Part 4 – Activities Subject to the HRPP

The conduct of human subjects research triggers a broad array of regulatory and institutional requirements, including advance approval from IRBs and other review units. To determine whether a particular activity is subject to U-M's HRPP or when the requirements of the HRPP are triggered, four questions must be answered. First, is it human subjects research under the Common Rule? Second, is it human subjects research under FDA regulations? Third, is U-M engaged in the research? And finally, when does the research begin and end? Analysis of these questions is described below and in the decision aids attached to the Appendix.

I. DETERMINING WHAT IS AND WHAT IS NOT HUMAN SUBJECTS RESEARCH

Refer to HRPP OM Part 4.I

II. DETERMINING WHETHER RESEARCH INVOLVES HUMAN SUBJECTS

Refer to HRPP OM Part 4.II

III. DETERMINING WHETHER THE UNIVERSITY IS ENGAGED IN HUMAN SUBJECTS RESEARCH

Refer to HRPP OM Part 4.III

IV. DETERMINING WHEN HUMAN SUBJECTS RESEARCH BEGINS AND ENDS

Refer to HRPP OM Part 4.IV

V. AUTHORITY TO MAKE REGULATED/NOT-REGULATED DETERMINATIONS (PER THE COMMON RULE AND FDA) AND NOTIFICATION OF DECISIONS

Refer to HRPP OM Part 4.V

A. Authority to Make Regulated/Not-Regulated Determinations

Refer to HRPP OM Part 4.V.A

As part of the administrative review process of submitted eResearch applications, the IRBMED Regulatory Teams (Senior Associate Regulatory Analysts (SARAs), Junior Associate Regulatory Analysts (JARAs) and Associate Regulatory Analysts (ARAs)) or other qualified IRBMED staff members assess whether the project meets the definition of human subjects research using the charts and guidance found in HRPP OM Part 4. The IRBMED Chairs or Directors may be consulted, as necessary.

Principal Investigators (PIs) may consult informally with an IRBMED Regulatory Team member to determine if their research project involves human subjects. To obtain a formal, documented regulated/not-regulated determination, an eResearch "Projects Not Regulated as Human Subjects Research" application must be prepared. This application permits PIs to respond to questions to determine whether such a determination is applicable. A self-generated determination letter that may be generated for qualifying responses and used for funding or publication purposes or the PI may request IRBMED review to confirm the not-regulated status.

Applications submitted in eResearch as "Projects Not Regulated as Human Subjects Research" may also be reviewed by the HIPAA Privacy Board Coordinator for appropriate determinations. PIs may contact the IRBMED Privacy Board Members, IRBMED Chairs or Directors for consultation.

B. Illustrations

Refer to HRPP OM Part 4.V.B

C. Student Practicum and Internships

Refer to HRPP OM Part 4.V.C

D. Notification of Decisions

Refer to HRPP OM Part 4.V.D

E. Review of Emergency Use of Investigational Agents

Refer to HRPP OM Part 8 and IRBMED SOP Part 8

F. Review of Humanitarian Use Devices (HUD) Under a Humanitarian Device Exemption (HDE)

Refer to IRBMED SOP Part 8

G. Non-Research Use of Investigational Products Regulated by the FDA

Refer to HRPP OM Part 8 and IRBMED SOP Part 8

VI. POLICY ON EXEMPT RESEARCH

Refer to HRPP OM Part 4.VI

A. Introduction

Refer to HRPP OM Part 4.VI.A

The eResearch application provides an exempt application pathway to assist the PI and the IRBMED in identifying exempt research. Under U-M policy, only IRBs are permitted to issue an exempt determination.

The IRBMED reviews exempt applications to assure that human subjects are protected under the relevant regulatory framework. Once an exemption has been granted, the project is not subject to continuing IRBMED oversight, unless the scope of the project changes such that it no longer meets the criteria required for exemption.

B. Categories of Eligibility for Exempt Determination

Refer to Federal Exemption Categories

Refer to HRPP OM Part 4.VI.B.

Research involving prisoners may not be granted exempt status, even if it falls into one or more of the federal exemption categories.

Special limitations on exemptions apply to research with children.

In addition to the six federal exemption categories, U-M permits IRBs to issue exemptions to qualifying research under additional categories. These are described at the HRPP Innovation and Demonstration website and defined as:

- Exemption 2a (minimal risk interventions are permitted in association with data collection)
- Expansion of Exemption 5 (to accommodate research sponsored by the State of Michigan)
- Exemption 7 (for analysis of identifiable data).

C. Authority to Grant Exempt Status

Refer to HRPP OM Part 4.VI.C

Designated IRBMED staff that have completed appropriate training and demonstrate a working knowledge of the regulations (e.g., the Exempt/Not Regulated Coordinator) or Chairs may determine as exempt any project that meets the exemption criteria set out at 45 CFR 46.101(b) or in institutional policy. However, final determination of Exemption 5 must be issued by the University of Michigan Office Research (UMOR) Institutional Official (IO) or their designee. Exempt determinations may not be conducted by PIs or others who may have a conflict of interest regarding the studies.

D. Notification and Documentation of Exempt Status

Refer to HRPP OM Part 4.VI.D

The exempt determination is issued to the PI via eResearch. The notification letter includes the exemption category assigned to the study, as well as instructions to amend the eResearch application for IRBMED review should the scope of the project change beyond the criteria for exemption.