POST-APPROVAL REPORTING REQUIREMENTS SUMMARY SHEET

Federal regulations and UCM's IRB require investigator reporting of any post-approval research-related event or information that may meet the institutional definitions of "*unanticipated problem involving risk to participants or others"* or *"serious or continuous noncompliance*." The IRB determines whether these definitions apply when evaluating investigator event reports. The following table summarizes which types of events or information should be reported to the IRB, the reporting window and appropriate reporting form to use.

What, When, and How to Report to the IRB

Type of Event	When to Report	Reporting Form
ADVERSE EVENTS		
Internal (on-site) adverse event that PI determines to be 1. Definitely, probably or possibly related *AND* 2. Serious or unexpected	Within **5 working days** of PI awareness **Internal, related deaths and life-threatening events:** Report **immediately**	SAE – Serious Adverse Event Form
External (off-site) adverse event that PI determines • Changes the study risks or benefits, *OR* • Necessitates modification to the IRB-approved consent document(s), and/or the IRB-approved application/protocol	Within **10 working days** of PI awareness	Adverse Event Form
OTHER TYPES OF EVENTS OR SAFETY INFORMATION		
Other Safety Information or Publication	**Change** to risk language: Within **10 working days** of awareness	Amendment
OTHER TYPES OF EVENTS OR SAFETY INFORMATION		
Major Violation including, but not limited to incorrect intervention given, enrollment of ineligible participant, key safety procedure/lab not done or done outside window.	Within **10 working days** of awareness	Contact Research Compliance Officer
Immediate Protocol Change to Protect Participant Safety	Within **10 working days** of occurrence	Contact Research Compliance Officer
Major Incident including, but not limited to problem with consent or recruitment process, significant complaint or concern, lapse in study approval, loss of adequate resources, potential breach of confidentiality or privacy.	**Potential breaches of privacy or confidentiality:** Within **48 hours** of awareness **Other major incidents:** Within **10 working days** of awareness	Contact Research Compliance Officer