Reporting for APPROVED studies REQUIRING CONTINUING REVIEW	**REPORTING MECHANISM AND TIMEFRAME for INFORMATION AND OCCURRENCES (NON-AE)**	
	Report as an ORIO within 7 CALENDAR DAYS of becoming aware of the event or information	**Report as part of SCHEDULED CONTINUING REVIEW (SCR)** *NOTE: These events or reports do not require a separate ORIO submission. They should be uploaded into section 4.1 of the Scheduled Continuing Review (SCR) and discussed within SCR field 1.2.*
Protocol Deviations (see further discussion at Examples heading of ORIO webpage)	○ Major protocol deviations that may adversely impact safety of participants, or impact integrity/validity of the data (e.g. missed or out of window labs, procedures, or visits that would have been conducted for safety purposes) ○ 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 an aggregate report into SCR submission* Minor protocol deviations that do not impact safety of participants or impact integrity/validity of the data, for example: ○ schedule deviations (out of window), except when the visit or test would assess subject safety ○ minor informed consent deviations (wrong version date, wrong expiration date, as long as the content is the same) The aggregate deviation report should contain the same information as it the events were reported individually, such as: ○ date of occurrence ○ subject ID (do **not** include direct identifiers) ○ adequate description of the event for IRBMED to determine the seriousness of the event ○ whether the sponsor was notified of the event ○ (if PI initiated) effects to subject and/or data safety

	ORIO within 7 CALENDAR DAYS	Part of SCHEDULED CONTINUING REVIEW (SCR)
Report(s) to or from oversight entity	○ DSMB/DSMC reports **with** findings that yield implications for the conduct of the study (issues of safety, data validity or regulatory compliance) ○ Routine monitoring reports **with** implications for the conduct of the study (issues of safety, data validity or regulatory compliance) This includes reports from sponsor or CRO monitoring visits, and internal monitoring committees such as ORCR, MICHR, and QARC ○ Reports of internal or external audits ○ Reports on Drug or Device recalls or safety notices 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 other reports from sponsor, oversight entity or other sources with safety or regulatory concerns	*Upload these reports individually into SCR submission or separately as required by the Sponsor's protocol or contract.* ○ DSMB/DSMC (formerly charged oversight entity) reports **without** any action items or safety issues ○ FDA annual reports: ▪ For UM held IND or IDE ▪ For industry-sponsored IDE, per FDA guidance ○ 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 ○ ORCR monitoring reports ○ **For UM held IND or IDE**: All monitoring reports (i.e. MICHR reports), per HRPP OM Part 8.VII.B **NOT REQUIRED TO SUBMIT**: Routine monitoring reports (Interim monitoring reports, or other) **without** issues impacting safety, data validity, or regulatory compliance. These must be retained by the study team and available upon request. This includes reports from sponsor or CRO monitoring visits, and internal monitoring committees such as QARC. (*Exception for UM held IND/IDE*: see above.)

	ORIO within 7 CALENDAR DAYS	Part of SCHEDULED CONTINUING REVIEW (SCR)
Notification of Audit/Inspection/Inquiry	○ For Federal audits (e.g., FDA, NIH, OHRP), contact the Office of Regulatory Affairs 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. ○ Internal Monitoring Committee (ORCR/MICHR) reports may need to be submitted as soon as they are received.	N/A
Report of lapse in IRB approval	○ Federally sponsored or FDA-regulated studies irrespective of study activity during lapse in approval *(see exceptions below**)* ○ 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 submission 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 ○ Breach of confidentiality – see further discussion at Examples heading of ORIO webpage **NOTE:** Additional reporting beyond IRB is also required per U-M SPG 601.25: if PHI is involved, contact the Compliance Office; if research data are involved, notify UMOR.	N/A

Other Reportable Information or Occurrence (ORIO) https://az.research.umich.edu/medschool/guidance/other-reportable-information-or-occurrence-orio

	ORIO within 7 CALENDAR DAYS	Part of SCHEDULED CONTINUING REVIEW (SCR)
Complaint	Complaints related to participant safety, study conduct, supporting documents content or unresolved participant payment— If any complaint cannot be readily resolved by the study team and requires numerous and/or detailed steps towards resolution, submit the plan to IRBMED for review and approval. If the study team must respond to the participant's complaint more quickly than the ORIO can be processed, please contact the IRBMED for guidance. **When in doubt** If you are not sure about your reporting obligation for a specific subject complaint, please reach out to the IRBMED office for assistance (734-763-4768; irbmed@umich.edu).	Complaints **not** related to subject safety, study conduct, or supporting document content, e.g.: ○ A participant is upset about a delay in payment or with making an appointment, but it is readily resolved by the study team and to the participant's satisfaction The SCR should include a summary or tabulation of complaints not previously reported to the IRBMED, along with their resolution. The study closure (termination) report should include summary of complaints not previously reported, and a summary of the number of participant complaints over the course of the study, a description of those complaints, and their resolution.
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	If the study team becomes aware that a previously enrolled subject became incarcerated while enrolled in the study and study related activities were missed (e.g. study procedure, survey, questionnaire). evaluate as a protocol deviation and report at SCR or within 7 days if it involved a subject safety issue or data integrity issue.
Subject Withdrawal	It is preferred that withdrawals are not routinely reported individually. **Only withdrawals for the following reasons should be reported individually**: ○ Safety reasons ○ Subject complaint ○ Atypical/unusual reason	Report routine withdrawals in section **02-3** of the SCR submission. ○ Withdrawal of a subject due to routine reasons such as: PI discretion Met protocol stopping rules Death Time restrictions Not wanting to complete study procedures

	ORIO within 7 CALENDAR DAYS	Part of SCHEDULED CONTINUING REVIEW (SCR)
Pertinent publication/public announcement	○ Urgent information affecting the risk/benefit ratio of the study when notification of IRB cannot wait for an amendment to be submitted (i.e., memo regarding newly identified risk, but the revised protocol/IB are not ready to be published yet) ○ Information affecting subjects' willingness to participate in the research ○ Newsletters that will be sent to enrolled subjects that need more timely review than annually	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.	

** *Exceptions for requiring an ORIO to report a lapse in approval for a federally funded or FDA regulated study:*

- *When a termination report (study closure) is being submitted*
- *When IRBMED initiates and processes Administrative terminations when the PI is no longer available*
- *As determined by IRBMED Director or designee*

NOTE: Although an ORIO is not being required, as applicable, IRBMED will make every reasonable effort to verify that no study activities took place during the lapse

Other Reportable Information or Occurrence (ORIO)
https://az.research.umich.edu/medschool/guidance/other-reportable-information-or-occurrence-orio