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DIVISION SCOPE OF SERVICE

Division: ALL HCA DIVISIONS-NOT INCLUDING SAN ANTONIO
Classification: CLINICAL RESEARCH COORDINATOR/ASSISTANT
Applicant Name:

Clinical Research Coordinator/Assistant:
The Clinical Research Coordinator/Assistant 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 Clinical Research Coordinator/Assistant 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 (as allowed by facility policy, and the Scope of Practice for their profession in the state).
- 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; consistent with professional scope of practice and facility policy
    - Collection of specimens
    - Participation in patient research consent process
    - 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 and consistent with professional scope of practice
- 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 Healthcare 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

DIVISION SCOPE OF SERVICE

- Escorted access to the facility may be required by facility security policies

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

Tier Level: 2

eSAF Access Required: YES

Qualifications:

- High School Diploma/GED or higher
- Documentation of training in the ICH Good Clinical Practices. For example:
  - Certified Clinical Research Professional (CCRP) through the Society of Clinical Research Associates (SoCRA)
  - Other training certificate that is approved by the Transcelerate consortium
  - Letter or Certificate with proof of Good Clinical Practices training

Preferred Qualifications:

- Certification from an NCCA accredited certification program is preferred:
  - Certified Clinical Research Coordinator (CCRC) through the Association of Clinical Research Professionals (ACRP)

NOTE: Where education may not be defined in qualifications area of the Scope, HCA Healthcare requires the highest level of education completed (not training or courses) confirmed on your background check.

State Requirements:

- N/A for the coordination of research
- Any interventions with patients (e.g. drawing blood, administering medications, EKG etc.) must be done in accordance with any state requirements when applicable

****Proof of training with drawing blood, administering medications, or working EKG must be shown on Skills Checklist if Coordinator ever needs to perform either for any study****

Experience:

- N/A

Preferred Experience:

- Experience requirements may be defined by the study primary investigator.

Competencies:

The Clinical Research Coordinator/Assistant 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
  - 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 Clinical Research Coordinator include:
  - Phlebotomy
  - 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

HEALTHTRUST
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DIVISION SCOPE OF SERVICE

- 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) when required
  - Required immunizations per Division requirements
  - Complies with Isolation precautions
  - Maintains sterile field

References:

(http://www.transceleratebiopharmainc.com/gcp-training-attestation/#headline4)

To verify ACRP certification:
http://www.avectraacrp.com/eWeb/DynamicPage.aspx?Site=ACRP&WebKey=078ec803-bceb-4265-9ca4-81780725fa6e

To verify an active SoCRA certificate: https://www.socra.org/certification/certification-program-overview/verify-certification/

To verify Transcelerate consortium
http://www.transceleratebiopharmainc.com/gcp-training-attestation/list-of-training-providers/

Guideline For Good Clinical Practice
https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf

Document Control:

- Made Global 8/21/2019
- Content updates 8/21/2019
- Cosmetic updates 11/26/2021

Your signature confirms you will be able to comply with the Qualifications and Competencies listed within this Scope of Service and that you will confirm education via your background check.

Applicant Printed Name: _____

Signature: _____

Date: _____