

RESEARCH COORDINATOR / STAFF RESPONSIBILITIES

1. **OBJECTIVE:** Outline the responsibilities of Research Coordinators and other staff assisting an Investigator in the conduct of a human research study
2. **DEFINITION:** The Principal Investigator (PI) through the Research Scope of Practice defines the responsibilities and roles of the research coordinator and/or staff. The Research Coordinator / Research Staff may be designated to act as a liaison between the PI, the sponsor, the IRB, and the R&D Committee.
3. **RESEARCH STAFF RESPONSIBILITIES:**
 - a) Completes required training and credentialing prior to engaging in study activities and must maintain current training and educational requirements
 - b) Conducts the study in accordance with the federal regulations and institutional policy
 - c) Follows the Privacy Rules regarding privacy and use of Protected Health Information (PHI)
 - d) Performs study activities as delegated by the PI and defined in the Research Scope of Practice
 - e) Assists with IRB and R&D regulatory issues as required
 - f) Ensures the safety and welfare of the study participants
 - g) Performs protocol activities correctly and completely
 - h) Recruits and screens potential study participants according to the protocol's criteria
 - i) If delegated, obtains and documents written informed consent and HIPAA Authorization
 - j) Keeps accurate records of all subjects screened and recruited in the study in an enrollment log (as required by the IRB)
 - k) Maintains adequate source documents for each study participant and records all observations during the study
 - l) Documents all research activities in source documents and CPRS (as appropriate) as required by VA policy
 - m) Collects study data accurately in the Case Report Forms (CRFs) for each participant
 - n) Promptly reports any Adverse Events and Unanticipated Problems to the Investigator, study sponsor and the IRB within the VA reporting window (5 days)
 - o) Maintains a current Regulatory Binder (refer to Regulatory Documents Policy)
 - p) Keeps the PI informed of all study-related activities