

Part 5 – IRB Jurisdiction and Cooperative Research

University research generally must be approved or declared exempt by a University IRB. This section describes the scope of jurisdiction of the various University IRBs and policies on cooperative research and ceded review.

I. UNIVERSITY OF MICHIGAN IRB JURISDICTION

Refer to [HRPP OM Part 5.I.](#)

A. IRBMED

1. Primary Jurisdiction

All research proposed by faculty, staff, students, or other trainees with a primary appointment with the Medical School or the University of Michigan Health System

All research using the patients, medical records, or facilities of the University of Michigan Hospitals and Health Centers

All research where the results will be submitted to FDA as part of an application for a research or marketing permit. This includes research involving investigational drugs, biologics or significant risk devices

All clinical investigations conducted by the School of Dentistry

Any research involving invasive techniques, such as deep muscle biopsies by the School of Kinesiology

Research using the Functional MRI (fMRI) Laboratory

2. Exceptions

By agreement of the IRBs, some categories of exempt research are reviewed by IRB-HSBS

B. IRB–Health Sciences and Behavioral Science (IRB-HSBS)

1. Primary Jurisdiction

All research conducted by the faculty, staff, students or other trainees with a primary appointment in U-M Ann Arbor schools, colleges, units or programs not subject to IRBMED jurisdiction. These include but are not limited to:

- U-M Institutional Research
- College of Architecture and Urban Planning
- College of Engineering
- College of Literature, Science, and the Arts
- College of Pharmacy
- Institute for Social Research (ISR)
- Ford School of Public Policy
- Law School
- Mary A. Rackham Institute
- Rackham Graduate School

- Ross School of Business
- School of Dentistry
- School of Education
- School of Information
- School of Music, Theatre, and Dance
- School of Natural Resources and Environment
- School of Kinesiology
- School of Nursing
- School of Public Health
- School of Social Work
- Stamps School of Art and Design
- University Health Services
- University of Michigan Transportation Institute (UMTRI)

2. Exceptions

By agreement with IRBMED, qualifying PIs with a primary appointment to IRB-HSBS may submit fMRI protocols to IRB-HSBS for review under the terms of the IRBMED-approved Master Protocol.

C. IRB-Dearborn

1. Primary Jurisdiction

- a)** All research conducted by faculty, staff, students or other trainees with a primary appointment at U-M-Dearborn

D. IRB-Flint

1. Primary Jurisdiction

- a)** All research conducted by faculty, staff, students or other trainees with a primary appointment at UM-Flint

E. General Exceptions

- 1.** In any case where the IRB with primary jurisdiction does not have the appropriate expertise or is not appropriately constituted (e.g. prisoner representative) to review a research proposal, the project may be transferred to the IRB with appropriate expertise for review and approval.
- 2.** In those instances in which conflicts of interest preclude a quorum for review, the project may be transferred to an alternate IRB with appropriate expertise for review and approval. The selection of an alternative IRB will be made by the chair of the referring IRB in consultation with the receiving IRB, if the chair does not have a disqualifying conflict. If the chair has a disqualifying conflict of interest, the selection will be made by the Vice President for Research or designee.
- 3.** In those instances in which another IRB or a faculty member, staff member, student, or other trainee requests review by an alternate U-M IRB, the chair will review the reasons for such a request; and if appropriate, consult with the other IRBs; and decide which IRB shall review the proposal. In extraordinary circumstances, the Vice President for Research

may overrule a chair's refusal to refer an application to another U-M IRB.

4. In rare instances, in which the rules below do not clearly define which IRB to use and the chairs cannot agree on jurisdiction, the matter may be referred to the IRB Council for a determination.

The IRB is also authorized, in its discretion, to invite individuals with special expertise to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals will identify any conflicts of interest to the IRB and they may not vote with the IRB.

II. COOPERATIVE RESEARCH

Refer to [HRPP OM Part 5.II.A-D](#)

- A. Engagement in Human Research
- B. Default Position on Outside Entities Engaged in University Research: Avoiding Duplicate Review
- C. Researcher and IRB Responsibilities with Regard to Performance Sites not Engaged in Research
- D. Special University IRB Responsibilities for Multi-Site Research in Which the University Is Involved

III. COORDINATED OR JOINT REVIEW

- A. IRB-of-Record

Refer to [HRPP OM Part 5.IV.A](#)

- B. Responsibilities of the HRPP and Local IRB in Multi-Site Research

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

IV. UNAFFILIATED INVESTIGATORS

Refer to [HRPP OM Part 5.V](#)

V. RESEARCH INVOLVING COMMUNITY MEMBERS IN THE RESEARCH PROCESS

Refer to [HRPP OM Part 5.VI](#)