FRI Institutional Review Board
Post-Approval Reporting Requirements: Summary Sheet for Principal Investigators

Federal regulations and the FRI IRB require investigator reporting of any post-approval research-related event or information that may meet the FRI IRB's definitions of unanticipated problem involving risk to participants or others, or serious or continuous noncompliance. The FRI 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 FRI IRB, and indicates the reporting window and appropriate reporting form to use.

Post-Approval Reporting Requirements: What, When & How to Report to the FRI IRB

Type of Event	When to Report	Reporting Form
ADVERSE EVENTS / UNANTICIPATED PROBLEM		
Greater than Minimal Risk Studies Adverse Events/Unanticipated Problems that PI determines to be **Serious**, regardless of relatedness or expectedness.	Report within 48 hours of FRI PI awareness. *All* deaths must be reported within 24 hours of discovery.	Adverse Event Reporting Form
Minimal Risk Studies 1. Adverse Events/Unanticipated Problems that PI determines to be: • Definitely related or possibly related, • Serious, AND • Unexpected	Report within 48 hours of FRI PI awareness. Deaths meeting the criteria to the left must be reported within 24 hours of discovery.	Adverse Event Reporting Form
2. All other adverse events not meeting the criteria above.	Do not need to be reported to the IRB (unless required by sponsor).	NA
External (off-site) serious adverse event that: • changes the study risks or benefits, AND/OR • necessitates modification to the FRI IRB-approved consent document(s), and/or the FRI IRB-approved application/protocol	Report within 10-working days of FRI PI awareness.	Adverse Event Reporting Form
OTHER TYPES OF EVENTS		
Audit or Monitoring Report with significant findings by oversight entity (e.g. DSMB, FDA)	Within 10-working-days of awareness (no significant findings, submit with continuing review)	Letter from FRI PI
Hold on Study Activities due to unexpected risk or required by any oversight entity (e.g. FDA, OHRP)	Within 10-working-days of awareness	
Updated Investigator Brochure (new risks identified)	Within 10-working-days of awareness	
Other Safety Information or Publication (e.g. pharmacy package inserts)	**Change** to risk/benefit: Within 10-working-days of awareness.	Letter from FRI PI
PROTOCOL DEVIATIONS AND RESEARCH RELATED INCIDENTS		
Major Deviation: Events that affect the rights, welfare and safety of a research subject, the integrity of the research data and/or a research subject's willingness to continue study participation. This may include, 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	Protocol Deviation Form
Immediate Protocol Change to Protect Participant Safety	Within 10-working-days of occurrence	
Minor Deviation: Events that do not affect the rights, welfare, or safety of the research subject or integrity of the research data.	At time of continuing review	