I. Policy

OHRCR promotes clear communication and transparent processes by using unambiguous terminology. This policy details how OHRCR establishes and maintains its tools of discourse.

II. Applicability

The terms and acronyms defined in the following pages are used by OHRCR in the conduct of OHRCR business.

III. Procedures

A. OHRCR will maintain a list of definitions, common terms and acronyms which will be accessible to all investigators and HRPP components and entities which may be subject to OHRCR review.

B. OHRCR will review the list for completeness and accuracy whenever

   1. A new SOP or a new section to an SOP is added.

C. This is an ongoing process; therefore, the document will be updated and revised on the basis of consensus within the office.

Approved by: 

[Signature]
Director, OHRCR

[Signature]
Effective Date
I. Definitions

For-cause review: A compliance activity is considered “for-cause” when allegations, indications or suspicions of possible human subjects related non-compliance is received from OVPR, IRBs, ancillary committees, the research administration, research subjects, faculty, research support staff, funding or regulatory agencies or OHRCR staff.

Not-for-cause review: A compliance activity is considered “not-for-cause” when it is a routine review of the investigators, studies, or systems that are chosen as described in OHRCR not-for-cause review procedures.

Routine Research Educational Regulatory Review (RRERR): A type of not-for-cause review based on a sampling plan for the current fiscal year.

Noncompliance: The failure of a person or organization to act in accordance with the requirements of a law, regulation, policy, or the requirements and/or determinations of an IRB

Serious Noncompliance: Noncompliance that materially increases risks or causes substantive harm to research participants or materially compromises the rights or welfare of participants

Continuing Noncompliance: A pattern of actions or omissions that suggest a likelihood that instances of noncompliance will recur without intervention, or a failure to comply with a directive from an IRB to address an episode of noncompliance

Faculty Review Committee: A committee that may be formed by the Office of the Vice-President for Research to review an issue regarding human subjects research regulatory non-compliance.

Human Research Protection Program: This term refers to all the various components of the University that have a role in protecting human subjects. These components range from individual investigators to IRBs and the Office of the Vice-President for Research.

Institutional Official: This is the organization's administrative official that has ultimate responsibility authority regulatory compliance in regard to the conduct of Human Subject Research. At the University of Michigan, the Institutional Official is the Vice-President for research.
**Sponsor/Investigator:** This is a term used specifically for FDA regulated studies. In this case, the word “Sponsor” does not refer to the financial supporter of the study, but the person or entity that conceived the study and has ultimate responsibility for the conduct of this study. For those studies requiring an IND or IDE, the sponsor is the person/entity that holds the IND or IDE and has specific sponsor responsibilities that must be completed. The “Investigator” is the individual that carries out the study for the sponsor. The investigator also has regulatory responsibilities that must be fulfilled. Sometimes faculty are conducting research where they are fulfilling both sponsor and investigator roles. These individuals are described as “Sponsor/Investigators”.

**Observations:** Observations are made by comparing human subjects research protections criteria with practices in the active study.

**Draft Report of Observations:** This is the first draft of the OHRCR report. After reviewing the draft, the investigator has the opportunity to comment on the observations made during the review.

**Report of Observations:** This report summarizes factual observations made during the review and providing corrective actions to address any regulatory noncompliance that is observed.

**Close-out Letter:** The Letter from OHRCR that confirms the corrective actions to address regulatory compliance have been implemented. It is only applicable if recommendations to address regulatory noncompliance have been made in the Report of Observations.

### II. Common Acronyms

- **FRC:** Faculty Review Committee
- **HRPP:** Human Research Protection Program
- **IO:** Institutional Official
- **OHRCR:** Office of Human Research Compliance Review
- **OVPR:** Office of the Vice-President for Research
- **RRERR:** Routine Research Educational Regulatory Review
- **SI:** Sponsor Investigator
- **VPR:** Vice President for Research