Single 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 single IRB plan aims to help sites be compliant with the applicable U-M IRBMED SOPs when U-M IRBMED is the single IRB. The following procedures apply to all research studies—and to all participating investigators and administrators involved in the implementation and coordination of research studies—under the single IRB plan and reliance 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: LEAD SITE AND RELYING SITE STUDY TEAM

**U-M PI and U-M study team**

The U-M PI is responsible for identifying a U-M study team, and for providing the U-M study team contact information to the Relying Site Investigator(s). The U-M PI and U-M study team (or their designees) are responsible for providing the information or performing the activities described below related to the reliance review process and once IRB review has been ceded:

• Work in collaboration with the U-M IRBMED and POC to determine and document specific roles and responsibilities for communicating and coordinating key information to Relying Institutions and the U-M IRBMED as described throughout this companion piece.

• Promptly responding to questions or requests for information from Relying Site Investigators and/or study teams or the Relying IRB.

• Providing the Relying Site Investigators with the U-M IRBMED policies. This will include but is not limited to policies for reporting unanticipated problems, noncompliance, and subject complaints.

• Obtaining and collating information from Relying Site Study Teams and/or Relying Site Points of Contacts (depending on who is designated to provide that information at the Relying Institution) regarding local variations in study conduct, such as recruitment materials and process, consent process and language, and subject identification processes.

• Participating in conference calls regarding a study as requested.

• Providing Relying Site Study Teams with the IRB-approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials).

• Assisting Relying Site Study Teams and/or POCs at the Relying Institution(s) (depending on who is designated to pro-vide that information) in ensuring consent documents follow the U-M IRBMED’s template form and include applicable site-specific required language from each Relying Institution.

• When agreed upon in coordination with the U-M IRBMED, promptly reporting to the Site Investigator (or designee on the Relying Site Study Team) any unanticipated problems involving risks to subjects or others research-related subject injuries, or significant subject complaints that are related to or may affect subjects participating in the Research (i.e., the specific study or studies ceded to the U-M IRBMED) at the Relying Institution.

• Notifying Site Investigators of all U-M IRBMED determinations and communications, including those for initial review, continuing review, amendments, and reportable events.

• If a Relying Site Study Team does not provide the U-M Study Team (or designee) with the required information before the continuing review application is submitted to the U-M IRBMED, reporting the absence of this information as part of the continuing review and notifying affected Relying Site Study Team of lapse in approval for their site and any applicable corrective action plans.

• Providing access, upon request, to study records for audit by the Relying Institution, the U-M IRBMED, and other regulatory or monitoring entities.

• Following all requirements of the Relying Institution with regard to ceded review, such as ensuring administrative requirements for documenting ceded review have been met before study activation occurs at a Relying Institution.

*Also 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.*

**Relying Site Study Teams**

The Relying Site Study Teams, which include Site Investigators, are responsible for providing the information or performing the activities described below related to the reliance review process and once IRB review has been ceded:

• Following all requirements of their home institution with regard to ceded review, such as ensuring other reviews or sign-offs required by the institution have been completed before a study is activated.

• Promptly responding to questions or requests for information from the U-M Study Team (or designee) as well as from the U-M IRBMED through the communication mechanism(s) established by these entities.

• Participating in conference calls regarding a study as requested by the U-M Study Team, U-M IRBMED, or home institution.

• Working with the U-M study team and the POC from their home institution, as applicable, to incorporate site-specific required language into the consent template to be used at their institution.

• Providing the sponsored programs office at their institution with documentation that IRB oversight for a study has been ceded to and approved by U-M IRBMED.

• Providing the POC from their home institution with information regarding local Site Investigator or other Relying Site Study Team personnel changes.

• Reporting to their home institution POC any changes in conflict of interest (COI) disclosures and resulting changes in COI management plans related to the Research (i.e., the specific study or studies ceded to the U-M IRBMED).

• Promptly reporting to the U-M study team (or designee) any applicable information for continuing review progress reports in accordance with the U-M IRBMED’s policies and procedures for timing and content of such submissions.

• Reporting to the U-M study team (or designee) any changes (including funding changes and personnel changes), reportable events, and continuing review progress reports, for submission to the U-M IRBMED in accordance with the U-M IRBMED’s policies and procedures for timing and content of such submissions.

