

Part 6 – Roles and Responsibilities of Investigators and Research Staff

Every person involved in human research plays a critical role in protecting the rights and welfare of research participants. This section describes the roles and responsibilities of investigators and research staff engaged in University research.

I. ELIGIBILITY TO PERFORM RESEARCH AT THE UNIVERSITY OF MICHIGAN

Refer to [HRPP OM Part 6.I](#)

II. ROLES AND RESPONSIBILITIES OF INVESTIGATORS AND RESEARCH STAFF FOR THE PROTECTION OF HUMAN SUBJECTS

Refer to [HRPP OM Part 6.II](#)

A. Generally

Refer to [HRPP OM Part 6.II.A](#)

Refer to [IRBMED Guidance – Investigator Responsibilities](#)

B. Key Responsibilities

1. Minimizing Risks to Subjects and Protecting Subject Rights and Welfare

Refer to [HRPP OM Part 6.II.B.1](#)

2. Obtaining and Documenting Informed Consent

Refer to [HRPP OM Part 6.II.B.2](#)

Refer to IRBMED Guidance - [Re-consenting Study Subjects](#).

3. Compliance with IRB and Other Requirements

Refer to [HRPP OM Part 6 II.B.3](#)

See also [IRBMED SOP Part 12.II](#)

4. Conflict of Interest Disclosures

Refer to [HRPP OM Part 6.II.B.4](#)

See also [IRBMED SOP Part 9.III](#)

The IRBMED coordinates with the appropriate University Conflict of Interest Committee to ensure that conflict of interest management plans and any relevant imposed terms of conflict management are considered in the review of applications submitted by the personnel in question.

5. ClinicalTrials.gov Registration

Refer to [HRPP OM Part 6.II.B.5](#)

Refer to [HRPP OM Part 11](#)

C. STUDIES REGULATED BY THE FOOD AND DRUG ADMINISTRATION

1. Generally

Refer to [HRPP OM Part 8](#)

2. Exception from Informed Consent Research

Refer to [IRBMED Guidance – Position Statement for Emergency Research with Exception from Informed Consent](#).

Refer to [IRBMED SOP Part 3](#)

3. Principal Investigator Responsibilities

Refer to [HRPP OM Part 6.II.A](#)

Refer to [IRBMED Guidance – Investigator Responsibilities](#).

4. Sponsor-Investigator

Refer to [HRPP OM Part 6.II.B.2](#)

Refer to [IRBMED Guidance – Investigational Device Exemption \(IDE\) Application and Investigational New Drug \(IND\) Application](#).

5. Manufacturers

Refer to [HRPP OM Part 8](#)

6. [Guidelines for Good Clinical Practice \(GCP\) of the International Conference of Harmonization \(ICH\)](#)

From time to time, especially in multi-site clinical research where UM is a proposed performance site, a Sponsor may represent that the FDA-approved protocol and any Principal Investigator SOPs associated with that protocol, if followed, assure ICH-GCP compliance. In those instances, IRBMED will make the determinations required by institutional policy and will also review the research plan submitted to identify aspects that may be inconsistent with ICH-GCP. Such review will include evaluation of the adequacy of the available nonclinical and clinical information on an investigational product to support the proposed clinical research project, and a review that proposed clinical research is scientifically sound and described in a clear, detailed protocol. IRBMED will bring any area of concern to the attention of the Principal Investigator, who may in turn ask for clarification from the Sponsor.

Principal Investigators who agree to perform research represented to be ICH-GCP compliant are required to follow the protocol as written and will be advised by IRBMED to review all Principal Investigator Obligations in the ICH-GCP as well as any aspects of ICH-GCP incompletely captured or not captured in the research protocol and investigator SOPs.

If a Principal Investigator in the research contract agrees to conduct an investigation in full compliance with the Principal Investigator Obligations under ICH-GCP, any compliance review conducted by OHRCR will be done against the complete set of ICH-GCP requirements.

III. EDUCATION

Refer to [IRBMED SOP Part 13](#)

IRBMED provides educational opportunities for researchers and their research teams. Workshops, conferences, and consults are provided on regulations, institutional policies, and the eResearch application. Further information is available on the IRBMED [website](#).