

BOSTON MEDICAL CENTER

JOB DESCRIPTION SUMMARY

JOB TITLE: Study Coordinator	DEPARTMENT: Section of Infectious Diseases International and Translational Research
CODE: _____	FLSA STATUS: Non-Exempt
REPORTS TO: Director of Data Coordinating Center	GRADE: D12
SUPERVISES: Student Interns	DATE REVISED: _____

APPROVALS
DIRECTOR: _____ VP: _____ HR: _____

POSITION SUMMARY:
Under the direction of the Data Coordinating Center (DCC) Director, the Study Coordinator is responsible for off-site study coordination and data management oversight of specific INDO-US RePORT protocols. The Study Coordinator will provide study coordination of specific RePORT protocols – including implementing and monitoring quality control SOPs, conducting period quality assurance monitoring, working with investigators to develop and implement protocols at the Ponducherry, India site. The Study Coordinator will work with investigators to develop case report forms consistent with clinical protocols, sets up SOPs for clinical conduct, data collection, assist site staff/investigators in study implementation and performs quality assurance audits to validate data in preparation for analysis by biostatisticians.

- ESSENTIAL RESPONSIBILITIES / DUTIES:**
- 1) Coordinate development of clinical/scientific protocol and translate protocol into operational implementation and conduct.
 - 2) Plans, coordinates and performs database design, development and implementation for assigned clinical studies. Ensures that data security and integrity is maintained.
 - 3) Maintains electronic data capture system (Teleform), develops/designs case report forms and data entry screens, programs CRFs for validation (edit checks, queries) of data prior to entry into database.
 - 4) Perform quality control/assurance per standard operating procedures for each protocol. Coordinate QA/QC with on-site staff and investigators.
 - 5) Maintains routine progress reports on protocol milestones.
 - 6) Develop clinical research databases using SAS software. Works with statisticians and investigators in creating the appropriate databases/datasets from collected data for analyses.
 - 7) Maintain data management plan documentation of each database including, but not limited to, Database Diagram, Data Dictionary, Data Entry SOPs, Data Validation/Error Checking SOPs and CRF specifications.
 - 8) Train on, and follow, sponsor's standard operating procedures (SOP) as applicable for participating studies.
 - 9) Assists data managers, study coordinators, statisticians and investigators in meeting data collection milestones and generation of specialized reports and databases.
 - 10) Provide end user training and support of developed customized applications for each clinical protocol.
 - 11) Performs other duties as needed or as assigned.
- (The above statements in this job description are intended to depict the general nature and level of work assigned to the employee(s) in this job. The above is not intended to represent an exhaustive list of accountable duties and responsibilities required).

JOB DESCRIPTION CHARACTERISTICS

EDUCATION:

BOSTON MEDICAL CENTER

MS/MPH degree required in public health, with concentration in international health/infectious diseases.

CERTIFICATES, LICENSES, REGISTRATIONS REQUIRED:

None

EXPERIENCE:

Must have minimum of two (2) years experience with statistical analysis software (SAS), understanding of data management in clinical research and experience with clinical/epidemiologic research, especially in international health/infectious diseases.

KNOWLEDGE AND SKILLS:

- Understanding of clinical research components – data collection issues, human subjects protection, quality assurance and control.
- Familiarity with ICH Good Clinical Practices (GCP) consistent with registration clinical trials (FDA Guidance for Industry for Computerized Systems used in Clinical Trials (Title 21 CFR Part 11) preferred.
- Excellent programming ability in SAS statistical software is required. Knowledge of other programming and other scripting language is advantageous.
- Intermediate proficiency with Microsoft Office applications, use of file transfer protocols (FTP) preferred.
- Proficiency in a high level programming language preferred.
- Working knowledge of electronic data capture systems, specifically, Teleform (Autonomy Cardiff, Vista, CA) software.
- Ability to learn and assimilate other related computer applications into data management practices.
- Demonstrated progressive work experience in project management and project planning.
- Excellent oral and written communication skills.
- Great interpersonal skills and flexibility to work in a collaborative environment.
- Excellent organizational skills, including ability to multi-task, set priorities and meet timetables while managing several simultaneous projects.

AGES OF POPULATION SERVED:

Employees in this position must be competent to provide care to the following age groups: Check all that apply:

<input type="checkbox"/> Neonatal: Birth to 1 month	<input type="checkbox"/> Infant: To 1 yrs	<input type="checkbox"/> Toddler: 1 to 3 yrs	<input type="checkbox"/> Pre-school: 3 – 6 yrs
<input type="checkbox"/> School age: 6 – 12 yrs	<input type="checkbox"/> Adolescent: 12 – 18 yrs	<input type="checkbox"/> Young Adult: 18 – 30 yrs	<input type="checkbox"/> Middle age: 30 – 60 yrs
<input type="checkbox"/> Elderly: 60 – over	<input checked="" type="checkbox"/> Not Applicable		

SPECIAL WORKING CONDITIONS (RESPONSIBLE FOR ON-CALL, 24 HR. COVERAGE, ETC.):

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PHYSICAL AND ENVIRONMENTAL DEMANDS

This form is used to assist departments in identifying the physical and environmental demands of the position .

Physical Demands Without Accommodations	Hours at one time					Total Hours per day				
	0	<1/2	1/2-1	1-2	2-4	<1	1-2	2-4	4-6	6-8
Sitting					√					√
Walking		√				√				
Standing		√				√				
Bending Neck		√				√				
Twisting Neck		√					√			
Bending Waist (Forward or sideways)		√				√				
Twisting Waist		√				√				
Squatting	√					√				
Climbing	√					√				
Kneeling	√					√				
Crawling	√					√				
Repetitive Movement: Hand		√							√	
<input type="checkbox"/> Simple grasping: 1 hand__ both__		√						√		
<input type="checkbox"/> Power grasping: 1 hand__ both__	√					√				
<input type="checkbox"/> Fine Manipulation: 1 hand__ both__	√					√				
<input type="checkbox"/> Pushing/Pulling: 1 hand__ both__	√					√				
Reaching above shoulder height	√					√				
Reaching below shoulder height	√					√				
Moving items weighing up to 10 lbs.		√				√				
Moving items weighing 11 – 25 lbs.		√				√				
Moving items weighing 26 – 50 lbs.	√					√				
Moving items weighing 51 – 75 lbs.	√					√				
Moving items weighing 76 – 100 lbs.	√					√				
Moving items weighing over 100 lbs.	√					√				

Environmental Demands (Check all that apply)

- Extreme Cold (below 32 degrees) Source _____
- Extreme Heat (above 100 degrees) Source _____
- Noise (Need to shout to be heard) Source _____
- Vibration Source _____
- Exposure to dust, gas, fumes, steam, chemicals Source _____
- Work outdoors (no effective protection from weather)
- Work at heights (such as scaffolding or ladders)
- Protective equipment required (Respirator, earplugs, mask, gloves, eyewear, etc) _____
- Potential exposure to infectious diseases.
- None (Not substantially exposed to adverse environmental conditions).

External and internal applicants, as well as position incumbents who become disabled as defined under the Americans With Disabilities Act, must be able to perform the essential job functions (as listed) either unaided or with the assistance of a reasonable accommodation to be determined by management on a case-by-case basis.