• Promptly reporting to the U-M PI via the U-M study team (or designee) any unanticipated problems involving risks to subjects or others, subject injuries related to the research, or significant complaints that could impact the conduct of the Research (i.e., the specific study or studies ceded to the U-M IRBMED) in accordance with the U-M IRBMED’s policies and procedures for timing and content of such submissions. Significant complaints are defined as those that cannot be resolved by the study team and a) suggest an increased or unexpected new risk or harm or b) change the risk/benefit ratio of the Research. Other complaints should be reported in accordance with the U-M IRBMED’s policies and procedures.

• Promptly reporting to the U-M PI via the U-M study team (or designee) any potential noncompliance that occurs in relation to the Research (i.e., the specific study or studies ceded to the U-M IRBMED) in accordance with the U-M IRBMED’s policies and procedures for timing of submission and content of such submissions.

• Providing, upon request, access to study records for audit by the local institution, the U-M IRBMED’s institution, and other regulatory or monitoring entities.

# RESPONSIBILITIES: U-M IRBMED AND RELYING INSTITUTIONS

This section of the companion piece provides an overview of the key responsibilities of U-M IRBMED and Relying Institutions. The responsibilities of the POC, who plays a critical role in ensuring that many of these U-M IRBMED and Relying Institution responsibilities are met, are addressed in detail in the next section.

**U-M IRBMED**

The U-M IRBMED is responsible for reviewing and overseeing any studies ceded to it for the life of the study, unless the Institution ends its participation in the specific study. In addition, the U-M IRBMED (or designee) is responsible for the following activities related to the initial reliance review process and subsequent management of the study:

• Working in collaboration with the POC and U-M study team (or designee) to determine and document specific roles and responsibilities for communicating key information to Relying Institutions and the U-M IRBMED as described throughout this companion piece.

• Providing POCs and Relying Site Study Teams with template informed consent form(s), which indicate areas where the Relying Institutions must add information (e.g., local contacts).

• Sending written notification to the U-M PI and U-M study team of: (i) its decision to approve or disapprove any Research (i.e., the specific study or studies ceded to the U-M IRBMED), (ii) any modifications required to secure approval of the Research, and (iii) the date by which renewal of an approval is required.

• Upon reasonable request, providing to the Relying Institution with access to relevant records related to the IRB review.

• Promptly notifying the U-M PI and relevant POCs from a Relying Institution of its findings and actions with respect to any unanticipated problems involving risks to subjects or others or any research-related subject injuries or significant subject complaints that occurred at the Relying Institution—or that occurred at another Relying Institution if such events or actions relate to or may affect the conduct of the Research or the safety, rights, or welfare of subjects participating in the Research at the Relying Institution.

• In the event a continuing review is submitted after IRB approval expires or the study expires before the U-M IRBMED can reapprove the study, notifying the POCs and Relying Site Study Teams from affected sites, in addition to the U-M PI and U-M study team, of the lapse in IRB approval and any applicable corrective action plans.

• Promptly notifying relevant POCs and Relying Site Study Teams, in addition to the U-M PI and U-M study team, of any finding of serious and or/continuing noncompliance that may affect the conduct of the Research or the safety, rights, or welfare of human subjects participating in the Research at the Relying Institution(s). If the finding of serious and/or continuing noncompliance has a study-wide impact, all Relying Institutions must be notified.

• Promptly notifying the U-M PI, U-M study team, relevant POCs, and relevant Relying Site Study Teams of any suspension or termination of IRB approval for that portion of the Research taking place at those Relying Institutions. If the suspension or termination is study-wide, all Relying Institutions must be notified.

• Unless an alternate reporting arrangement has been previously agreed upon between the Relying Institutions and U-M IRBMED, reporting to regulatory agencies and/or sponsors any findings of unanticipated problems involving risks to subjects or others, determinations of serious and/or continuing noncompliance, and/or any suspensions or terminations of IRB approval on behalf of all applicable institutions covered by this Agreement. The U-M IRBMED will also provide the involved Relying Institutions the opportunity to review and comment on the report before it is sent to federal authorities, such as OHRP, the FDA, or others.

• If the U-M IRBMED terminates the specific study, informing all Relying Institutions of this change.

