		ISSUED: 11/4/2021
TITLE: Regulatory Affairs Specialist	**SALARY TABLE: AP**	**CLASS CODE: PN384**
UNION: P&A, Local, 1979, UAW	**SALARY GRADE: 13**	**EEO CODE 30**
JOB GROUPING: None	**FLSA: Non-Exempt**	**EMPLOYEE CLASS: PN**

POSITION PURPOSE

Support the Clinical Research Division of the Department of Emergency Medicine by accurately submitting regulatory and IRB documents for new and ongoing studies. This position will work independently to ensure that the department is following internal and external policies and regulations, including and not limited to local and central Institutional Review Boards (IRB), Standard Operating Procedures (SOPs), study sponsors, Contract Research Organizations (CRO), US Food and Drug Administration (FDA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), and Good Clinical Practice (GCP) guidelines. This position reports to the Director, Clinical Research Operations.

Essential Job Functions	% Time
In accordance with the Federal Code of Federal Regulations (CFR), prepare, analyze, review, submit, maintain, and track regulatory files (paper and electronic) including key personnel forms, informed consents, appendices, amendments, continuations, unexpected problem reports, protocol deviations, revisions, modifications, and new study applications and protocols to local and central Institutional Review Board (IRB) and DMC Research Review (DMCRR). Creates cost and time analyses distinguishing between standard of care treatments and protocol specific tasks.	40%
Ensure the most current copies of documents are on file pertaining to department Master Delegation of Authority log, sponsor and site regulatory files including 1572, Financial Disclosure Forms (FDFs), investigator brochures, current staff and Principal Investigator (PI) CVs, PI medical licenses, staff and PI's human subject protection training (HSP), good clinical practice (GCP), and Health Insurance Portability and Accountability Act (HIPAA) training, College of American Pathologists Certificate (CAP)/ Clinical Laboratory Improvement Amendments (CLIA), and study binders. Assist with the development of standard operating procedures and training of study staff on regulatory procedures and compliance issues, adverse events, and protocol deviations. Make recommendations for improvements.	35%
Serve as a liaison and responds to queries from sponsors, contract research organizations, IRB, DMCRR and the department. Works with study monitors to process, review, and collect the appropriate regulatory documents in a timely manner. Prepare regulatory files for auditors and in anticipation of visits from monitors who oversee the progress of a clinical trial that occur at site initiation, close out, and intermittently throughout the clinical trial.	20%
Other duties as assigned	5%

MINIMUM QUALIFICATIONS

Education Bachelor's degree

Bachelor’s degree. Certified Clinical Research Professional certification, preferred.

Experience Specialist (minimum 5 years of job-related experience)

Five (5) years of experience involving clinical research regulatory responsibilities. Experience with submissions to the IRB and other regulatory entities. Demonstrated knowledge of good clinical practices for clinical research as defined by the Code of Federal Regulations (CFR).

WORKING CONDITIONS

Office setting with regular visits to external sites.
Ability to work after hours or weekends to meet study deadlines and requirements.