ANDREWS | RESEARCH & EDUCATION FOUNDATION

Job Description: Clinical Research Coordinator

ABOUT ANDREWS RESEARCH & EDUCATION FOUNDATION:

Andrews Research & Education Foundation (AREF) is seeking a motivated professional to join our research team as a Clinical Research Coordinator. AREF is the research and education arm of the Andrews Institute. All efforts of AREF are under the leadership of internationally renowned orthopedic surgeon Dr. James Andrews. The goal of AREF's research and educational initiatives are to provide evidence-based best practices for injury prevention, injury treatment, return to play or work rehabilitation programs, and increased performance. AREF's programs provide service to a wide range of clientele including athletes at all levels, the general population, physicians, rehabilitation professionals, health providers, and wounded warriors.

AREF's Regenerative Medicine Center (RMC) includes clinical space for regenerative medicine procedures and a facility for GMP/GTP compliant tissue processing and storage for developing stem cell technologies. The tissue processing and storage facility includes a classified ISO 7 clean room, cryopreservation equipment, and flow cytometry.

AREF's Surgical Skills Lab provides space for physicians and medical professionals to experience hands-on training in the latest surgical techniques and orthopaedic devices. The lab features full arthroscopic capabilities at five stations, mobile workstations equipped with cadaver stands and hardware, a walk-in freezer for specimen storage, an Instron machine for device testing, and C-arm capabilities for imaging purposes.

SUMMARY OF MAJOR FUNCTIONS:

The Clinical Research Coordinator works directly with physicians and other clinical research team members to oversee and implement enrollment into clinical research projects; performs all tasks related to enrollment including screening medical histories and records, determines if inclusion/exclusion criteria have been met, performs consent process, performs all follow up visits of enrolled subjects, maintains records of research to comply with HIPAA guidelines, meets regularly with clinical trial sponsor representatives to review clinical data, prepares biological samples to be analyzed or shipped to other facilities for analysis, and assists with surgical skills lab operations. This is a salaried/exempt position eligible for benefits.

Reports to:
Manager, Research & Development

FLSA:
Salaried Exempt

Major Duties and Responsibilities:

- Screens and recruits potential study participants for inclusion/exclusion criteria
- Explains and implements the informed consent process
- Maintains familiarity with FDA regulations for clinical research
- Maintains familiarity with HIPAA guidelines
- Maintains Good Clinical Practice certifications
- Schedules patient and provider visits
- Assumes responsibility for complete and accurate data entry

Designs and administers methods to increase subject recruitment and retention

Maintains Institutional Review Board Regulatory aspects for studies

Creates and maintains study patient materials and charts

Prepares biological samples

Documents participant data on case report forms (CRFs) and source at each study visit

Coordinates patient care

Develops credible relationships with patients, customers, and physicians

Implements protocols as designed by sponsors and physicians

Implements standard operating procedures for the facility

Assists in preparation of revisions of standard operating procedures

Responsible for environmental monitoring

Responsible for record retention

Participates in research proposal planning and cost estimation

Works with clinical faculty in developing strategies for expanding and promoting research

Works directly with physicians and other staff to manage clinical trials, outcomes research, and investigator-initiated research.

Attends and participates in research meetings.

Submits accurate data for computer data base and electronic data capture (EDC).

Reviews schedule, on a daily basis, to ensure availability and timely scheduling.

Provides telephone coverage and back up coverage when appropriate.

Participates and prepares for site and monitoring visits with sponsors.

Assists and works with outcomes data tool and serves as liaison to medical office staff.

Works with staff and outside groups to attract and schedule users to Surgical Skills Lab

Cleans, organizes, and maintains lab facility including dissection tables and instruments, Instron, surgical instruments, and cold room

Assists teammates as needed with organizing community outreach events, conferences, and in-house education seminars

Assists physicians and staff with research procedures and protocol.

Adheres to the essential functions of Andrews Research and Education Foundation's Standard of Performance and Code of Conduct.

Performs other duties as assigned to support the essential functions of the job and operational needs of the department and AREF.

The person in this position may be subject to over 40 hours per week. This is a Monday-Friday (daytime) position and may be subject to occasional evening or weekend hours.

QUALIFICATIONS FOR POSITION: Summary of required and preferred education, experience, knowledge skills and abilities.

Minimal Qualifications/Competencies:

Undergraduate Degree in health-related field

Knowledge of regulatory policies and procedures related to cGCP, cGMP, and/or cGTP

Excellent verbal and written communication

Strong organization, time management, problem solving and critical thinking skills

Proficiency in common computer software including but not limited to spreadsheets, databases, word processing (Microsoft Office Suite)

Ability to work with diverse populations and be sensitive to gender, disabilities, cultural, and ethnic diversity

Ability to maintain confidentiality of sensitive information

Familiarity with orthopedics and medical terminology

Familiarity with research and data collection

Highly self-motivated with the ability to work independently and as part of a team

Preferred Qualifications:

1+ years of Clinical Research Coordinator or equivalent experience

Phlebotomy experience

Experience working with laboratory equipment such as flow cytometer, hemocytometer, ELISA, dissection equipment, video equipment and Instron

Experience in writing standard operating procedures

Certification in the handling and shipping of hazardous waste materials

Any relevant education, certifications, and/or work experience in the following settings may be considered: regenerative medicine lab, tissue processing facility, testing laboratory, pharmacy clean room, pharmaceutical manufacturing facility, cadaveric research lab, or postmortem care facility

Application Process: A completed application consists of:

Cover letter describing the candidate's career aspirations and their relevant skills, education and work experience that has prepared them for the position of Clinical Research Coordinator.

Curriculum vita or resume including references (names, titles, addresses, telephone numbers, and email) of at least three (3) individuals who can speak to the candidate's potential for success in this position.

This position is open until filled. First consideration will be given to complete applications received on or before April 4, 2022. Early response is encouraged. Only complete applications will be considered. Submit applications and questions to the email below.

Job Type: Full Time