *The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research*

VII. COLLABORATED WITH: Hospital Administrator, Medical Director.

VIII. RESCISSIONS: TX-24, *Institutional Review Board* dated April 20, 2016; TX-24, *Institutional Review Board* dated July 13, 2007.

IX. DISTRIBUTION: All hospital policy manuals.

X. ANNUAL REVIEW AND AUTHORIZATION: This policy is subject to annual review and authorization for use by either the Administrator or the Medical Director with written documentation of the review per ARM § 37-106-330.

XI. FOLLOW-UP RESPONSIBILITY: Medical Director.

XII. ATTACHMENTS: None.

Signatures:

Kyle Fouts
Hospital Administrator

Thomas Gray, M.D.
Medical Director