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DIVISION SCOPE OF SERVICE

Division: GULF COAST
DHP Classification: CLINICAL RESEARCH ASSOCIATE / MONITOR
Name of Dependent Healthcare Professional (DHP):

Clinical Research Associate / Monitor (Note: Tier 1):**
The Clinical Research Associate / Monitor (DHP) must have equivalent qualifications and competence as employed individuals performing the same or similar services at the facility.

Definition of Care or Service:
Monitors and accesses Protected Health Information of patients enrolled in a research study. The Clinical Research Associate **does not** perform any patient interactions or interventions.
Scope of Service may include:

- Monitors patient care for compliance with a research protocol
- Accesses the patient's medical record pursuant to the written HIPAA authorization that is part of the patient's research consent process
- Ensures that the facility has the proper equipment / space / resources to conduct a given clinical study
- Assists with accountability of investigational products
- Validates that the study activity occurred per the research protocol
- Monitors the quality of study data through periodic review
    - Verifies that study data submitted by the investigator matches the source documentation of the facility
- 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
- May be granted remote access to patient records (as approved by facility)

Supervision:

- Direct supervision by department director, site manager or designee of areas of facility visited
    - 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:

- Has obtained approval for access to the facility and patient records for the scope of service
- Qualifications may be defined by the study primary investigator

State Requirements:

- N/A for monitoring duties.

Experience:
Experience requirements may be defined by the study primary investigator

Competencies:
The Clinical Research Associate / Monitor (Tier 1) will demonstrate:

- Accurate patient information review and evaluation
    - Uses at least two ways to identify patients before interviewing

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- Accesses the patient medical record appropriately
- Documents in the medical record according to the facility standard / policy when appropriate

- Infection Prevention
  - Practices consistent hand hygiene
  - Uses personal protective equipment (PPE)
  - Maintains current immunization for influenza
  - Complies with Isolation precautions

As a DHP I am requesting approval to provide services in the following patient care area(s): (check all applicable)

Areas

☐*Cardiac Catheterization Lab*
☐*Endoscopy Lab*
☐*Operating Room*
☐*Radiology Department*
☐*ER (Emergency Department)*
☐*Pharmacy*
☐*Respiratory*
☐*Nursing Station (specify i.e. ICU)* _____
☐*Other:* _____

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

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