SMART IRB Companion Piece

when U-M IRBMED is the Single IRB.

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# INTRODUCTION

This University of Michigan(U-M) Companion piece to the SMART IRB Standard Operating Procedures (SOPs) aims to help sites be compliant with the SMART IRB and applicable U-M IRBMED SOPs. The SOPs apply to all research studies—and to all participating investigators and administrators involved in the implementation and coordination of research studies—under the SMART IRB Agreement.

Investigators submitting applications for multi-site research funded by federal agencies that are signatories of the Common Rule must describe the sIRB plan in the funding proposal (grant application or contract proposal). When the sIRB is named in the proposal, the IRB must have agreed to take on this responsibility in advance. Requests for the U-M IRBMED to serve as the sIRB should be directed to the U-M IRBMED office.

# RESPONSIBILITIES

**Study team -** See “Relying Site Study Teams” in SMART IRB SOPs, page 9.

See “Roles and Responsibilities of Investigators and Research Staff for the Protection of Human Subjects” in U-M IRBMED SOP Part 6.II, page 77.

**Institutions –** See “Relying Institutions” in SMART IRB SOPs, page 11.

See “Responsibilities of the HRPP and Local IRB in Multi-Site Research” in U-M IRBMED SOP Part 5.III.B, page 76.

# SITE SPECIFIC INFORMATION AND DOCUMENTS

U-M IRBMED will disseminate information and template documents to collect site specific information. Each performance site will be given access to reliance agreement materials and current U-M IRBMED approved documents. Documents that may be included in this process are:

• Reliance Agreement (SMART IRB for eligible institutions; IRB Authorization Agreement IAA for all others)

• Reliance Agreement Addendum for Indemnification (if applicable)

• Local Context Profile - This local context profile will provide a method to document information related to the relying site such as local study procedures, state/local laws and regulations, institutional policy, conflict of interest policies and determinations.

• Relying site personnel list - U-M IRBMED requires the site-specific PI, Co-Is, and up to two primary study coordinators to be named for review and approval. All other study team personnel must be identified, tracked, and overseen locally at each relying site. Relying sites are responsible for evaluating study team member education, training, qualifications to perform in the role, and any conflicts of interest which should be identified and forwarded to U-M IRBMED for review.

• Protocol document

• U-M IRBMED approved informed consent/assents templates – U-M IRBMED provides a two part informed consent template for use by relying sites. Part 1 is not modifiable and contains overall study information. Part 2 permits the incorporation of site-specific information such as compensation of injury language, variations in costs, local contact information, and conflict of interest disclosures.

# INITIAL REVIEW: SUBMISSION AND REVIEW PROCESS

See “Initial review: Submission and Review process” in SMART IRB SOPs, page 18.

U-M IRBMED will conduct a review of the site specific documentation submitted by the relying site. This review will not be conducted until the reliance agreement, local context survey, site specific informed consent/assent documents and site personnel list has been submitted to U-M IRBMED. Once this review has been conducted by U-M IRBMED, the relying site will receive notification of site activation via eResearch that it is approved to proceed under U-M IRBMED oversight.

Do not initiate any local study activity without this notice of site activation from U-M IRBMED.

# CONTINUING REVIEW: SUBMISSION AND REVIEW PROCESS

See “Continuing review: submission and review process” in SMART IRB SOPs, page 20.

U-M IRBMED will conduct a review of the study activity performed throughout all relying sites. For this to be accomplished, each relying site will be expected to report the study activity that has taken place at least 60-days prior to the study’s expiration date. If a relying site does not submit their study activity report by the time the continuing review is ready to be reviewed by U-M IRBMED, this may result in a lapse of IRB approval. If a lapse in IRB approval takes place, all study activity must cease at the affected relying site(s) until IRB approval has taken place.

# PROTOCOL AMENDMENT: SUBMISSION AND REVIEW PROCESS

See “Protocol amendment: Submission and Review process” in SMART IRB SOPs, page 21.

# RECORD KEEPING AND DOCUMENT RETENTION

See “Record keeping and document retention” in SMART IRB SOPs, page 22.

See “Records and Documentation” in U-M IRBMED SOPs, Part 8.VII.F, page 83.

# HIPAA PRIVACY RULE

See “Waiver and Alterations of Authorization” in SMART IRB SOPs, page 26.

Waivers and Alterations of Authorization – U-M IRBMED will perform required HIPAA determinations on behalf of all sites unless sites explicitly identify, and U-M IRBMED agrees, that the relying site will retain the responsibility for HIPAA oversight including waivers or alterations.

See “HIPAA Authorization Language” in SMART IRB SOPs, page 26.

HIPAA Authorization Language – U-M IRBMED allows the use of site-specific HIPAA Authorization language. The relying institution will be given the chance to provide the site-specific HIPAA Authorization language during the local context survey platform.

See “Confidentiality of and Access to Research Records and Other Information” in U-M IRBMED SOP Part 11.II.B.1, page 90.

# FINANCIAL AND OTHER CONFLICTS OF INTERERST

See “Financial and other conflicts of interest” in SMART IRB SOPs, page 28.

See “Conflicts of Interest and Commitment” in U-M IRBMED SOP Part 9.II, page 84.

# REPORTABLE EVENT SUBMISSION AND REVIEW PROCESS

See “Reportable event submission and review process” in SMART IRB SOPs, page 29.

***U-M IRBMED***

***Multi-site Research Reporting Plan***

***Definitions, Reporting Timeframes, Procedures***

REPORTABLE WITHIN 7 DAYS

The following types of events must be reported to the lead site (University of Michigan) study team within 7 calendar days of *becoming aware of the event.*

**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 AT CONTINUING REVIEW

The following types of events must be reported to the lead site (University of Michigan) study team

at the next scheduled 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.

# OTHER REPORTING REQUIREMENTS

See “Other Reporting Requirements” in SMART IRB SOPs, page 30.

See “Reporting Unanticipated Problems, Serious and/or Continuing Noncompliance, Suspensions, and Termination of IRB Approval” in U-M IRBMED SOPs, Part 12.II.C.3, page 96.