		ISSUED: 9/18/2020
TITLE: Clinical Research Coordinator	**SALARY TABLE:** PA	**CLASS CODE:** PN375
UNION: P&A Local 1979, U.A.W	**SALARY GRADE:** 12	**EEO CODE:** 30
JOB GROUPING: None	**FLSA:** Non-Exempt	**EMPLOYEE CLASS:** PN

POSITION PURPOSE

Coordinate and participate in clinical research studies by performing activities involved in the collection, compilation, documentation of research data. The position will work with principal investigators and other research team members to accurately and efficiently carry out a range of tasks associated with a variety of clinical research studies.

ESSENTIAL FUNCTIONS	% TIME
Recruit, screen, obtain informed consent, and enroll eligible participants according to protocol for clinical studies. Schedule and coordinate participant's study visits and/or work with outpatient scheduler. Directly interact with subjects in a clinic setting, including subject interviews, administering survey instruments, etc., per protocol requirement.	25 %
Collect and record participants' study-related data into electronic and paper case report forms. Ensure all study related documentation is completed accurately, in a timely manner, per sponsor requirements. Ensure compliance with protocol guidelines and regulatory agency requriements.	20 %
Collect, process, label, store, and ship bio-specimens for clinical studies. May obtain blood samples (including blood draws), cultures, tissues, urine, stool, nasal swabs, plasma microbiological isolates and other specimens for laboratory analysis and processing, depending upon on the study. Track and monitor participants' condition and test results during the course of the clinical studies. Relay relevant results to the clinical team. Perform study drug accountability, if needed, as per protocol.	15%
Manage all the regulatory activities and requirements relevant to the research. Manage the collection of essential regulatory documents and the execution of study protocol. Prepare IRB (Intitutional Research Board) initial applications, amendments, continuations, closures and submit electronically (ePortal for example) as well as manually, as needed. Prepare for sponsor monitoring visits, site initiation and closeout visits.	15 %
Assist the Principal Investigator with the sponsor budget. Work with administrative staff to ensure appropriate billing for study-related care. Coordinate with billing department to make sure that all the research related activities are billed to the sponsor and paid by the sponsor. Review billing calendars and study budgets to ensure appropriate care designations and costs for clinical studies.	10 %
Design source documents/ generic forms for data collection, recruitment materials, consent forms and other relevant documents for clinical studies as required. Perform general office and administrative duties related to clinical studies.	5 %

Participate in recruitment strategy meetings to enhance subject awareness of studies and boost subject participation. Attend investigator meetings and training as a study team member.	5 %
Other duties as assigned.	5 %

MINIMUM QUALIFICATIONS

Education:
Bachelor's degree in a medical or health science discipline or equivalent combination of education and experience.

Years of Experience Required:
Minimum one year experience working in a research or clinic environment and interaction with study populations.

Knowledge, Skills and Abilities:
Excellent interpersonal and communication skills. Experience with Microsoft Office products (i.e., Microsoft Word, Excel, Power Point) and Electronic Data Entry/Capture (EDC). Excellent multi-tasking, problem solving and record-keeping skills. Strong ability to work independently, exercising good judgement, with minimal supervision. Organizational and analytical and problem solving skills. Ability to function with diverse teams of people in a diplomatic, collaborative, and effective manner. Ability to work independently and adhere to established timelines to accomplish tasks. Understanding of ICH-GCP guidelines, OHRP, HIPAA, and FDA regulations. Ability to maintain data confidentiality and participant/subject/patient privacy. Working knowledge of medical terminology and assessment of laboratory values.

WORKING CONDITIONS

Hospital, outpatient clinic and office environments.