



Institutional Engagement in Research A Guidance Document

Purpose

This document provides guidance on when Metro Health is engaged in research, and when the Metro Health IRB must provide oversight of the research activities.

Regulatory Guidance

- 45 CFR 46: Protection of Human Subjects
- OHRP Guidance on Engagement of Institutions in Human Subjects Research dated October 16, 2008

Definitions

Institution: Any public or private entity or agency (including federal, state, and other agencies). [45 CFR 46.102(b)]

Metro Health Employee or Employed Provider: A person who is employed by a Metro Health Entity.

Metro Health Provider: Any non-employed MD, DO, DPM, DDS, or advanced practice professional who has privileges or is credentialed at a Metro Health entity.

Metro Health Agent: A non-employee functioning on behalf of Metro Health, including volunteers, contractors and students.

Discussion

What is Institutional Engagement?

The OHRP Engagement Guidance defines engagement this way: “In general, an institution is considered engaged in a ... research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.”

Why is this determination important?

The regulations require research activities involving human subjects to be overseen by institutional review boards (IRBs). Only those institutions engaged in research activities need to obtain IRB review. By accurately determining when Metro Health is engaged or not engaged in research, we can mitigate the unnecessary review by multiple IRBs and therefore reduce the regulatory burden for the research team.

Examples of when Metro Health is Engaged

**Metro Health Institutional Review Board
Metro Health Professional Building**

2122 Health Dr. SW, Suite 233 | Wyoming, MI 49519
p 616.252.5026 | irb@metrogr.org | metrohealth.net



Metro Health is engaged in the research and the research must be reviewed by the Metro Health IRB when:

- Metro Health receives an award through a grant, contract or cooperative agreement from a federal agency to conduct the research activities.
- A Metro Health employee, provider, or agent:
 - conducts a research intervention (e.g. experimental process) or interaction (e.g. research interview) on the research participant;
 - obtains the informed consent of the research participant;
 - obtains private identifiable data and/or biospecimens.

Examples of Research Activities where Metro Health might be Engaged

If a Metro Health employee, provider or agent performs any of the following activities, then Metro Health may or may not be engaged in the research and the research must be reviewed by the Metro Health IRB for determination:

- Releasing identifiable or coded data/specimens to a researcher.
- Interacting with participants to perform research-related services, administer study interventions, or provide clinical monitoring.
- Allowing an investigator access to Metro Health facilities and patients for purposes of conducting research.

Examples of when Metro Health is not Engaged

If a Metro Health employee, provider or agent only informs potential subjects about the availability of research at another institution, then Metro Health is not engaged in the research and the research does not need to be reviewed by the Metro Health IRB. The following activities can occur without Metro Health IRB review:

- Informing prospective subjects about the availability of the research
- Providing prospective subjects with information about the research (including an informed consent form) but does not obtain the subject's consent nor acts as a representative of the investigator.
- Providing prospective subjects with information about contacting investigators for information or enrollment.
- Seeking or obtaining the prospective subjects' permission for investigators to contact them.

Conclusions

- If you are obtaining the participant's informed consent, Metro Health is engaged in the research and it must be reviewed by the Metro Health IRB.
- If you are referring potential participants for a research project being conducted by another institution's employees, providers or agents, it does not require Metro Health IRB review.
- If you are unsure if a research project requires review by the Metro Health IRB, submit the research to the IRB and request an engagement determination.

Contact the Office of the IRB for additional instructions at irb@metrogr.org or by phone at 616-252-5026.

- This guidance relates only to Metro Health IRB review. You may need to comply with additional institutional policies unrelated to IRB review (i.e. HIPAA requirements and business contracts for services provided). Discuss the research project with your upline to determine what additional requirements may apply.