**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)

<table>
<thead>
<tr>
<th>TYPE OF EVENT OR INFORMATION</th>
<th>Report as an ORIO within 7 CALENDAR DAYS of becoming aware of the event or information</th>
<th>Report as part of SCHEDULED CONTINUING REVIEW (SCR)*</th>
</tr>
</thead>
</table>
|                             | • 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 | *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.*  
  • 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) |
| Protocol Deviations         | • 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 a spreadsheet with aggregate reports 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** |
| Report(s) to or from oversight entity | • 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 | Upload these reports individually into SCR application-Section 4: Additional Supporting Documents  
  • 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.** |
| Report of lapse in IRB approval | • 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 |
| Accident/Incident           |                                                                                                  |                                                                 |

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

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<th>Category</th>
<th>Description</th>
<th>Note</th>
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<tbody>
<tr>
<td><strong>Complaint</strong></td>
<td>- Complaints related to subject safety or study conduct or supporting documents content</td>
<td>N/A</td>
</tr>
</tbody>
</table>
| **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.                                                                                                             |                           |

Effective March 6, 2017
Updated June 16, 2017