

Part 7 – Participant Protection

All non-exempt human research subject to the HRPP is reviewed and must be approved by the applicable Institutional Review Board (IRB) or other duly constituted committee approved by the University of Michigan Office of Research (UMOR), using criteria similar to those applied to federally-funded research and consistent with the principles outlined in the Belmont Report. This section describes some of the ways research participants are protected under the HRPP.

I. HRPP PROTECTION EXTENDS TO ALL SUBJECTS

Refer to [HRPP OM Part 7.I](#)

II. DATA AND SAFETY MONITORING PLANS AND BOARDS

Refer to [HRPP OM Part 7.II](#)

The IRBMED offers a workshop to review requirements for developing Data and Safety Monitoring Plans (DSMP) for qualifying studies and Data and Safety Monitoring Boards (DSMB) to address studies with risks to subjects, NIH multi-site clinical trials and higher risk, Principal Investigator (PI)-initiated studies.

The IRB may require PIs to submit a DSMP before approving an initial or amended application, or may require one in response to an adverse event or other report.

Also, see IRBMED educational information [here](#).

III. PAYMENT TO RESEARCH SUBJECTS

Refer to [HRPP OM Part 7.III](#)

Refer to <http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/guidance/payment-research-subjects>.

Refer to [Human Subject Incentive Program Standard Practice Guide \(HSIP SPG 501.7\)](#).

IV. VULNERABLE SUBJECTS

Refer to [HRPP OM Part 7.IV. A-D](#)

Refer to [IRBMED SOP Part 11.III. 2. A](#)

Refer to [IRBMED Guidance](#).

Refer to [IRBMED Education](#).

Special rules apply to research involving vulnerable populations. For federally-supported research, IRBMED complies with the requirements of 45 CFR 46 to the extent the sponsoring agency has adopted its subparts B-D.

For FDA-regulated research involving children, IRBMED complies with the requirements of 21 CFR 50, subpart D.

For research not subject to the above regulations, IRBMED may choose to apply the regulations as stated or apply equivalent protections adopted by the University as stated in [HRPP OM Part 7.IV](#).

A. Research Involving Pregnant Women, Fetuses, and Neonates

Refer to <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb>

Refer to [HRPP OM Part 7.IV.A](#)

B. Research Involving Prisoners

Refer to [IRBMED Guidance: Incarcerated Subjects](#)

Refer to [IRBMED Guidance: Prisoners](#)

Refer to <http://www.hhs.gov/ohrp/policy/index.html#prisoners>

Refer to [HRPP OM Part 7.IV.B](#)

1. IRB Composition

IRBMED is permanently constituted with a prisoner representative with appropriate background and experience to serve in that capacity.

Prior to enrolling any prisoners on a study, IRBMED must certify to the Institutional Official or Deputy Institutional Official that all requirements have been fulfilled except as allowed in urgent situations where the best interests of the subject requires participation in the research prior to fulfillment of all requirements as described in federal guidance at <http://www.hhs.gov/ohrp/policy/prisoner.html> and <http://answers.hhs.gov/ohrp/categories/1568>.

C. Research Involving Children

Refer to [IRBMED Guidance: Children in Research](#)

Refer to [IRBMED Assent Guidelines](#)

Refer to [IRBMED Guidance: Wards](#)

Refer to [HRPP OM Part 11.II. A.2](#)

Refer to [HRPP OM Part 7.IV.C](#)

D. Research Involving Adults with Cognitive Impairment or Otherwise Impaired Decision-making Capacity

Refer to [HRPP OM Part 7.IV.D](#)

V. COMPENSATION FOR INJURIES

Refer to [HRPP OM Part 7.V](#)

Refer to [OHRP "Exculpatory Language" in Informed Consent](#)

Refer to [UM Clinical Research Calendar Review & Analysis Office \(CRAO\)](#)

VI. ADVERTISING MATERIALS

Refer to [HRPP OM Part 7.VI](#)

Refer to [IRBMED Guidance: Advertising Materials](#)

Refer to <http://www.hhs.gov/ohrp/policy/clinicaltrials.html>

Refer to <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm>