PURPOSE

This policy provides for the ethical conduct of human subjects research in which the Michigan Department of Health and Human Services (MDHHS) and its employees and/or agents are engaged by requiring Institutional Review Board (IRB) or administrative review and oversight over all such research. This policy establishes the MDHHS IRB and its administrative office to serve as the entity primarily responsible for the oversight of human subjects research in which MDHHS is engaged, and ensures MDHHS follows the terms of the department's Federalwide Assurance (FWA) and corresponding regulations governing the protection of human subjects of research.

REVISION HISTORY

Issued: March 8, 2006
Revised: February 23, 2007, May 21, 2010.
Historical policy will be available to State of Michigan (SOM) users by entering an effective date of October 1, 2017 or later.

DEFINITIONS

Where terms used in this policy are defined within The Common Rule Regulations for the Protection of Human Subjects, 45 CFR 46, those terms have the same meaning as given them in The Common Rule Regulations.

Authorizing Supervisor: an official within MDHHS responsible for ensuring the ethical conduct of human subjects research within his or her work area. An authorizing supervisor should be the director or highest ranking official in the largest organizational sub-unit of a MDHHS administration (typically a bureau or office). In general, an authorizing supervisor will report directly to a deputy director and will oversee organizational units including divisions and sections. The authorizing supervisor ensures IRB or administrative review of human subjects research associated with his or her work area is occurring by either seeking approval of research as a responsible department employee, or by delegating authority to seek approval to other responsible department employees.

Engagement: a degree of department involvement in human subjects research that requires the research receive Institutional Review Board or other administrative review. MDHHS is considered engaged when research is sponsored or funded by MDHHS, conducted by or under the direction of any employee or agent of MDHHS in connection with his or her responsibilities to MDHHS, conducted by or under the direction of any employee or agent of

MDHHS using any property or facilities of MDHHS, or involves potentially identifiable, non-public MDHHS information about individuals.

Institutional Review Board: the board established in accord with and for the purposes expressed in this policy and The Common Rule Regulations for the Protection of Human Subjects, 45 CFR 46.

Institutional Review Board Administrator: the manager responsible for operations of the Institutional Review Board and its administrative office.

Institutional Review Board Member: an individual appointed to the Institutional Review Board by the MDHHS director. Institutional review board members may be voting members, or may be alternates to voting members. Alternate members may serve as voting members during convened meetings at which the voting member for whom they are designated an alternate is not in attendance or is otherwise unable to vote on a matter under consideration by the board.

Noncompliance: any failure to follow either:

1. Federal regulations, state laws, or institutional policies relevant to human subjects research.

2. The requirements and/or determinations of the reviewing IRB.

When non-compliance occurs, the IRB must determine if the noncompliance is serious, continuing, or both. Serious noncompliance is noncompliance demonstrably affecting the rights and welfare of participants, or noncompliance that places participants at risk of demonstrable harm. Whether noncompliance was inadvertent, negligent, reckless, or intentional may be taken into consideration by the IRB in a determination of seriousness. Continuing noncompliance is defined as multiple or repeated instances of noncompliance (occurring within one protocol or across more than one protocol by the same primary investigator), after written notice from the IRB has been issued indicating that action to correct noncompliance is necessary.

Office for Human Research Protections: the federal agency overseeing the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services.

Primary Investigator: the lead scientist for a particular research project. In general, the primary investigator is the person who takes direct responsibility for the design and conduct of the research, and the individual with the greatest responsibility for the protection of human subjects involved in research.

Responsible Department Employee: an individual approved by an authorizing supervisor to submit applications for review by the Institutional Review Board. A responsible department employee must be an employee or contractor of MDHHS, must have a michigan.gov email address, and must be able to provide a programmatic review of the research proposed to determine the appropriateness of MDHHS engagement in the activity. Where the conduct of research or the use of data in research may be governed by administrative rules, the responsible department employee should ensure the requirements of those administrative rules are satisfied prior to submitting an application to the IRB.

Signatory Official: the director of MDHHS, or his or her designee. This official signs the Federalwide Assurance to the United States Department of Health and Human Services, and maintains the registration of the department's Institutional Review Board. The signatory official must be a senior institutional official who has the authority to commit the entire institution named in the Federalwide Assurance application to a legally binding agreement, and must also have the authority to assure compliance of the institution and all of its components to the terms of the assurance. The signatory official has the authority to set policy and approve practices for the Institutional Review Board, and to determine when an IRB authorization agreement with another institution or another institution's IRB is appropriate.

