This document provides the reporting requirements to IRBMED for both Multi-Site HUM application and Performance Site HUM application when U-M

- *is a coordinating center*
- *is not the single IRB (sIRB)/IRB of record/reviewing IRB for sites other than U-M."

When U-M IRBMED is the sIRB/IRB of record/reviewing IRB, follow the Multi-Site Research reporting plan available in the IRBMED Multi-site Research Documents folders.

<table>
<thead>
<tr>
<th>Report Type</th>
<th>Within Multi-Site Application HUM Reporting (Events at non-UM Participating Sites, and reports addressing the whole study – U-M and other sites)</th>
<th>Within Performance Site HUM Application Reporting (Events at U-M Site)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAEs</td>
<td>N/A (unless UaP, see below)</td>
<td>Report per Adverse Event Reporting or approved Study-Specific Reporting Plan.</td>
</tr>
<tr>
<td>UaPs, including both AEs and ORIOs</td>
<td>Report UaPs per Statement of Practice: External Adverse Event Reports &amp; Unanticipated Problems. Identify in the submission title whether the UaP is or will be accompanying an Amendment updating study documents (ICD, protocol, IB, etc.)</td>
<td>Report potential UaPs per Unanticipated Problems Involving Risks to Subjects or Others.</td>
</tr>
</tbody>
</table>
| Deviations, including time-sensitive modifications | **Report within 7 days of becoming aware of the event or information:**  
- Protocol deviations that may represent a systematic problem requiring local evaluation by IRBMED to determine that sufficient local resources are available for safe conduct of the study  
- Major protocol deviations that may impact the safety of subjects (including breaches of confidentiality) and/or put the institution at risk  
- Deviations from eligibility criteria for one or two subjects. *(Not available for investigator-initiated studies managed through O-CTSU.)* | Report per Other Reportable Information or Occurrence (ORIO) Guidance  
If seeking IRB approval beforehand: See guidance: Time-Sensitive Modifications |
| Data and Safety Monitoring (DSMB, DSMC, DMC) Correspondence (Reports, Letters) |  
- Submit determination / outcome reports received individually during the year per IRB Other Reportable Information or Occurrence (ORIO) Guidance.  
- Annual summary report *(e.g. CERVANT report for oncology)* must be submitted as part of SCR (upload into 4.1).  
  o On the summary, identify any reports previously submitted individually by writing the Adv# next to the item(s). |  
- If determination / outcome requires a response from UM *(i.e., UM site action item)*, report as an ORIO per IRB reporting guidance.  
  o When a single report addresses U-M and external events, Performance Site ORIO should respond only to the U-M event(s). |
| Annual Report to the FDA | If the IND/IDE holder is from UM, upload into the SCR submission  
N/A if the IND/IDE holder is not from UM | N/A |
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<td>Other Correspondence to the FDA (i.e. amendment)</td>
<td>Upload into eResearch in an amendment</td>
<td>N/A</td>
</tr>
</tbody>
</table>
| Other ORIOs | Anything else that affects the entire study, e.g.:  
- Safety information that could affect risk to participants, or otherwise require changes to study materials  
- Study being terminated and all remaining patients in FU are being taken off study;  
- Study closed to accrual;  
- Response to PRC due to low accrual for the entire study | Report per Other Reportable Information or Occurrence (ORIO) Guidance  
In many cases, a report from the Coordinating Center to Performance Sites can be submitted by Performance Site as part of SCR. |