**Supervisory Clinical Research Coordinator (SCRC)**

The primary purpose of the work is to supervise the Clinical Research Coordinators (CRCs), provide guidance on research regulations and operations to the CRCs and Investigators, and oversee the day to day operations of the Clinical Studies Center (CSC). These functions require interaction between many entities of the medical/scientific field and may involve controversial, unconventional or novel issues. The Supervisory Clinical Research Coordinator, is an employee of the Arizona Veterans Research and Education Foundation, reporting directly to Deputy Associate Chief of Staff (DACOS) for Research at the Phoenix VA Health Care System.

The SCRC is responsible for clinical administration, resource assessment and personnel management to ensure the safe and successful conduct of research protocols involving interactions with human subjects. The SCRC is responsible for:

* supervising non-nurse CRCs
* training coordinators and aspiring investigators
* serving as a clinical liaison to pharmaceutical and medical device companies
* assisting with site selection communication and initiation visits
* facilitating preparation and submission of regulatory documents to the appropriate research committees
* maintaining continuity and timeliness of required reporting documents
* training and facilitating support staff and principal investigators on submission of new proposals, continuation requests and closure requests for compliance with the various regulating bodies including the Office of Research Oversight (ORO)
* chairing the Research Performance Improvement Committee (RPIC)
* facilitating protection of human subjects and the safekeeping of all Protected Health Information (PHI), Individually Identifiable Information (Ill) and research study data

**MAJOR DUTIES**

**Provides Operational Oversight Management and Supervision- 45%**

Supervises all non-nurse CRCs in conjunction with the Principal Investigators (PIs) of the studies the CRCs are assigned to. Lends supervisory support to the non-nurse CRCs to assure compliance with study protocols, regulations and standard operating procedures. Assesses compliance with protection of human subjects, environmental safety, and infection control. Advises PIs of CRCs’ performance or conduct issues as they arise. Evaluates CRCs’ performance, recommends or provides training as appropriate, and prepares annual appraisals in conjunction with the PIs. Participates in decision making regarding staffing, equipment needs and space allocation.

Coaches CRCs on sources of research subjects, recruitment techniques, proper consenting of subjects, documentation, format to be used for study records, information security and the safe keeping of PHI and Ill. May screen and evaluate candidates for clinical projects with complex criteria or provide guidance to other CRCs on the proper processes to be used. Recommends the use of objective rating techniques to identify potential candidates for participation in study where project design is of limited complexity.

**Develops Policies and Procedures- 15%**

Develops the policies and procedures by which the Clinical Studies Center (CSC) operates. Serves as the principal advisor on day-to-day operation of the CSC. In collaboration with the Deputy ACOS/R and the Research Nurse Leader, develops priorities and plans for the full and efficient use of clinic space, coordinating scheduling and use. Develops and coordinates implementation of research methods and design standards, criteria and protocols relating to the operation of the CSC.

**Regulatory, Reporting, and Organizational Expertise- 30%**

Oversees the preparation of submission paperwork required for studies involving interactions with human subjects. Assists PIs in preparing proposals that meet the review process of all relevant committees of the Phoenix VA Health Care System. Serves as the liaison between the study team, sponsor, Contract/Clinical Research Organization (CRO), study navigators, and research leadership. Assists study teams respond to Research Committee requirements and requested changes. Maintains the regular reporting to research leadership of study progress, from invitation to closure.

Prepares in-depth reports for review by the R&D Committee and Sub-Committees. Performs a variety of administrative duties to maintain specialized data and implement study designs. Conducts program assessments and study pre-audits, and prepares reports requested by the Research office or the R&D Committee and Sub-Committees. Identifies problems and negotiates corrective action with the PIs concerning study related and programmatic issues. Determines the need for additional ad hoc review from safety and infection control staff.

Reviews project reports and audits from the facility Research Compliance Officer to assess Investigators conformity with research program guidelines and directives. Reviews and evaluates the CSC and provides recommendations for program strategies, modifications, budgeting, or improvements.

Monitors dates of recurring maintenance, and the disposal of expired medication and supplies to assure compliance with Joint Commission (JC), Office of Safety and Health Administration (OSHA) and other regulatory agencies. Consults with researchers within the VA, in academic settings (e.g. ASU, U of A, TGen, etc.), in the community and/or private industry to develop research projects opportunities that support the Phoenix VAHCS's research mission. Acts as a liaison to represent the facilities capabilities.

**Conducts Scientific Studies/Surveys/Investigations- 10%**

The SCRC designs, oversees, implements, and/ or participates in scientific research studies including the development, supervision and performing of surveys, investigations, or projects, to develop information in such areas as disease prevention, pathophysiology, etiology, treatment and control. Collaborates with other investigators and clinicians to foster bench to bedside, and other translational programs of study. Serves as the back-up CRC as needed to facilitate the initiation, continuation or closure of a study.

Performs other related duties as assigned.

**Knowledge Required:**

* Expert knowledgeable of VHA, ORO, JC, FDA and OSHA research policies and procedures, Human subject protection regulations
* Good clinical practices.
* Complete understanding of the complex research committee review process including paperwork requirements.

**Skills required**

* Certified Clinical Research Coordinator preferred
* Strong clinical and research experience and full knowledge of the research submission process, and VHA, ORO, JC, FDA, and OSHA regulations
* Ability to successfully provide oversight of multiple research protocols and coordinators
* Adeptness in prioritizing and making decisions regarding conflicting and ever-changing regulatory requirements
* Capacity to critically analyze and provide expert advice and consultation to the CRCs concerning complex and controversial methods and approaches
* Consistently communicate and treat customers (Veterans, their representatives, visitors, and all VA staff) in a courteous, tactful, and respectful manner. Provides the customer with consistent information according to established policies and procedures. Handles conflict and problems in dealing with customer constructively and appropriately.

**General skills**

Ability to communicate, both orally and in writing, to make clear, convincing presentations, explain and justify recommendations, represent the agency and assigned program or project areas, provide guidance and advise research leadership, respond to inquiries, and prepare reports.

Ability to motivate others to follow many complex regulatory requirements and the local Standard Operation Procedures.

Protects printed and electronic files containing sensitive data in accordance with the provisions of the Privacy Act of 1974 and other applicable laws, federal regulations VA statutes and policy, and VHA policy. Protects the data from unauthorized release or from loss, alteration, or unauthorized deletion. Follows applicable regulations and instructions regarding access to computerized files, release of access codes, etc., as set out in the computer access agreement that the employee signs.

**Compensation:**

$70,000 – 90,000 plus generous benefits, including paid 85-100% of the medical premiums for employees. AVREF pays 100% of the vision benefit premium and 100% of the dental premium. AVREF offers life insurance, short and long-term disability benefits, a Simple IRA with matching funds, vacation, and sick leave.

**Employer:**

The person hired for this position will be an employee of Arizona Veterans Research and Education Foundation, a 501 c 3, non-profit corporation, organized in the State of Arizona.

Arizona Veterans Research and Education Foundation is an equal opportunity employer.