DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Responsibility and Delegation of Responsibility in Clinical Research	Policy #: CRP-1011
DEPARTMENT: DHR Health Institute for Research & Development	PAGE: 1 OF: 6
	EFFECTIVE: 02/19
APPROVED BY: Sohail Rao, MD, D.PHIL, President & Chief Executive Officer (Institutional Official, OHRP, DHHS)	REVIEWED/REVISED: 02/19, 02/20, 11/20, 01/21, 04/21, 05/21, 03/22

Purpose:
The principal investigator (PI) is the individual of record who assumes the authority and responsibility for the conduct of a clinical study. By signing Form FDA 1572, the PI agrees to comply with the conditions required by FDA for use of investigational articles. The PI has the authority to delegate duties to individual members of the research team; however, the PI is ultimately responsible for the overall conduct of the study.

APPLIES TO
This policy applies to the following potential research investigator; Physician staff employed by RMF and its affiliates; staff employed by DHR Health and its affiliates; faculty, fellows, residents, students of academic institutions with a current affiliation agreement with DHR Health Institute for Research & Development; staff and physicians of non-academic institutions with a current affiliation agreement with DHR Health Institute for Research & Development; Physicians with privileges to practice medicine in DHR Health, Physicians and staff employed by Starr County Memorial Hospital and its affiliates; faculty, fellows, residents, students of academic institutions with a current affiliation agreement with Starr County Memorial Hospital and its affiliates; staff and physicians of non-academic institutions with a current affiliation agreement with Starr County Memorial Hospital and its affiliates; Physicians with privileges to practice medicine in Starr County Memorial Hospital and its affiliates.

DEFINITION
This standard operating procedure (SOP) defines the responsibilities of the research team for conducting clinical studies at DHR Health Institute for Research & Development. It identifies administrative accountability as well as general responsibilities of the research team and of individual team members for fulfilling regulatory and clinical requirements. Regulations and guidelines that pertain to overall responsibility and delegation include:

21 CFR 312.53	Selecting investigators and monitors
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.61	Control of the investigational drug
21 CFR 312.62	Investigator record keeping and record retention
21 CFR 312.64	Investigator reports
21 CFR 312.66	Assurance of IRB review
21 CFR 312.68	Inspection of investigator's records and reports
21 CFR 312.69	Handling of controlled substances
21 CFR 812 Subpart E	Responsibilities of Investigators
21 CFR 812 Subpart G	Records and Reports

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Definitions:

- **A. Clinical trial/study:** Refers to any experiment in which one or more human subjects receives a drug, device or intervention for the purpose of determining the safety and efficacy of a diagnostic, therapeutic, or preventive use in human subjects.
- **B. Investigator:** A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.
- **C. Sub-investigator:** Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).

POLICY
PROCEDURE

A. Responsibility of Site Research Team

1. Principal Investigator

- The Principal Investigator (PI) has the primary responsibility for ensuring the ethical conduct of the research study. This includes protecting human subjects' rights, safety and welfare, protocol compliance, and adherence to institutional, state and federal regulations and guidance.
- The PI is responsible for ensuring informed consent is appropriately obtained from each participant and for appropriately maintaining study records.
- The PI is also responsible for complying with the financial and administrative policies and regulations associated with the award, overall fiscal management of the project, and conflict of interest disclosure.
- The PI oversees all aspects of a clinical trial from protocol design, recruitment, data collection, analysis and interpretation of results, but some tasks can be delegated to other research team members (Co- Investigators and Key Personnel).
- The PI is responsible for ensuring that all research team members have appropriate education, training and qualifications to assume delegated study tests. All study team members are responsible for ensuring that the conduct of the study is compliant with institutional, state, federal and industry guidance and regulations.

2. Sub-Investigator

- The Sub-Investigator/Co-Investigator may perform all or some of the PI functions, but they do not accept primary responsibility for the research study.
- The sub-investigator/co-Investigator is under the supervision of the PI and is responsible for performing study–related procedures and /or to make important study-related decisions in compliance with the ethical conduct of the study.

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3. Clinical Research Coordinator

- The Coordinator is responsible for drafting or editing the protocol document and submitting new protocols, protocol amendments, continuing reviews and safety reports to the appropriate IRB for review. They are responsible for maintaining regulatory binders in accordance with sponsor specifications and general industry standards. They often are the keepers of the delegation of authority log for key personnel involved in the study.
- The Coordinator is responsible for the overall data management of a research study. Data points for analysis must be extracted from multiple source documents and entered into specific databases. Coordinators ensure accurate and timely data entry in electronic databases, electronic case report forms (eCRFs) or paper case report forms (CRF). They work closely with sponsor monitors and resolve any data queries that may be generated. They also work closely with the research team in the study development process to identify key data points for collection and analysis for investigator initiated trials.
- The Coordinator oversees and coordinates the daily activities of clinical research studies. They work closely with the clinical teams and investigators to ensure that all protocol required procedures and visits occur according to protocol specified guidelines. Coordinators generally manage participant enrollment and ensure compliance with the protocol and other applicable regulations. This includes but is not limited to; participant recruitment, obtaining informed consent, educating participants on the details of the research study, assessing participant eligibility, facilitating participant care and follow-up per protocol, creating source documentation, assisting in the assessment of toxicities/adverse events and reporting serious adverse events per IRB and sponsor requirements.

