Document Title: *Multi-site Research Reporting Plan*

A. Introduction:

The purpose of this document is to help study teams that are relying upon an University of Michigan (U-M) IRB for the purpose of regulatory oversight understand the continued reporting requirements. U-M IRBs use a PSite application to collect information from the external sites. This guidance document has been prepared jointly by the IRB-HSBS and IRBMED to summarize harmonized procedures established between the two departments.

Definitions, Reporting Timeframes, Procedures
REPORTABLE TO THE LEAD SITE (U-M) WITHIN 7 DAYS

Unanticipated Problems Involving Risks to Human Subjects or Others: an actual incident, experience, or outcome that warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects or others. The following criteria must be met:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied
2. Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research);
3. Suggests that the research places subject(s) or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Non-compliance: The failure of a person or organization to act in accordance with the requirements of a law, regulation, policy, or the requirements and/or determination of an IRB. *Major* protocol deviations that may adversely impact safety of participants, or impact integrity/validity of the data are considered non-compliance (such as dosage errors/intervention errors, consent process deviations, deliberate procedural deviations, and accidental procedural deviations)

Continuing non-compliance: Noncompliance that recurs after an investigator has been notified of a similar or related noncompliance concern pertaining to one or more protocols.

Serious non-compliance: Non-compliance that, in the judgment of the IRB, materially increases the risks or causes substantive harm to research participants or materially compromises the rights or welfare of participants including consideration of the following:

1. Harm to participants;
2. Exposure of participants to a significant risk of substantive harm;
3. Compromised privacy and confidentiality of participants;
4. Willful or knowing research misconduct on the part of the investigator;
5. A violation of ethical principles for human research; or

6. Damage caused to the scientific integrity of the data collected.

Complaints: Complaints from any individual related to participant safety, study conduct, or study related materials.

Accident/Incident: Accidents/Incidents involving participants, their data, biospecimens or facilities associated with the research (e.g., breach of confidentiality, loss of research data or biospecimens).

Subject Incarceration: Incarceration of a participant when the research was not previously approved for the enrollment of prisoners under Subpart C and the investigator believes it is in the best interest of the subject to remain on the study.

Oversight Reports: Reports of internal or external audits; study holds or suspensions that are not built into the study design and affect the local site only. Reports of monitoring (such as Data Safety Monitoring) outcomes that have concerns of subject safety or suggested revision of study materials.

Subject Withdrawal: Withdrawal due to safety reasons.

Pertinent publication/public announcement: Information affecting the risk/benefit ration of the study or information affecting subjects' willingness to participate in the research.

IRB Approval Lapse: Report of any study activity during the lapse in approval (this can happen if a site does not get information to lead site in time for the submission of the continuing review).

REPORTABLE TO THE LEAD SITE (U-M) AT CONTINUING REVIEW

Site Status Reports: Site enrollment closed and/or completed interaction/intervention notifications without safety or regulatory concerns

Subject Withdrawal: Withdrawal of a subject due to PI discretion, subject discretion/request or other reasons, such as meeting protocol stopping rules.