INTERNAL U-M Reporting - Other Reportable Information or Occurrence (ORIO)
IRBMED Guidance

When notified of an **Audit by a Federal Regulatory Agency (i.e., FDA, NIH, OHRP etc.), immediately call the Office of Regulatory Affairs (647-1576) and IRBMED (763-4768) to inform each unit of the date of inspection. See below (in red).

** If an ORIO indicates **notification of research subjects is necessary,** IRBMED must review and approve materials prior to utilization.

REPORTING MECHANISM AND TIMEFRAME for INFORMATION AND OCCURRENCES (NON-AE)

TYPE OF EVENT OR INFORMATION	Report as an ORIO within 7 CALENDAR DAYS of becoming aware of the event or information	Report as part of SCHEDULED CONTINUING REVIEW (SCR)* *NEW: These events or reports should be uploaded as supporting documents into the SCR application, and/or discussed in the SCR application. They do not require a separate ORIO submission.
Protocol Deviations	• Major protocol deviations that may adversely impact safety of participants, or impact integrity/validity of the data • Minor protocol deviations as part of a pattern and/or suggesting a systemic problem in study conduct that potentially places subjects or others at a greater risk of harm than was previously known or recognized	*Upload a spreadsheet with aggregate reports into SCR application- Section 4: Additional Supporting Documents* • Minor protocol deviations that do not impact safety of participants or impact integrity/validity of the data – for example, schedule deviations, minor informed consent deviations (wrong version date, wrong expiration date, as long as the content is same)
Report(s) to or from oversight entity	• Monitoring reports (DSMB or other) with issues of safety or data validity at U-M • Reports of internal or external audits (see below for specific instructions) • Reports on Drug or Device recalls from the sponsor • Study holds or suspensions that are not built into the study design • Study completed or enrollment closed/completed notifications with safety or regulatory concerns • Any reports from sponsor or oversight entity with safety or regulatory concerns	*Upload these reports individually into SCR application- Section 4: Additional Supporting Documents* • Routine monitoring reports (DSMB or other) without safety issues **NOTE: may be submitted to IRBMED by separate ORIO if required by the protocol or contract** • Reports related to routine monitoring/periodic visit without any action items or safety concerns • IND/IDE annual reports • Temporary Hold notifications as indicated in the approved protocol and limited to activities not impacting subject safety, such as routine interim data analyses • Study completed or enrollment closed/completed notifications without safety or regulatory concerns
Report of lapse in IRB approval	• Federally sponsored or FDA regulated studies irrespective of study activity during lapse in approval • Non-federally sponsored and non-FDA regulated studies with any study activity during lapse in approval	• Non-federally sponsored and non-FDA regulated studies with a lapse in IRB approval and with no study activities – *post-correspondence or indicate in the SCR application question **1.2** (free-text field on study progress) that no study activity occurred during the lapse in approval*.
Accident/Incident	• Accidents/Incidents involving subjects/data/specimens/facilities (e.g., breach of confidentiality). Also, if PHI is involved, contact the Compliance Office; if research data are involved, notify UMOR	• N/A

Effective March 6, 2017
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Complaint	• Complaints related to subject safety or study conduct or supporting documents content	• N/A
Subject Incarceration	For studies, not previously approved by IRBMED to enroll prisoners and there is: • Unintentional enrollment of a prisoner or • Intent to continue participation of a previously enrolled subject who becomes incarcerated	• N/A
Subject Withdrawal	• Withdrawal due to safety reasons	• Withdrawal of a subject due to PI discretion or other reasons, such as meeting protocol stopping rules (NOTE: *Include in Withdrawals section 02-3 of the SCR application)*
Pertinent publication/public announcement	• Information affecting the risk/benefit ratio of the study • Information affecting subjects willingness to participate in the research	• N/A
Notification of Audit/Inspection/ Inquiry	• For Federal audits (e.g., FDA, NIH, OHRP), contact the Office of Regulatory Affairs (ORA) and IRBMED by phone **immediately upon notification of audit**. Submit **"Report(s) to or from oversight entity" ORIO** to IRBMED once the audit has been conducted • All other audits (e.g., by Sponsor or an external IRB), submit ORIO via eResearch notifying IRBMED when the audit will occur and the anticipated length	• N/A
Not Regulated activities including QA/QI projects	• Contact the IRB	• N/A
Other Miscellaneous Information	• If there is any event or information that is not identified above or identified but needs immediate IRBMED attention, contact the IRBMED office for guidance. • IRBMED must review - in advance - any communication provided to research subjects.	