POLICY

All human subjects research involving MDHHS will be guided by the ethical principles documented in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Primary investigators and staff (whether employees or agents of MDHHS or employees or agents of another institution) involved in research in which MDHHS is engaged will design and conduct research:

1. Demonstrating appropriate respect for the human subjects of the research.

2. Minimizing risks to the human subjects of the research.

3. Maximizing the possible benefits to the human subjects of research.

4. Ensuring the benefits of the research to the human subjects outweigh the risks of the research to the human subjects.

5. Ensuring the selection of the human research subjects is just, appropriately distributing any associated risks such that those who may bear the most risk are also most likely to receive the most benefit.

The MDHHS Institutional Review Board (IRB) and its administrative office will provide oversight (through primary review or through an agreement to rely on the review of another institution's Institutional Review Board) over all human subjects research in which MDHHS is engaged including:

1. Conducting IRB initial and continuing review of research as a convened board or using expedited review procedures, conducting limited IRB review of some exempt research, conducting administrative review of some exempt research, and reporting IRB findings to the primary investigator, responsible department employee and other institutional officials.

2. Determining what research requires review more often than annually and what research needs verification from sources other than the investigator that no material changes have occurred since the previous review.

3. Conducting periodic IRB or administrative review of research until study completion.

4. Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to research subjects.

Research covered by this policy that has been approved by the IRB or its administrative office may be subject to further appropriate review by other MDHHS institutional officials. However, those officials may not permit the conduct of non-exempt human subjects research if it has not been approved by the IRB.

In accordance with its Federalwide Assurance, MDHHS will ensure that its Institutional Review Board has meeting space and sufficient administrative office staff to support the IRB's review and recordkeeping duties. Whenever MDHHS relies upon an IRB operated by another institution or organization for oversight of human subjects research, MDHHS will document that arrangement in writing.

PROCEDURE

Responsible Party	Action Required
Employee or Agent of MDHHS	Obtains supervisory and IRB approval prior to beginning involvement in the conduct of human subjects research in which MDHHS is engaged. Consults the IRB or its administrative office with questions on this policy or procedures to be followed.
Signatory Official	Maintains the IRB registration for the MDHHS IRB and signs the MDHHS Federalwide Assurance for the protection of human subjects of research. The signatory official promotes an organizational culture supporting the ethical treatment of human subjects of research. The signatory official ensures prompt reporting to the head of any U.S. federal department or agency conducting or supporting research and the Office for Human Research Protections of any serious or continuing noncompliance with the applicable U.S. federal regulations on the part of the IRB. When it is appropriate for MDHHS to agree to rely on the review of an IRB operated by another institution or organization, or when it is appropriate for another institution or organization to rely on the review provided by the MDHHS IRB, the signatory official signs the agreement permitting that reliance.
IRB Administrator	Manages the operations of the IRB, maintains procedures that ensure appropriate review of human subjects research in which MDHHS is engaged, ensures training in human research protections is available to all individuals responsible for the conduct of research in which MDHHS is engaged. The IRB administrator ensures forms and instructions are available to facilitate application for approval of research, for ongoing review of research, and for reporting of unanticipated problems or requests for changes to approved research. The IRB administrator is available for technical assistance in the design of ethical research. The IRB administrator ensures prompt reporting to appropriate institutional officials, the head of any U.S. federal department or agency conducting or supporting the

Responsible Party	Action Required
	research, and the Officer for Human Research Protections of any: 1. Unanticipated problems involving risks to subjects or others. 2. Serious or continuing noncompliance with the applicable U.S. federal regulations or the requirements or determinations of the IRB. 3. Suspension or termination of IRB approval. Provides appropriate referrals to other entities within MDHHS involved in the oversight or administrative review of human subjects research and related activities (such as, the Compliance Office, Research Integrity Officer, Central Grants Management, FOIA coordinator, etc.).
Authorizing Supervisor	Ensures all human subjects research associated with his or her work area receives appropriate IRB or administrative review and approval before initiation. To meet this expectation, the authorizing supervisor submits applications for research approval to the IRB administrative office as a responsible department employee, or designates staff within his or her work area to serve as responsible department employees. The authorizing supervisor will not permit the conduct of human subjects research within his or her work area if it has not received appropriate IRB or administrative approval.
Responsible Department Employee	Performs programmatic review of human subjects research (whether the research is to be conducted by MDHHS employees or agents or employees or agents of unaffiliated agencies) determining the appropriateness for MDHHS involvement. Ensures all administrative rules applicable to the research are followed and ensures that provisions in any signed agreements related to the research are followed. Submits applications for approval of research and for renewal of approved research to the MDHHS IRB administrative office. If the responsible department employee becomes aware of any unanticipated problem involving risks to subjects or others, or any noncompliance with applicable U.S. federal regulations or the requirements or determinations of the IRB, he or she promptly (usually within 48 hours) reports this information to the IRB. Facilitates communication between the IRB administrative office and the primary investigator if the primary investigator is not the responsible department employee.
Primary Investigator	Designs and conducts research in an ethically appropriate manner. Takes responsibility for protecting the rights and welfare

