

Human Research Protections Program (HRPP)

What is a Study Coordinator (SC)?

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. Broadly speaking, the coordinator generally manages the administrative responsibilities of the trial including research subject participation and acts as a liaison between the trial site, sponsor, and research subject.

The coordinator must make every effort to:

- 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.
- 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.
- Provide safety and protection to all subjects while collecting and managing data obtained from the subject for the study.
- For some studies, the SC may promote, advertise, and conduct telephone and face-to-face screenings to recruit potential subjects.
- May assess and coordinate the research subject's clinical/laboratory testing and physical exams, if licensed and 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 a great deal of paperwork, electronic correspondence and data.
- May also be listed as a Sub-I at the discretion of the PI.
- Reporting to the IRB any findings and allegations of non-compliance.

What are My Responsibilities as a Study Coordinator?

The responsibilities of a SC may vary from study to study but generally include the following broad guidelines:

- 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.
- Ensure that all subjects are fairly and equitably chosen.
- 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 research team member, as applicable. A patient is no longer just a patient when

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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 licensed and/or otherwise qualified individuals perform study related procedures with the appropriate level of supervision under the laws of the state of Georgia and the policies of MCG, MCGHI, and/or the Charlie Norwood VA Medical Center.
- The SC will not deviate in any way from the IRB (either HAC or CRRI, as appropriate) 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.
- Report to the IRB any findings and allegations of non-compliance.

Is There a Checklist to Help Me Understand My Responsibilities as a Study Coordinator?

Please be aware that not all responsibilities or scenarios can be covered. The following checklist is a brief listing of items and systems that will aid the clinical and non-clinical SC in assisting the investigator in meeting the requirements of a protocol:

- Be aware of and utilize resources available, including, but not limited to:
 - Human Assurance Committee (HAC) and web page, as applicable
 - Chesapeake Research Review, Inc. (CRRI), as applicable
 - Office of Human Research Protection (OHRP) web page
 - Division of Sponsored Programs Administration (DSPA) and web page
 - Clinical Research Pharmacy (CRP)
 - Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP) web page
 - Food and Drug Administration (FDA) web page
 - MCG Home Page
 - Notify investigators of changes, updates, etc. when appropriate.
- Have access to the internet, specifically the MCG home page (www.mcg.edu), the FDA home page (www.fda.gov), Center for Drug Evaluation and Research (CDER) home page, etc.
- Understand and follow institutional policies and procedures concerning human subject research. Notify investigators of changes, updates, etc. when appropriate.
- Understand and follow FDA rules and regulations concerning human subjects. Notify investigators of changes, updates, etc. when appropriate.
- Understand and follow DHHS OHRP rules and regulations for human subject research.
 - Notify investigators of changes, updates, etc. when appropriate.
- Understand ICH guidelines, if applicable. Notify investigators of changes, updates, etc., when appropriate.
- Have access and read/respond to email.
- Have access to the electronic medical records system, if appropriate.

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- Have access to the electronic scheduling system for patient/subject information, if appropriate.
- Attend and participate in the training classes offered by the OHRP.
- Accurately and promptly complete case report forms (CRF) or data collection tools (DCT).
- Assume personal responsibility for professional growth through such avenues as certification, education, etc.
- Attend and participate in the bi-monthly **RESCUE** meetings.
- Facilitate information among sponsor/CRO, investigators, faculty, staff, research subjects, subjects' representatives and/or families.
- Understand and abide by responsibilities as outlined by MCG Health, Inc. (MCGHI), if appropriate.
- Complete required education for human subjects' protections per MCG administrative policies and procedures.
- Ask questions when needed and encourage other research team members to do the same.

Who Are Research Team Members?

Research team members are all persons who will have a significant role in the design or conduct of the research. At a minimum, the team consists of the Principal Investigator (PI), Sub- Investigators (Sub-I), Study Coordinators and other individuals or personnel who may be named on a grant or contract application, who may be listed on the Form FDA 1572, who are named as contact persons in the informed consent document (ICD) or any recruitment materials, or who provide supervision of the persons conducting the research. For additional information on the roles and responsibilities of these individuals please refer to the section on Investigators and Research Team Members.