HEALTHTRUST
Workforce Solutions

DIVISION SCOPE OF SERVICE

Division: CENTRAL/WEST TEXAS

DHP Classification: RESEARCH COORDINATOR

Name of Dependent Healthcare Professional (DHP):

Research Coordinator:
The Research Coordinator must have equivalent qualifications, competence and function in the same role as employed individuals performing the same or similar services at the facility, as defined by facility job description.

Definition of Care or Service:
The Research Coordinator acts as a delegate of the Principle Investigator of a research study for the purposes of conducting the research protocol. Scope of Service may include:

- Assesses and reassess patients / study subjects
- Screens and monitors processes specific to the research protocol
- Collaborates with the Interdisciplinary Care Team for care planning and discharge planning / coordination
- Delivers patient education related to the study
- Participates in patient care and treatment specific to the research study protocol that may include:
    - Administration of study medication
    - Accountability for investigational products
    - Collection and preparation of specimens
    - Participation in the recruitment, screening and consenting of study subjects
    - Diagnostic testing and procedures specific to the study protocol
    - Coordination of care with the interdisciplinary healthcare team
    - Observation of operative or invasive procedures
- Obtains and records patient medical history relevant to the research protocol
- Documents physician orders specific to the research protocol
    - Complies with facility policy for verbal physician orders
- Accesses and documents in the patient record of study subjects according to facility policy
    - Documents study related events in the patient medical record
- Maintains and secures patient data and records
- Demonstrates Clinical and Service excellence behaviors to include code of HCA conduct core fundamentals in daily interactions with patients, families, co-workers and physicians.

Setting(s):

- Healthcare facilities including but not limited to hospitals, outpatient treatment facilities, imaging centers, and physician practices

Supervision:

- Direct supervision by department director, site manager or designee of department caring for the patient / study subject
    - Indirect supervision by the study primary investigator
- Escorted access to the facility may be required by facility security policies

Evaluator: Department director or designee in conjunction with study primary investigator

Qualifications:

- Qualifications will be defined by study primary investigator
    - Qualifications should be appropriate for the interventions required to conduct the research protocol
    - Appropriate licensure and certification should be defined by the facility as appropriate for the patient care activities associated with the study protocol
        - The Research Coordinator must meet the same standards as facility staff performing the same patient care activity

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- Qualifications to consent subjects present in facility:
  - Proper training is required to consent subjects into clinical studies.
  - Individuals that have achieved Certified Clinical Research Coordinator (CCRC) status through the Association of Clinical Research Professionals shall meet this criterion by default.
  - Absent such official certification, documentation of other training of human subject protection or in the International Council of Harmonisation's Good Clinical Practice (GCP) guidance must be deemed acceptable by the facility.

State Requirements:

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Experience:

Experience requirements must be the same as the experience requirements of facility staff performing the same patient care activities.

Competencies:

The Research Coordinator will demonstrate:

- Accurate patient information review and evaluation
  - Uses at least two ways to identify patients before providing care or treatment
  - Accesses the patient medical record appropriately and maintains confidentiality and privacy in accordance with HIPAA regulations.
  - Documents in the medical record according to the facility standard / policy when appropriate
- Demonstrates skill and competence related to the clinical tasks/interventions required by the research protocol. Common clinical tasks / interventions performed by the Research Coordinator include:
  - Phlebotomy
  - Preparation of specimens for shipment
  - Assessment of vital signs
  - Administration of study related medication
  - Obtain EKG
- Adheres to the research protocol, particularly for safety evaluations.
- Communicates and coordinates study protocol activities with the interdisciplinary care team
  - Notifies the appropriate member of the interdisciplinary care team health provider when immediate intervention or treatment is necessary
- Adheres to chain of command and reporting requirements as related to adverse events or other patient safety issues
- Infection Prevention
  - Practices consistent hand hygiene
  - Uses personal protective equipment (PPE)
  - Required immunizations per DHP Division requirements
  - Complies with Isolation precautions

References:

DHP Printed Name: _____ **DHP Signature:** _____

Company/Vendor: _____ **Date:** _____