Multi-Site & Performance Site Reporting to IRBMED https://az.research.umich.edu/node/1596/

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.

Report Type	Within Multi-Site Application HUM Reporting (Events at non-UM Participating Sites, and reports addressing the whole study – U-M and other sites)	Within Performance Site HUM Application Reporting (Events at U-M Site)
SAEs	N/A (unless UaP, see below)	Report per Adverse Event Reporting or approved Study-Specific Reporting Plan.
UaPs , including both AEs and ORIOs	Report UaPs per Statement of Practice: External Adverse Event Reports & Unanticipated Problems. Identify in the submission title whether the UaP is or will be accompanying an Amendment updating study documents (ICD, protocol, IB, etc.)	Report potential UaPs per Unanticipated Problems Involving Risks to Subjects or Others.
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).
	  ○ 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.
		  ○ 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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Other Correspondence to the FDA (i.e. amendment)	Upload into eResearch in an amendment	N/A
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.