ICAP – COLUMBIA UNIVERSITY
JOB DESCRIPTION

Job Title:	Study Coordinator (for COVID grant-funded research)
Reports To (Title):	Principal Investigator
Location:	**ICAP Harlem Prevention Center, 215 West 125th Street**

POSITION SUMMARY

Under the supervision of the Principal Investigator, the Study Coordinator will collaborate and oversee all activities related to COVID grant-funded research conducted at designated NYC satellite sites of Harlem Prevention Center (HPC) Clinical Research Site (CRS), including site initiation and protocol start-up activities, regulatory requirements, recruitment and retention plans and implementation, data management, and quality assurance and control activities. The Study Coordinator will work closely with the CRS Leader, CRS Coordinator, site Principal Investigator, satellite site study investigators and coordinators and staff in the implementation of study goals and objectives.

MAJOR ACCOUNTABILITIES

- Conduct all research activities in accordance with study protocol, standard operating procedures and other appropriate institutional regulations, procedures, and policies, including procedures to safeguard confidentiality of study participants. 5%

- Conduct pre-site activation visits to facilitate site readiness, trouble shoot any areas of concern, and support satellite staff to develop schedules, logistics, and supply management to implement study activities. 10%
- In collaboration with the satellite site pharmacists of record, laboratory managers and study coordinators, ensure coordination between the study, pharmacy and lab staff in the handling, accountability and chain of custody of the study product and laboratory specimens. 10%
- In collaboration with the satellite site investigators and study coordinators, assist in the development of an effective and continuous quality improvement plan to ensure the soundness and efficiency of all operational processes related to study activities at the satellite sites. 10%
- In collaboration with satellite site investigators and study coordinators, assist in data quality management activities and utilize the findings to develop strategies for improvements. 10%
- In collaboration with the satellite site investigators and study coordinators, ensure timely submission of protocol specific regulatory documents to the central IRB. 10%
- In collaboration with the satellite site investigators and study coordinators, ensure up-to-date essential documents and regulatory files. 10%
- In collaboration with the satellite site investigators and study coordinators, ensure timely collection and reporting of research information and that data is verifiable by internal and external reviewers. 5%

- Prepare reports of satellite site activities to the CRS Leader and Principal Investigator, if requested. 5%
- Conduct regular monitoring of satellite sites during study enrollment and follow up period. 10%
- Assist satellite sites during external monitoring visits and take proactive measures to ensure successful outcomes. 5%
- Attend staff meetings, study specific and other study related trainings as requested by the CRS Leader, CRS Coordinator and site Principal Investigator. 5%
- Perform other duties as assigned. 5%

EDUCATION

- Bachelor's degree in Nursing and a graduate from an accredited nursing program with current New York State RN License OR an International Medical (MD, MBBS) Graduate (IMG)
- At least 2-3 years research experience as a study coordinator of multicenter IND trials.

EXPERIENCE, SKILLS & MINIMUM REQUIRED QUALIFICATIONS

- Holds a CCRC credential from ACRP or CCRP credential from SoCRA or other clinical research certifications accredited by the National Commission for Certifying Agencies (NCCA).
- Knowledge of research data management and regulatory compliance.
- Excellent clinical, organizational, interpersonal and communication skills.
- Must be able to adapt to flexible schedule.
- Proficiency in computer applications.
- Meticulous attention to detail with the ability to multi-task.
- Ability to work under pressure and react effectively to urgent situations.
- Ability to work independently and as part of a team.

EXPERIENCE, SKILLS & PREFERRED QUALIFICATIONS

- An interest in/or experience with COVID related research
- Experience working with an ethnically, culturally, and racially diverse environment

TRAVEL REQUIREMENTS

- No international travel required
- Local travel required