Study Coordinator (SC) Responsibilities

I. Definition

Study coordinators serve to aid in the coordination, management and conduct of clinical research under the supervision of a designated physician/investigator.

II. Responsibilities

Many investigators delegate the day-to-day administrative requirements of a protocol to the clinical and non-clinical research study coordinator (SC). The link between the subject, the investigator and the sponsor is important to the safe and ethical conduct of any clinical research trial. The duties and responsibilities of a SC may vary across different infrastructures. Some general duties are listed below:

• Facilitate information exchange among sponsor/Contract Research Organization (CRO), investigators, faculty, staff, research subjects, the subject’s representatives and/or families or other support system.
• Work directly with prospective and enrolled subjects and their families or caregivers, as applicable.
• For some studies, the SC may promote, advertise, and conduct telephone and face-to-face screenings to recruit potential subjects.
• Ensure that all subjects are fairly and equitably chosen.
• May assess and coordinate the research subject’s clinical/laboratory testing and physical exams, if trained appropriately.
• May obtain vital signs such as height, weight, blood pressure, respiration rate, and pulse.
• May withdraw blood and/or obtain, process and ship blood/urine specimens.
• May follow up with subjects after the study activity ends.
• Manage paperwork, electronic correspondence and data.
• May also be listed as a Sub-I at the discretion of the PI.
  Provide safety and protection to all subjects while collecting and managing data obtained from the subject for the study.
• Ensure subject safety by providing information regarding adverse events and any pertinent information to subjects and investigators in a prompt manner.
• Serve as an advocate for the research subject.
• Communicate with all members of the research team regarding the study, the research subjects or any items related to the conduct of the research study.
• Personally assure that every reasonable precaution is taken to reduce to a minimum any risk to the subject.
• Compliance with all federal, state, and institutional rules and regulations related to research involving human subjects and human subject-derived information and materials.
• Understand the implications of his/her evolving role from health care provider to
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research team member, as applicable. A patient is no longer just a patient when they become a research subject. The protocol will determine the care of the subject while a physician may determine the care of his patient.

- Assist the principal investigator to assure that only qualified individuals perform study related procedures with the appropriate level of supervision under the laws of the state of Georgia and the policies of GRU and/or the Charlie Norwood VA Medical Center.
- The SC will not deviate in any way from the IRB (either external or internal) approved protocol unless the Committee has provided written notice of approval to the investigator’s written request unless such a change is immediately required to reduce risk to the subjects. This includes such changes that may be part of the routine standard of care for patients unless it reduces risks.
- Provide the subject’s health care provider with any important information regarding the subject’s health that may occur during the course of the research, if requested by the research subject.
- Report to the IRB any findings and allegations of non-compliance.