I. Definitions

**OHRCR Review:** A systematic, objective review of human subjects regulations applied by principal investigators and study teams during the conduct of research.

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

**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:** Noncompliance that reoccurs after an investigator has been notified of a similar or related noncompliance concern pertaining to one or more protocols.

**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 UMOR.

**Observations:** Observations are factual statements when human subjects research protections regulations are compared to actual practices.

**Draft Report of Observations:** Any version preceding the Final Report which is still open to editorial review and revision. The draft is reviewed by the investigator, HRPP Director, the appropriate IRB staff and leadership. All parties have an opportunity to comment on the observations and corrective actions made during an OHRCR review.

**Final Report of Observations:** The final OHRCR report summarizes factual observations made during the review and provides corrective actions to address any regulatory noncompliance that was observed.
Close-out Letter: A close-out letter from OHRCR confirms that all corrective actions to address regulatory noncompliance have been implemented.

II. Common Acronyms

HRPP: Human Research Protection Program
OHRCR: Office of Human Research Compliance Review
U-M University of Michigan
UMOR: University of Michigan Office of Research
VPR: Vice President for Research