Protecting Research Participants and the Michigan Department of Health and Human Services Institutional Review Board

MDHHS-IRB@michigan.gov

517-241-1928

Who at MDHHS is Responsible for Protecting Research Subjects?

- Everybody!
  - We all have a responsibility for the well being of people involved in MDHHS sponsored research
- Oversight by our Human Research Protections Program
  - Although not an organizational unit of MDHHS, our Institutional Official and coordinating central office staff have oversight responsibility for all research in which MDHHS is engaged
- Implementation by our Institutional Review Board (IRB)

What is the MDHHS IRB?

- The MDHHS IRB is the most visible part of our Department's Human Research Protections Program.
  - Administrative Office: IRB Administrator and Administrative Assistant
  - The Full Board: Colleagues from various areas of MDHHS and community members

- Responsible for the initial and ongoing review of all research that involves human subjects and involves MDHHS

- A resource to you, especially if you might be, and definitely if you are planning to conduct research for MDHHS

Why are there IRBs at all?

- Research is important
- People who participate in research have rights
- Historically, there are examples of research in which the way it was conducted was at odds with the rights of the participants
- Having a mechanism to ensure the rights of individuals participating in research are not compromised is a good idea, and the IRB is that mechanism

What is the IRB's principle mandate?

- In response to public reaction regarding various troubled research efforts (of particular note in the U.S. is the Tuskegee syphilis research conducted by the U.S. Public Health Service) the federal government convened a commission to outline ethical principles important to research

- The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research released the Belmont Report documenting those principles in 1979

- In 1981, regulations based upon the ethical principles outlined in the Belmont Report were adopted by the federal government. The U.S. Department of Health and Human Services and Food and Drug Administration regulations describe the structure and function of Institutional Review Boards, and codify the requirement for Institutional Review Board review and approval of all federally regulated research involving humans as subjects.

Why does MDHHS have an IRB?

- The federal government tells us we should: – To receive federal funding for research, MDHHS has made an assurance that we will conduct any research we do according to federal regulations. Part of those federal regulations require we make sure that research involving humans as subjects is reviewed and approved by an IRB

- It demonstrates our commitment to serve the best interests of Michigan's population

- It's a tool to help researchers at MDHHS do the important research they do, but do it in a way that respects the rights of the people involved

What does IRB review entail?

- Initial review of research protocols
- Ongoing review of approved research
  - Review of changes to approved research
  - Review of research that continues past the initial approval period (usually 1 year)
- Follow-up on reports of protocol deviations, severe adverse events, unanticipated problems, or research subject complaints

When must IRB review occur?

- *Research* is a systematic investigation designed to develop or contribute to new, generalizable knowledge.
- *Human Subjects* are living individuals about whom an investigator obtains (1) data through intervention or interaction, or (2) identifiable private information.
- *Engagement* includes (1) obtaining data about subjects of research through intervention or interaction, (2) obtaining identifiable private information about subjects of research, or (3) obtaining informed consent of human subjects.

When is MDHHS engaged in research?

- The MDHHS IRB is responsible when:
  - Research is sponsored by the Department
  - Research is conducted by or under the direction of any employee or agent of the Department in connection with his or her responsibilities
  - Research is conducted by or under the direction of any employee or agent of the Department using any property or facilities of the Department
  - Research involves any of the Department's non-public information
- The MDHHS IRB is responsible for all research that involves the department, even if another institution's IRB is also involved.

Review Requirements at MDHHS

- You must not engage in human subjects research without approval from the IRB. If there is any question, ask the IRB

- Policy requires the MDHHS bureau, center or office director responsible for a project that may involve human subjects research to submit (or designate a Responsible MDHHS Employee to submit) an application to the MDHHS IRB or ensure that a MDHHS IRB representative is consulted

- Not everything requires IRB review

Public Health Research vs. Public Health Practice

- *Public Health Research* is designed to develop or contribute to generalizable knowledge that will inform improvements in the practice of public health. Although research subjects may benefit from participation, there is the potential they will not; and the expected benefits of the project will always extend beyond study participants. Data collected for research can extend beyond what would normally be required for the scope of a public health activity.