Responsible Party	Action Required
	of human subjects involved in his or her research. Obtains the appropriate training to conduct ethically responsible research. Ensures colleagues to be engaged in research have also obtained the appropriate training to be engaged in ethically appropriate research. Prepares or works with a responsible department employee (if the investigator is not a responsible department employee) to prepare an application for approval of human subjects research to be submitted to the IRB administrative office for review. If approved, the primary investigator conducts human subjects research only as described in the approved IRB application. The primary investigator promptly (usually within 48 hours) notifies the IRB and the responsible department employee of any unanticipated problems involving research subjects or others, any severe adverse events involving locally enrolled subjects, and any deviations from an IRB approved protocol. The primary investigator requests changes to approved research, having those changes approved by the IRB prior to implementation unless the change is necessary to eliminate an immediate hazard to study subjects. If a change is implemented without prior IRB approval in order to eliminate an immediate hazard to study subjects, the primary investigator promptly notifies the IRB and the responsible department employee of the change (usually within 48 hours). As the individual most responsible for the conduct of the human subjects research, the primary investigator ensures the research is conducted according to this policy, the federal research regulations, the requirements and determinations of the IRB, and applicable state and federal laws.
Institutional Review Board Member	Obtains appropriate training to ensure familiarity with research regulations and other protections to the rights and welfare of human research subjects. Reviews IRB applications, study materials, and other materials made available by the IRB administrative office prior to convened meetings of the IRB. Attends IRB meetings and actively participates in discussion on the ethical appropriateness of research studies reviewed by the convened board. Alternate members attend meetings and participate in discussions (particularly when the members for whom they are designated as alternates are not able to attend) but may not vote if the members for whom they are designated alternates are in attendance and otherwise available to vote. Where colleagues have questions or concerns about the ethical

Responsible Party	Action Required
	conduct of research, IRB members assist in responding to those questions or provide referrals to the IRB administrative office.
Institutional Review Board	Determines whether activities proposed to the Institutional Review Board (IRB) include research, include human subjects, are or are not within an exempt category of human subjects research, are or are not research meeting the requirements for approval at 45 CFR 46.111 and/or 21 CFR 56.111. The IRB has the authority to approve, require modifications in, or disapprove human subjects research in which MDHHS is engaged. Provides continuing oversight of approved research. Provides recommendations to the signatory official regarding the appropriateness of potential agreements to rely on IRB review provided by the IRB of another institution or organization. Only the convened board disapproves of human subjects research that does not meet regulatory requirements for approval. Serves as the Privacy Board for the Michigan Department of Health and Human Services. In convened meetings or through expedited procedures, reviews requests for waivers in whole or in part of authorization to use or disclose protected health information for research under the Privacy Rule, 45 CFR 164.512(i)(1)(i). MDHHS shall not engage in any human subjects research that is not provided appropriate oversight by the Institutional Review Board or its administrative office.

REFERENCES

The Belmont Report at U.S. Department of Health and Human Services internet site Office for Human Research Protections (OHRP)/Regulations & Policy/The Belmont Report.

The Common Rule Regulations for the Protection of Human Subjects at U.S. Department of Health and Human Services internet site Office for Human Research Protections (OHRP) Regulations & Policy/Regulations, 45 CFR 46.

U.S. Department of Health and Human Services/For Scientists & Researchers/Clinical Trails and Human Subject Protection/Regulations, 21 CFR 50 and 56.

CONTACT

For additional information concerning this policy, contact the MDHHS Institutional Review Board at 517-241-1928.

A detailed set of procedures and forms for the Institutional Review Board are available at www.michigan.gov/irb.