*Also see “IRB-of-Record” in U-M IRBMED SOP Part 5.III.A, page 76.*

**Relying Institutions**

Relying Institutions are responsible for the following activities related to the initial reliance review process and subsequent management of the study; these will generally occur through the U-M PI and U-M study team:

• Communicating local considerations to the U-M IRBMED, including requirements of applicable state or local laws, regulations, policies, and ancillary review processes as are relevant to the Research (i.e., the specific study or studies ceded to the U-M IRBMED).

• Providing information about local restrictions, stipulations, or requested substitutions to informed consent documents to the U-M IRBMED for its approval, including institution-specific language (such as the Relying Institution’s standard injury compensation language).

• Notifying the U-M IRBMED of the following:

o Any unanticipated problems or findings of serious and/or continuing noncompliance that occurred on research that has not been ceded under this Agreement but that may have relevance to ceded Research, or

o Any suspension or restriction of a Relying Site’s Study Team member(s) ability to conduct human subjects research.

• Disclosing any COI related to Research conducted under this Agreement and providing applicable management plans to the U-M IRBMED.

• If the U-M IRBMED requests that the Relying Institution conduct an audit, reporting audit findings to the U-M IRBMED within a reasonable timeframe.

• Notifying the U-M IRBMED(s) of communications regarding Research covered by this Agreement to/from the Relying Institution and FDA, OHRP, and/or other regulatory agencies (e.g., re. unanticipated problems or serious and/or continuing noncompliance), as applicable.

• Informing the U-M IRBMED if the Relying Institution ends its participation in the IRB Reliance Agreement or the specific study.

*Also see “Responsibilities of the HRPP and Local IRB In Multi-site Research” in 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 (IRB Authorization Agreement)

• 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

The U-M IRBMED will review initial applications for new Research in accordance with the human subject protection requirements of each Relying Institution’s FWA, the federal regulations and ethical principles referenced therein, any other applicable federal human subjects research regulations or policies, and any local considerations of the U-M IRBMED (e.g., state law). The processes and procedures for review will be in accord with the U-M IRBMED’s own policies and procedures.

The U-M IRBMED will notify the U-M study team when it has approved the Research through its established processes. The U-M IRBMED may rely on the U-M study team to notify the U-M PI and Relying Site Study Teams of the IRB approval or notify the Relying Site Study Team directly.

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.

Unless an issue is discovered during the course of review that requires input from the Relying Institution, the U-M IRBMED generally will not provide any direct communication to the Relying Institution regarding the initial review of the application other than notifications about the Research review. Once this review has been conducted by U-M IRBMED, the relying site will receive notification of site activation 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

The U-M study team will submit a continuing review progress report to the U-M IRBMED in accordance with the U-M IRBMED’s policies and procedures (e.g., when the report is due and the mechanism through which it is submitted to the IRB). The U-M study team (or designee) is responsible for obtaining information from each Relying Site Study Team so that the U-M IRBMED can assess a comprehensive report regarding study progress, new information, and problems that have occurred. For this to be accomplished, each relying site will be expected to report the local site study activity that has taken place, to the U-M study team at least 60-days prior to the study’s expiration date.

If a Relying Site Study Team does not provide the U-M study team with required information before the continuing review application is submitted to the U-M IRBMED, the U-M study team must report the absence of this information as part of the continuing review submission. This may result in a lapse of IRB approval at the specific relying site.

The U-M IRBMED is responsible for reviewing all relevant information for the U-M study team’s and Relying Study Team’s sites until the Research is closed. The U-M IRBMED will conduct continuing reviews in accordance with the human subject protection requirements of each Relying Institution’s FWA, the federal regulations and ethical principles referenced therein, any other applicable federal human subjects research regulations or policies, and any local requirements communicated to the U-M IRBMED (e.g., state law). The processes and procedures for review will be in accord with the U-M IRBMED’s own policies and procedures.

Unless a Reportable Event is discovered in the course of the continuing review, the U-M IRBMED generally will not provide any direct communication to the Relying Institution regarding the review. The U-M IRBMED will notify the U-M study team when it has reapproved the Research through its established processes. The U-M IRBMED may rely on the U-M study team to notify Relying Site Study Teams of the IRB re-approval (or disapproval) of the Research or notify the Relying Site Study Team directly. If Research is disapproved by a U-M IRBMED at continuing review, and the U-M PI chooses to seek approval from a different IRB rather than substantively revise the study materials to address the concerns of the IRB that disapproved the Research, the Research cannot be subsequently submitted to another Relying Institution for review without disclosing the nature of the previous IRB’s disapproval.

