Part 1 – Introduction, Purpose, and Ethical Principles

This section describes the mission of the Medical School Institutional Review Board (IRBMED), the purpose of the IRBMED, the authority under which it operates, and the scope of research conducted at the University.

I. MISSION STATEMENT AND ORGANIZATIONAL SUMMARY

The mission of the IRBMED is to protect the rights and welfare of participants in clinical trials and other human subject research studies by careful review and monitoring of research in accordance with applicable laws, regulations, and University policies. The IRBMED assists investigators with the design and conduct of research projects to minimize risk to human subjects, provides guidance to the University and its researchers on ethical and procedural issues related to the use of human subjects in research, and facilitates compliance with governmental and University policies pertaining to human subjects research. To perform its review, approval, and monitoring functions, the IRBMED is composed of five (5) review boards, each of which complies with applicable regulations concerning membership and conduct.

The IRBMED oversees the protection of human participants in research conducted at the Medical School and the UM Hospitals and Health Centers (UMHHC), including research conducted off-site by UM Health System (UMHS) faculty and staff as University employees or in connection with their University appointments. The IRBMED also reviews FDA-regulated research or medical intervention research conducted by faculty and staff from other U-M units including Dentistry, and the campuses of U-M Ann Arbor, Flint and Dearborn.

The Human Research Protection Program (HRPP) is an integrated institution-wide program for promoting excellence in all aspects of research with humans. Components include the IRBs, other review units, oversight functions, and educational and quality assurance activities, which together seek to assure the rights and welfare of human subjects participating in biomedical and behavioral research and promote excellence in all aspects of human subject research. HRPP policies are compiled in the Operation's Manual (OM).

The IRBMED, designated by the University to review and monitor human subjects research under its Federal-Wide Assurance, maintains written SOPs, and may issue additional guidance as necessary. These SOPs are consistent with and supplemental to the HRPP OM.

II. SCOPE OF HUMAN RESEARCH AT THE UNIVERSITY

Refer to HRPP OM Part 1.II.

III. AUTHORITY UNDER WHICH THE HRPP OPERATES

Refer to HRPP OM Part 1.III

Refer to HRPP OM Part 11

The HRPP, of which the IRBMED is a part, operates under the authority of and in accordance with applicable federal regulations, including:

A. The Public Health Service Act and its amendments, which empower the DHHS to issue regulations for the protection of human subjects. These are compiled in the "Common Rule", 45 CFR 46 subpart A. The Common Rule, which seventeen federal departments and independent agencies have adopted (see below), codifies and expands on the ethical principles described in the Belmont Report.

DHHS has issued additional rules for federally funded research involving pregnant women, fetuses, and neonates (45 CFR 46 subpart B); prisoners (45 CFR 46 subpart C); and

children (45 CFR 46 subpart D). The special protections applicable to federally supported research under these subparts have not been widely adopted by other agencies but generally are applicable to University research, as further described in Part 7 of the SOPs and OM.

DHHS provides guidance and information concerning its interpretation of the Common Rule and related regulations through determination letters directed to organizations performing research under federal-wide or other assurances following investigations of research noncompliance, and other guidance documents.

The Common Rule has been adopted by more than a dozen federal agencies involved with human subjects research. These are:

- Agency for International Development/International Development Cooperation Agency (22 CFR 225)
- Central Intelligence Agency (by Executive Order 12333, 46 FR 59941)
- Consumer Product Safety Commission (16 CFR 1028)
- Department of Agriculture (7 CFR 1c)
- Department of Commerce (15 CFR 27)
- Department of Defense (32 CFR 219)
- Department of Education (34 CFR 97)
- Department of Energy (10 CFR 745)
- Department of Health and Human Services (45 CFR 46)
- Department of Housing and Urban Development (24 CFR 60)
- Department of Justice (28 CFR 46)
- Department of Transportation (49 CFR 11)
- Department of Veterans Affairs (38 CFR 16)
- Environmental Protection Agency (40 CFR 26)
- National Aeronautics and Space Administration (14 CFR 123)
- National Science Foundation (45 CFR 690)
- Social Security Administration (See P.L. 296 [103rd Congress])

The Office of Science and Technology Policy signed the federal policy for protection of human research subjects but did not codify the Common Rule, because it does not conduct or sponsor research.

Although they have not issued the Common Rule in regulations, three other departments and agencies comply with all subparts of 45 CFR 46. These include:

- The Central Intelligence Agency, by executive order, (Executive Order 12333, paragraph 2.10)
- The Department of Homeland Security, created after issuance of the Common Rule, applies all subparts of 45 CFR 46 (6 U.S.C. section 112)
- The Social Security Administration separated from HHS in 1994. Absent action by the Administrator, it applies all regulations previously applied to SSA before the separation. (42 U.S.C. section 901)

The Common Rule is not uniformly interpreted or enforced. In addition, the subparts of 45 CFR 46 imposing special protections for identified vulnerable populations (other than children) have not been widely adopted. When a federal agency other than OHRP is responsible for oversight of a particular project or category of projects, the standards set by that agency's interpretation of the Common Rule and adoption or failure to adopt the additional subparts of 45 CFR 46 generally will inform the manner in which the corresponding University research is reviewed and conducted.

Absent an interpretation from a federal funding agency to the contrary, the requirements of all of the subparts of 45 CFR 46 are applied to all University research, regardless of funding source. For non-federally supported research, administrative requirements involving reports or applications to the relevant federal agencies are addressed through alternative mechanisms. Part 7 of the OM and these SOPs provide additional information on University policy for research involving vulnerable subjects.

B. FDA regulations for human subjects protections found in 21 CFR 50; for institutional review boards, 21 CFR 56; for investigational drugs and biologics, 21 CFR 312; and for investigational devices, 21 CFR 812. Additional information about research regulated by the FDA and special requirements for that research is provided in Parts 6 and 8 of the IRBMED SOPs, HRPP OM and at http://www.fda.gov.

C. Rules for research involving recombinant DNA or research otherwise regulated by the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA). The OBA develops and implements NIH policies and procedures for the safe conduct of recombinant DNA activities and human gene (see NIH guidelines for rDNA and Gene Transfer). Its duties include review and evaluation of the research that is subject to oversight by the University's Institutional Biosafety Committee.

D. Research regulated by the Department of Education (34 CFR 97, 98, 99, 350, and 356).

Refer to http://www.ed.gov/about/offices/list/ocfo/humansub.html.

E. Privacy regulations issued under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (45 CFR 160 and 164).

F. Principles stated in Guidelines for Good Clinical Practice (GCP) of the International Conference of Harmonization (ICH)

Refer to IRBMED SOP Part 6 – Roles and Responsibilities of Investigators and Research Staff

Refer to OM Part 6 – Roles and Responsibilities of Investigators and Research Staff

G. Additional Governing Laws, Regulations and Other Standards

Refer to HRPP OM Part 11.II

IV. LIMITATION ON INSTITUTIONAL AUTHORITY

Refer to HRPP OM Part 1.III.B

All regulated human subject research conducted by the University must be approved by an IRB or granted an exemption by a University IRB (through its members or staff, as specified in the IRBs SOPs and the OM) or the Vice President for Research. Research that has been reviewed and approved with the necessary expertise by the IRBMED may be subject to further review and disapproval by other review bodies or officials (including the Vice President for Research); however, no person or organization may override an IRBMED disapproval determination.

V. ETHICAL PRINCIPLES

Refer to HRPP OM Part 1.IV.

VI. PROTECTION FROM UNDUE INFLUENCE

Refer to HRPP OM Part 1.V.