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
   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 both unanticipated and research related local SAEs and serious problems to the IRB within 5 days
   o) Immediately provides oral report to the IRB for both unanticipated and research related local deaths. Submits a written report to the IRB within 5 days.
   p) Maintains a current Regulatory Binder (refer to Regulatory Documents Policy)
   q) Keeps the PI informed of all study-related activities