- *Public Health Practice* is designed to identify and control a specific health problem, or to directly improve a public health program or service. Service recipients (current and future) should receive a definite benefit from participating in the activity. Data collected should be limited to what is required routinely for the scope of the activity.

Program Evaluation/Quality Improvement vs. Research

- If the intent is to document the efficacy of a new program in general, you are likely engaged in research.
- If the intent is to make sure an evidenced based program is functioning as expected when implemented locally, you are likely conducting a nonresearch program evaluation.
- If part of your evaluation design includes a control group (a group that is eligible but will not take part in the intervention) then you are likely engaged in research.
- If your evaluation design includes only individuals receiving an intervention, it could be either research or evaluation.
- Some federally funded program evaluations might be considered research, but the funding agency should be consulted to determine if the research is eligible for an exemption from federal research regulation.

And what about publication?

- Publishing information about an activity, even if it includes data about subjects that participated in the activity, does not in and of itself indicate that the activity is research.
- All that said, if you might publish about what you think is a non-research activity, it may be a benefit to you to ask the IRB for a formal determination that an activity is not human subjects research.

The MDHHS IRB Review Process

- Identify a Responsible MDHHS Employee. – Approved to submit IRB applications for the Bureau.
  - Has completed required human research protections training at www.citiprogram.org.
  - Is able to facilitate communication between researcher and IRB.
- Complete an IRB initial review application.
  - Use the full form for projects reviewed only at MDHHS.
  - Use the abbreviated form along with application materials submitted to another IRB if applicable.
- Respond to any follow-up questions asked by the IRB.
- Review conducted as not human subjects research, exempt research, or research eligible for expedited approval.
  - Should take days to a couple of weeks.
- Review of research by the convened board.
  - Occurs the first Tuesday of most months. May require more than one meeting for approval.
- Keep in touch with the IRB regarding changes to approved research, adverse events, and renewal requirements (at least annually).

What is the IRB looking for when it reviews research?

- *The Belmont Report*: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html This document outlines the ethical principles on which regulations governing the protection of research subjects are based:
  - Respect for persons
  - Beneficence – Justice

- Title 45 Code of Federal Regulations Part 46 – "The Common Rule": http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

- Title 21 Code of Federal Regulations Parts 50, 56, 312, and 812 are the FDA regulations governing clinical investigations of drugs, biological products, and medical devices. http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinic al Trials/ucm155713.htm

Tips for Preparing an IRB Application

- Describe what you plan to do and why you think it should be done.
- Describe why these specific human subjects must be involved.
- Indicate how the Belmont Principles are addressed:

– Respect for Persons:
  - How are you going to inform subjects about what the research entails including risks and benefits?
  - How are you going to ensure they are participating voluntarily?
  - If you aren't going to inform them, how can you justify that?

– Beneficence:
  - Have you minimized risks to participants?
  - Can the level of risk be justified by the potential for benefit?
  - If there are potential benefits to the subjects themselves, have you maximized the prospect for those benefits?

– Justice:
  - Are the risks associated distributed evenly among the population?
  - Do the people that bear the most risk stand to gain the most benefit?

Other things to think about

- As a public health agency, we do a lot of things that directly benefit the public we serve. The thing about research is, it may or may not prove to be of any benefit… So when we choose to involve people in research, we have a different responsibility to them than when we interact with them as a public health agency.
- When something goes wrong in a research project, it's a different kind of wrong than when something goes wrong in a public health intervention. When people are harmed, or if their rights are violated through an activity that may not have any benefit to them, there is a more extreme loss of trust. This loss of trust goes beyond research activities and impacts every important public health function of the Department.
- Once trust is lost, it takes a significant amount of time and effort to restore that trust.
- Protecting research subjects is everybody's responsibility, and the IRB can help.

Resources

- More information on the IRB, required training, and applications is available at: www.michigan.gov/irb
- Responsible MDHHS Employees can submit applications to MDHHS-IRB@michigan.gov
- You can contact the IRB at 517-241-1928 or at: MDHHS-IRB@michigan.gov
- You can contact Ian Horste, the Chair of the IRB, at: horstei@michigan.gov or at: 517-284-4840