In the event a continuing review is submitted after IRB approval expires or the study expires before the U-M IRBMED can reapprove the study, the U-M IRBMED will notify all Relying site POCs, U-M PI, U-M study team, and Relying Site Investigators of the expiration of IRB approval. The U-M IRBMED will notify the U-M study team and applicable Relying Institution POCs of any applicable corrective action plans required.

If a lapse in IRB approval takes place, all study activity needs to cease, at all sites that are affected, until IRB oversight approval has taken place.

Relying Site Study Teams may be required by their home institutions to provide study updates to local officials (e.g., local IRB offices) and are responsible for meeting these requirements.

# PROTOCOL AMENDMENT: SUBMISSION AND REVIEW PROCESS

The U-M study team is responsible for submitting amendments (study-wide or local amendments for Relying Sites) to the U-M IRBMED for review in accordance with the U-M IRBMED’s policies and procedures (e.g., timing and mechanism of submission).

The U-M IRBMED will conduct reviews of changes in research in accordance with the human subject protection requirements of each Relying Institution’s FWA(s), the federal regulations and ethical principles referenced therein, any other applicable federal human subjects research regulations or policies, and any local considerations communicated to the U-M IRBMED (e.g., state law). The processes and procedures for review will be in accord with the U-M IRBMED’s own policies and procedures.

A Relying Institution POC must authorize their Relying Site Study Team’s submissions of the following types of changes to the U-M study team for consideration by the U-M IRBMED POC:

• Changes to a Site Investigator or other Relying Site Study Team personnel, in order to ensure these personnel meet the institutional requirements for the Relying Institution;

• Changes that appear to affect any state law or local considerations a Relying Institution noted as part of its agreement to cede review; or

• Changes that indicate a newly identified COI.

Relying Site Study Teams will report changes in COI to their local Relying Institution in accordance with the local procedures and policies for COI reporting and management already established at each site. Relying Institution POCs will coordinate with local COI administrators and the local Relying Site Study Team in order to communicate this information to the U-M IRBMED. Reporting new or updated COI information, as well as personnel changes, to local POCs will occur in accord with the Relying Institution’s processes.

The U-M IRBMED will notify the U-M study team when it has approved an amendment/change in research through its established processes. The U-M IRBMED may rely on the U-M study team to notify applicable Relying Institutions of the IRB approval, where agreed upon in advance when determining and documenting specific roles and responsibilities for communicating and coordinating key information to Relying Institutions and the U-M IRBMED. In the case of local amendments (e.g., local recruitment materials, site-specific changes to consent documents) that do not affect all Relying Institutions, only the sites affected by the approved amendment must be notified of the IRB approval.

# RECORD KEEPING AND DOCUMENT RETENTION

|  |  |
| --- | --- |
| ***Record Type*** | ***Responsible Party*** |
| Current IRB policies and procedures including: SOPs, forms, templates, etc. | U-M IRBMED |
| Current executed IRB Reliance Agreements and Joinder Agreements, as well as any amendments | U-M IRBMED and Relying Institutions |
| Study-specific reliance requests including: identification of U-M IRBMED(s) and Relying Institutions, and Study Team information | Relying Institutions |
| Minutes from IRB meetings at which Research ceded under the IRB Reliance Agreement was reviewed; portions of the minutes that are relevant to a Relying Institution available upon request to designated officials of the Relying Institution. | U-M IRBMED |
| Records of any applicable COI management plans provided by the Relying Institution and received by the Reviewing Institution | U-M IRBMED and Relying Institution |
| Records of events reported by Relying Institution and received by the Reviewing Institutions | U-M IRBMED and Relying Institution |
| Study-specific review and approval notifications | U-M IRBMED and Relying Institutions |
| Other general correspondence between the Relying Institution and the U-M IRBMED | U-M IRBMED and Relying Institution |
| Study-specific determinations related to ceding review to a U-M IRBMED (e.g., forms documenting decision to cede review; any outstanding concerns or requirements that must be addressed by the U-M IRBMED, and any institutional requirements related to the ceded study that the U-M IRBMED must take into consideration.) | U-M IRBMED and Relying Institution |

The records described in the table above will be retained by the respective responsible parties for a minimum of seven years after the closure or termination of the study by the U-M IRBMED. Relying Institutions, including U-M study teams and Relying Site Study Teams, are advised to refer to their local institutional policies, as they may require a longer period of retention.

