

Institutional Review Board (IRB) Basics

Ian A. Horste, MPH

IRB Administrator/Chair

Legal Affairs Administration, MDHHS



What is the MDHHS IRB?



- The MDHHS office responsible for protecting the rights and welfare of people participating in MDHHS supported research
- An actual board
- An administrative office

www.michigan.gov/irb

How does the MDHHS IRB Protect Research Participants?



- Train researchers and staff in the ethical conduct of research
- Review research proposals to ensure adequate protection of human participants up front
- Monitor the conduct of approved studies and respond to problems including concerns from participants

Human Research Protections Training

Encouraged for all MDHHS employees and contractors

Required for responsible department employees and primary investigators

Free to anyone and more flexible to complete than previous trainings



[When HHS Regulations Apply \(Lesson 1\)](#)

This lesson introduces human research protections, the Common Rule, and the offices and agencies that oversee human subjects research. It takes approximately 35 min to complete.



[What is Human Subjects Research \(Lesson 2\)](#)

This lesson details how the Common Rule regulations define "research" and "human subjects" and explains what it means to be exempt from the Common Rule regulatory requirements. It takes approximately 1 hr and 35 min to complete.



[What are IRBs \(Lesson 3\)](#)

This lesson explains the purpose of and membership requirements for Institutional Review Boards, or IRBs. It takes approximately 45 min to complete.



[IRB Review of Research \(Lesson 4\)](#)

This lesson describes the regulatory requirements for IRB review and the criteria for IRB review and approval under the Common Rule. It takes approximately 1 hr and 40 min to complete.



Understanding Roles in MDHHS Supported Research

Where MDHHS is conducting research, the primary investigator and responsible department employee can be the same person.

Where MDHHS is supporting research conducted elsewhere, the primary investigator will be the external researcher and the responsible department employee will be the individual at MDHHS connecting the external research to the MDHHS IRB

- Primary Investigator
 - Most responsible for the research and the treatment of participants
 - Writes the protocol and IRB application, initiates requests to change approved research, writes annual status reports
 - Has responsibility to identify and report problems to the MDHHS IRB
- Responsible Department Employee
 - MDHHS employee or contractor with a Michigan.gov email address
 - Submits materials to the MDHHS IRB following programmatic review
 - Helps monitor for changes, problems, etc. that may need to be reported to the MDHHS IRB

What Does the IRB Review? (And What Does it Not Review?)



- The MDHHS IRB Reviews Research Involving MDHHS and Including Humans as Subjects
 - Activities that do not involve MDHHS do not require MDHHS IRB review
 - Activities that don't include research do not require MDHHS IRB review
 - Activities (even research) that do not include human subjects do not require MDHHS IRB review

Applying to the MDHHS IRB

1. Identify a Responsible Department Employee and the Correct Application Form
 1. Forms are available at: www.Michigan.gov/irb or the forms library.
 2. If the MDHHS IRB is the only reviewing IRB, the DCH-1277 is the appropriate application
 3. If an IRB application is already prepared for another institution, the abbreviated form DCH-1277(A) is appropriate
2. Complete an MDHHS IRB Initial Review Application
 1. The primary investigator will complete most of the application
 2. If the primary investigator is not part of MDHHS, then the responsible department employee should look through the application to make sure the requirements on MDHHS are reasonable and the research is appropriate for MDHHS support/endorsement
3. Submit the application to: MDHHS-IRB@michigan.gov

What Does the IRB Consider During Review?

What are the risks to the participants in the research? Are those risks minimized? Does the potential for benefit from the research justify the risks participants may face?

Is participating in research voluntary? If so, how is that choice made clear to participants? If not, can involuntary participation be justified?

Is the selection of potential participants equitable? Does the research target vulnerable populations in a way that isn't necessary? Do those that are put most at risk also stand to benefit the most from the research? Are there vulnerable populations selected that need extra protections?

Key Points About Initial Review



MDHHS must NOT engage in human subjects research without clearance/approval from the MDHHS IRB first



The MDHHS authorizing supervisor is responsible for making sure research conducted or supported by their work area follows MDHHS policy for IRB review



An application is required if a formal IRB determination is needed/requested, but consultation with the IRB is welcome any time

What Happens After IRB Approval?



- Responsible department employees should anticipate being in contact with the MDHHS IRB at least once a year to complete a status update
- If approved research needs to be changed, a revision request must be made to the IRB and given approval before the change is made (unless the change is required to prevent an immediate hazard)
- The IRB must be notified as soon as possible if a problem occurs
- Once the research is complete, a status update should be provided to close the research file

The MDHHS IRB Welcomes Your Feedback

We're thankful for the chance to share information with you, but we are also happy to learn from you as well! If there are things the MDHHS IRB can improve or if you have experiences you want to share, please don't hesitate to let us know.

Resources for You

Please feel free to contact the MDHHS
IRB Administrative Office with questions,
comments or concerns

- Contact the IRB:
 - MDHHS-IRB@michigan.gov
 - 517-241-1928
 - www.michigan.gov/irb
- Contact Ian Horste, Chair of the IRB:
 - horstei@michigan.gov
 - 517-852-4371

Thank You

