

## MIS Clinical Research Site (CRS) Roles Terms and Definitions

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**ACTG Coordinator:** In instances in which the designated CRS Coordinator is not directly involved with ACTG studies, this person serves as the primary Coordinator for ACTG work.

**CAB Member (not CRS staff):** Volunteer from the general public and from the diverse community affected by AIDS who ensures representation of the community's needs. This person is **not** employed as a paid staff member at a CRS.

**Community Educator:** Person who develops and implements a community education plan to increase awareness and understanding of research activities.

**Counselor:** Individual trained to give advice, guidance, and emotional support to research participants.

**CRS CAB Coordinator (ACTG):** CRS staff person responsible for supporting and coordinating with the CRS's affiliated CAB. A CRS may have multiple CRS CAB Coordinators.

**CRS Coordinator:** One officially designated site/study/protocol coordinator who is responsible for the day-to-day conduct of the research activities and oversight or performance of actual duties surrounding conduct of research activities at an individual site. Only one per CRS as determined by DAIDS. Considered Key Personnel.

**CRS Leader:** Individual who manages a Clinical Research Site as an Investigator.

**CRS Staff:** Any site staff person whose role is unknown or not included in the list of defined site roles.

**CTU Business Official:** By signing a grant application, this individual certifies that the applicant organization will comply with all applicable assurances and certifications referenced in the application. This individual as the Authorized Organizational Official (AOO) is the designated representative of the grantee organization in matters related to the award and administration of its NIH grants, including those that require NIH approval.

**CTU Coordinator:** Individual responsible for coordination and facilitation of research activities across the CTU that may include administration, financial management, training, staff supervision and evaluation, and logistics.

**CTU Principal Investigator:** Individual designated by the applicant organization to direct the project or program supported by the grant, with responsibility and accountability to applicant organization officials for the proper conduct of the project or program and the grant funds. Typically, this individual has ultimate responsibility for the research activities at the site.

**DAIDS Program Officer:** DAIDS representative for site development at the Office of Clinical Site Oversight.

**Data Manager:** Individual delegated the responsibility of ensuring complete and accurate data entry and submission to the Data Management Center regarding research activities conducted at their site.

**GCAB Representative (ACTG):** One CAB Member (Not CRS Staff) per CAB identified to serve as the representative from the CAB to the ACTG Network. Responsible for completing ACTG CAB surveys. This person may or may not be the CAB member who travels to the ACTG group meetings.

**Investigator:** Individual involved with the principal investigator in the scientific development or execution of the project. Employment or affiliation may be with the applicant/grantee organization or another organization participating in the project under a consortium agreement. Typically, these individuals have doctoral or other professional degrees,

although individuals at the masters or baccalaureate level should be included if their involvement is substantial.

**Laboratory Director:** Person, usually an MD or PhD scientist, who reviews and signs all operating procedures and reports and is ultimately responsible for a laboratory's performance and capabilities.

**Laboratory Manager/Supervisor:** One or more persons responsible for overseeing daily laboratory operations, review and release of patient reports and proficiency testing results, and writing laboratory SOPs.

**Laboratory QA/QC Coordinator:** Individual responsible for overseeing laboratory staff safety and training, QC performance, equipment preventative maintenance schedules, and performs internal audits. This person normally does not perform testing in the laboratory.

**Laboratory Technician/Technologist:** Individual who performs laboratory tests and is usually involved with data submission. This person may be the primary laboratory contact for communication with the DAIDS contractors.

**Mentor:** Experienced professional who is contracted to coach and provide guidance to another individual or site.

**NCC International Site Specialist:** Network Coordinating Center representative working with sites and the International Scientific Officer to ensure all Network and DAIDS requirements are met before protocol activation at sites.

**Pharmacist of Record:** The primary licensed/registered pharmacist who performs the day to day pharmacy activities and study product management including but not limited to the procurement, storage, preparation, dispensing and final disposition of study products for DAIDS funded and/or sponsored clinical trial(s).

**Pharmacist:** Individual with a pharmacy degree licensed or registered at the practice location to prepare and dispense drugs.

**Pharmacy Technician:** Individual who provides technical assistance under the supervision of the pharmacists.

**Recruitment/Retention Specialist:** Person who identifies and relocates potential research participants through a variety of recruitment and retention activities.

**Regulatory Coordinator:** Individual delegated with the responsibility of ensuring and facilitating regulatory compliance with Federal Regulations, sponsor requirements, and institutional policies regarding research activities conducted at their clinical site.

**Research Clinician (not medical doctor):** Individual considered a mid-level practitioner directly involved with the research activities, performing clinical assessments and data collection of research participants. Typically these individuals have degrees that qualify them as a Nurse Midwife, Nurse Practitioner, or Physician's Assistant.

**Research Nurse:** Individual with a degree in nursing licensed or registered at the practice location and who is directly involved with the research activities, performing assessments and data collection of research participants.

**Social Worker:** Person, generally with a professional degree, who provides social services such as counseling, assistance, and guidance for establishing home care, transportation, long-term medical care, financial support, and other resources.

**Study Coordinator:** One or more persons responsible for the day-to-day conduct of the research activities and oversight or performance of actual duties surrounding conduct of research activities at an individual site.