



HRPP Notes

Human Research Protection Program


Maine Medical Center
Research Institute

Volume 17, July 08, 2011

Continuing Review: What is New Information?



MMC has a new online tool to help guide you to the correct form and when they should be reported- [Event Reporting Guide](#)

TYPES OF EVENTS

- * Non-Compliance – [click for definition](#)
- * Continuous Non-compliance – [click for definition](#)
- * Safety Reports – All new or updated study product safety information and a summary of changes.
- * Monitor reports – Any reports received from the SeQR office, the sponsor, or any other monitoring agency.
- * Serious Adverse Events – [click for definition](#)
- * Deviations or Violations – [click for definition](#)
- * Data Integrity – Report any alterations to data or storage issues (ie: data sitting open on an unmonitored machine).
- * Medication Errors – Errors that have or could have caused risk to subjects or others.
- * Complaints – Complaint from a participant regarding a research-related injury or study activities or a complaint from study personnel regarding fabrication of data or research misconduct
- * Misconduct of Study Personnel – Conduct that has adversely affected the safety and welfare of the study participant, the integrity of the study, or changed the risk/benefit balance.
- * HIPAA Violations – When identifiable private health information is disclosed or made public on purpose or by accident.
- * DSMB Reports – Some studies have a Data and Safety Monitoring Board that will issue reports based on current study data.
- * Breach of Confidentiality – When confidential information is disclosure or loss/stolen (ie: lost laptop, inadvertent email distribution)
- * FDA Reports – Any adverse finding issued to, or enforcement action taken against, the PI (ie: FDA Form 483 or Warning Letter).
- * Protocol Changes (for one individual) – Any changes to a protocol that effects one patient only (ie: crushing a pill for ease of swallowing).
- * Incarceration of a Research Subject – If the subject is incarcerated during a study, no matter if the incarceration is related to the study or not.