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

# HIPAA PRIVACY RULE

**Waivers and Alterations of Authorization**

U-M IRBMED is responsible for making determinations regarding waivers or alterations of authorization under the HIPAA Privacy Rule for all Covered Entities for which it serves as the IRB of record, and will follow their institutional policies and procedures as well as federal regulations for the review and approval of waivers or alterations of authorization. Relying Institutions requesting approval of a waiver or alteration of authorization must provide the U-M IRBMED with specific local requirements and restrictions on use and disclosure of PHI that could prevent the IRB from approving the request; the U-M IRBMED will consider the specific requirements and restrictions during the review.

When considering waivers or alterations of authorization, U-M IRBMEDs will not approve waivers for the release of directly identifiable data outside the Covered Entity without consulting with Relying Institution POCs to determine whether the policies of the Relying Institutions would allow such a disclosure.

In the event that the U-M IRBMED approves a waiver of authorization for use and disclosure of PHI, a Relying Institution may rely on the U-M IRBMED’s determination to the extent that it comports with institutional requirements.

If the Relying Institution has a concern about a waiver, partial waiver, or alteration of authorization the U-M IRBMED has granted, then the Relying Institution should discuss alternative approaches with the U-M IRBMED. Until an alternative approach is agreed upon between the U-M IRBMED and the Relying Institution, the Relying Site Study Team cannot perform the activity covered by the waiver, partial waiver, or alteration of authorization.

In the event that a research subject revokes permission to use his or her PHI, the affected investigator will determine whether the revocation occurred due to circumstances that require reporting to the U-M IRBMED in accordance with the U-M IRBMED’s policies and procedures.

**HIPAA Authorization Language**

The language required under the HIPAA Privacy Rule to obtain authorization for the use and/or disclosure of PHI will be incorporated into informed consent documents (ICDs), unless the U-M IRBMED agrees to the use of separate consent and HIPAA authorization forms. The U-M IRBMED will allow the use of site-specific HIPAA authorization language. The Relying Institutions will be given the chance to provide the site-specific HIPAA Authorization language during the local context survey platform. The U-M IRBMED will ensure that certain elements of authorization are sufficient.

*Also see “Confidentiality of and Access to Research Records and Other Information” in IRBMED SOP Part 11.II.B.1, page 90.*

# FINANCIAL AND OTHER CONFLICTS OF INTERERST

Relying Institutions are responsible for review and management of any COIs related to Research ceded to U-M IRBMED. The Relying Institution POC will coordinate with the appropriate COI administrator at his/her institution to ensure any COIs and applicable management plans are communicated to the U-M IRBMED. The Relying Institution POC may communicate this COI information directly to the POC for the U-M IRBMED or delegate this responsibility to the local Relying Site Study Team for submission to U-M study team, who will provide this information to the U-M IRBMED. If a Relying Institution’s policies require IRB review of institutional COI, the U-M IRBMED will review such conflicts upon request.

Relying Site Study Teams must disclose any COI and applicable management plans to the U-M study team at the time a reliance request is submitted and when the initial site activation application is submitted to the U-M IRBMED. Any new COIs identified for any Study Team member or updates to management plans must be reported to the U-M IRBMED. In these cases, Relying Site Study Teams provide information about new COIs or updated management plans to their local POC through the process established at his/her institution. The Relying Institution POC will coordinate with the appropriate COI administrator at his/her institution to determine whether any additional action is required by his/her institution regarding the new COI and/or updated management plan.

Relying Site Study Teams are also responsible for disclosing to the U-M study team any new COIs or updated management plans issued by the Relying Institution after the study is ceded. The U-M study team is responsible for submitting information about new COIs or updated management plans to the U-M IRBMED.

