**PURPOSE:** To establish standard procedures required for reporting unanticipated problems, serious adverse events (SAEs) & adverse drug/device events.

**SCOPE:** Applies to all site personnel involved in the implementation and coordination of clinical research.

**PERSONNEL RESPONSIBLE:**  Principal Investigator and when delegated by the Principal Investigator---- Sub-Investigators, Study Coordinator and/or other pertinent staff.

**PROCEDURES:**

Unanticipated problems, serious adverse events (SAEs) & adverse drug/device events will be reported in accordance with the Washington University IRB policy:

[**http://hrpohome.wustl.edu/**](http://hrpohome.wustl.edu/)

**RESOURCES**:

* 21 CR 312.32 IND Safety Reports
* 21 CFR 312.64 Investigator Reports
* ICH GCP Consolidated Guideline Part 4.11 Safety Reporting

**TOOLS:**

* Washington University Human Research Protection Office (HRPO)