

Part 2 – Organization of the HRPP and IRBMED

This section describes the organization of the University of Michigan Medical School Institutional Review Board (IRBMED) and the roles and responsibilities of the various units that guide and support the program.

I. KEY ORGANIZATIONAL REPRESENTATIVES

An organizational chart identifies key organizational officials and units in the University, Medical School, and IRBMED.

Refer to [UMOR website](#) and the [IRBMED website](#)

II. ORGANIZATIONAL ENTITIES THAT SUPPORT IRBMED

Refer to [HRPP OM Part 2](#)

Numerous organizational entities contribute to the operation of the University's HRPP and the IRBMED. Entities closely associated with IRBMED providing oversight and assistance include but are not limited to:

- [University of Michigan Office of Research \(UMOR\)](#)
- [Medical School Office of Research](#)
- [Medical School Office of Regulatory Affairs](#)
- [UMHS Compliance Office](#)
- [Office for Human Research Compliance Review \(OHRCCR\)](#)
- [Office of Research and Sponsored Projects \(ORSP\)](#)
- [Michigan Institute for Clinical Health Research \(MICHHR\)](#)
- IRB Council (advisory)
- [Executive Vice President for Medical Affairs \(EVPMA\)](#)
- [Office of the Vice President and General Counsel](#)

A. University of Michigan Office of Research

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

B. The Academic Units

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

C. Other University of Michigan Institutional Review Boards

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

D. Other Research Review and Support Units

Refer to [HRPP OM, Part 2.II.D](#)

Other HRPP and UMHS committees review the science, ethics, and additional regulatory requirements that apply to a given study to protect the rights and welfare of the research subjects.

Certain types of research involving human subjects must be reviewed and approved by additional departments, divisions, or units of the University. Depending on the nature and

scope of a project, the IRBMED may withhold its approval pending confirmation of approval by or receipt of additional information from any of the following:

- [Michigan Clinical Research Unit](#) (MCRU), formerly the General Clinical Research Center (GCRC)
- [Research Pharmacy](#) (formerly the Investigational Drug Service)
- [Clinical Research Calendar Review Analysis Office](#) (CRAO), formerly the Clinical Research Billing Unit (CRBU)
- [University of Michigan Medical School](#) (UMMS)
- [Radioactive Drug Research Committee/Subcommittee on the Human Use of Radioisotopes](#) (RDRC/SHUR)
- [Central Biorepository](#) (CBR)
- [Institutional Biosafety Committee](#) (IBC)
- [Human Pluripotent Stem Cell Research Oversight Committee](#) (hPSCRO)
- [Hospital Biomedical Engineering Unit](#) (BEU)
- [Tissue Procurement Core](#) (TPC)
- [Medical School or UMOR Conflict of Interest Committees](#) (COI)
- [Michigan Alzheimer's Disease Research Center](#) (MADRC)
- Department or organization peer review committees (e.g., Comprehensive Cancer Center Protocol Review Committee)
- IRBs at other performance sites or coordinating centers
- Core service groups (e.g., Biomedical Engineering Unit (BEU))

The IRBMED is responsible for review and final approval of the human subject research application in those cases where other committees are also involved in the review process.

E. Independence of Research Review Units and Response to Undue Influence

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

F. Resources

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

The Medical School Office of Research provides oversight and administrative support for the IRBMED office. On an annual basis, the fiscal year operating budget for the IRBMED is reviewed and approved by the Senior Associate Dean for Research and the Dean of the Medical School.

The IRBMED works closely with the Office of Regulatory Affairs, for example, to obtain assistance with FDA inspections, board member recruitment, and mandatory training requirements.