The U-M IRBMED is responsible for the consideration of any COIs and applicable management plan(s) for Study Teams participating in Research that has been ceded to them under the IRB Reliance Agreement. The U-M IRBMED will ensure that any management plan is incorporated into its deliberations and that any mandated disclosures to subjects are included in the approved informed consent documents, as the U-M IRBMED deems applicable. The U-M IRBMED may not modify any management plan or mandated disclosure to subjects without discussion and acceptance by the Relying Institution, and retains the authority to impose additional prohibitions or conflict management requirements that are more stringent or restrictive than those included in the Relying Institution’s management plan. In the extraordinary circumstance that the U-M IRBMED is unable to implement or approve a Relying Institution’s prohibitions or management plans, the U-M IRBMED will so inform the Relying Institution and withdraw the Ceded Review with respect to that Relying Institution.

If a proposed U-M IRBMED knows of any institutional COI involving its institution, that IRB should decline to serve as the IRB of record.

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

# REPORTABLE EVENT SUBMISSION AND REVIEW PROCESS

All study teams under the purview of the U-M IRBMED will follow the U-M IRBMED’s policies and procedures for reportable events (e.g., what requires reporting, reporting timeframes, and mechanism for reporting). See the below reportable event procedures. Relying Site Study Teams may be required by their local institutions to provide additional reports to local officials (e.g., local IRB offices) and are responsible for meeting these requirements.

***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:

This section describes other events that may occur that require reporting to the U-M IRBMED Institution and/or Relying Institutions.

**Suspensions and Terminations of U-M IRBMED Approval**

The U-M IRBMED will suspend or terminate the approval of studies in accordance its own policies and procedures. If the Research as a whole is suspended or terminated, the U-M IRBMED POC will promptly notify in writing all Relying Institution POCs, U-M PI, U-M study team, and Site Investigators of the suspension or termination. If a Relying Institution(s) is suspended or terminated, the U-M IRBMED POC will promptly notify the Relying Institution POC(s), U-M PI, U-M study team, and Site Investigators from affected Relying Institutions (and in some circumstances other sites) in writing of the decision to suspend or terminate the site(s). In the event of a suspension, the U-M IRBMED will determine whether it can continue to accept IRB oversight for the Relying Institution(s) or determine that it will end its oversight or participation in the specific Research.

*Also 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.*

**Research Misconduct**

Both the University of Michigan and Relying Institutions are responsible for notifying each other regarding potential research misconduct. Any individual at a University of Michigan or Relying Institution who becomes aware of a potential instance of research misconduct must notify their local Research Integrity Officer (RIO) in accordance with local policies and procedures for handling cases of potential research misconduct. When the research involves a study ceded, the relying institution’s RIO will notify and confer with the RIOs at other affected institutions, including the U-M IRBMED’s institution. If a U-M IRBMED discovers or receives information regarding potential or actual research misconduct, the U-M IRBMED will handle the report as a potential unanticipated problem with further notifications to Relying Institutions.

**Changes in FWA, IRB Registration, or Accreditation Status**

U-M IRBMED Institution and Relying Institutions are responsible for notifications regarding changes to FWA or accreditation status:

• U-M IRBMED Institution will promptly notify all Relying Institutions:

o If its FWA is suspended or restricted, lapses, or changes in scope.

o Of any loss or change in its accreditation status.

o Of any expiration of or change to its IRB registration status.

• Relying Sites will promptly notify U-M IRBMED:

o If their FWA is suspended or restricted or if its FWA lapses or changes in scope.

o If there was any loss or change in its accreditation status.

**Federal Audits and Legal Actions**

The U-M IRBMED and Relying Institutions are responsible for notifying each other regarding audits findings related to studies ceded under the IRB Reliance Agreement that represent reportable information per the U-M IRBMED’s policies and procedures (e.g., unanticipated problems, serious or continuing noncompliance, or other reportable information) as well as legal actions related to any studies for which the U-M IRBMED provides IRB oversight. Relying Institutions will assist, as appropriate, the other(s) in investigating and responding to such issues.

**Suspension or Restriction of Relying Site Investigator or Relying Site Study Team Member**

Relying Institution POCs are responsible for promptly notifying the U-M IRBMED of any suspension or restriction of Site PI and/or Relying Site Study Team member status to conduct research at the institution.