**PURPOSE:** To establish standard procedures required for obtaining and maintaining Human Research Protection Office (HRPO) approval.

**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:**

Study Documents will be submitted, processed, and maintained in accordance with the Washington University IRB policy:

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

**RESOURCES**:

* 21 CFR 54.25—Institutional Review Board
* 21 CFR 56.103 –Circumstances in which IRB Review is Required
* 21 CFR 56.109- IRB Review of Research
* 21 CFR 56.111 Criteria for IRB Approval of Research
* 45 CFR 46.109—IRB Review of Research (if applicable)
* ICH GCP Consolidated Guideline—Part 4.4 Communication with IRB/IEC

**TOOLS:**

* Washington University Human Research Protection Office (HRPO)