4. Clinical Research Assistant

- The Research Assistant assists the Coordinator in drafting or editing the protocol document and submitting new protocols, protocol amendments, continuing reviews and safety reports to the appropriate IRB for review. They assist in maintaining regulatory binders in accordance with sponsor specifications and general industry standards.
- The Research Assistant assists the Coordinator in the overall data management of a research study.
- The Research Assistant assists the Coordinator in the daily activities of clinical research studies. Aide the Coordinator to ensure that all protocol required procedures and visits occur according to protocol specified guidelines.

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5. Research Nurse

- The Research nurse, in conjunction with the coordinator, is responsible for drafting or editing the protocol document and submitting new protocols, protocol amendments, continuing reviews and safety reports to the appropriate IRB for review. They are responsible for maintaining regulatory binders in accordance with sponsor specifications and general industry standards.

6. DHR Health Institute for Research & Development

- Participate as appropriate in the hiring and training of individuals recruited as members of the research team.
- Assign trained Research Coordinator/coordinators to manage each clinical study project, planned or ongoing at this site.
- Manage the business aspects of studies, including developing and negotiating study budgets and contracts.
- Finalize and approve Standard Operating Procedures for this research site.
- Liaison between health system and external collaborators including pharmaceutical industry leaders, academic institution leaders
- Works to obtain external funding for research program
- The Research nurse, in conjunction with the coordinator, is responsible for the data management of a research study. The Research nurse ensures accurate and timely data entry in electronic databases, electronic case report forms (eCRFs) or paper case report forms (CRF). They work closely with sponsor monitors and resolve any data queries that may be generated. They also work closely with the research team in the study development process to identify key data points for collection and analysis for investigator initiated trials.
- The Research nurse, in conjunction with the coordinator, oversees and coordinates the daily activities of clinical research studies. They work closely with the clinical teams and investigators to ensure that all protocol required procedures and visits occur according to protocol specified guidelines. The Research nurse, in conjunction with the coordinator, manage participant enrollment and ensure compliance with the protocol and other applicable regulations. This includes but is not limited to; participant recruitment, obtaining informed consent, educating participants on the details of the research study, assessing participant eligibility, facilitating participant care and follow-up per protocol, creating source documentation, assisting in the assessment of toxicities/adverse events and reporting serious adverse events per IRB and sponsor requirements.
    - Clinical responsibilities are protocol specific within scope of practice.

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B. Delegation of Responsibility

1. As per the requirements stated in ICH GCP E6 Guideline Section 4.1.5: "the investigator should maintain a list of appropriately qualified and trained persons to whom the investigator has delegated significant trial –related duties".
   - A Delegation of Responsibilities Log must be completed per study, delegating study-specific roles and responsibilities to assigned staff and signed by the Principal Investigator (PI).
   - The PI must ensure delegated staff is qualified and trained to perform the study specific roles assigned.
2. FDA regulations 21 CFR 312.53 (g) state a commitment by the investigator that he or she "will ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations".
   - The PI must ensure that delegated staff acknowledges and understands the study specific roles and responsibilities assigned to them.
3. Section 8 of ICH GCP 8.3.24 states that the "signature sheet" contain documentation of signatures and initials of all persons authorized to make entries and/ or corrections on CRFs and documents study- specific roles and responsibilities assigned to all staff on the study team by the Principal Investigator (PI).
   - Delegated staff acknowledges their roles and responsibilities by initialing, signing and dating the Delegation of Responsibilities log.

C. Training and Education: Documentation of Training

As per the requirements stated in ICH GCP E6 Guideline Section 4.1.5: "the investigator should maintain a list of appropriately qualified and trained persons to whom the investigator has delegated significant trial –related duties".

- The PI must ensure that all delegated staff is appropriately qualified and trained.
- An Employee Training Log will document training and qualification for study specific duties.

D. Transfer of Responsibility to Contractors

1. Contractors must complete all training, institute and study specific (if applicable), prior to delegation of contractual duties.
   a. Institute/Site completed in any order:
      i. Protecting Human Subjects Training current within two years
      ii. Good Clinical Practice Training current within two years.
      iii. DHR Health Institute for Research & Development Orientation
      iv. DHR Health Institute for Research & Development Standard Operating Procedures (Specific to contractual Duties) for onboarding.

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b. Study Specific Training (if Applicable):
   i. Current Protocol & Procedures Manual Training-This training may be available via webinar. PI must contact Sponsor monitor to obtain access if there is no active coordinator.
   ii. Case Report Form Completion Training and Access: Source Documentation Requirements and Electronic Data Capture
   iii. IVRS/IWRS Training and Access (if applicable)
   iv. Study Portal Training and Access (if applicable)

2. Employee Training Log must be appropriately completed, documenting all training and training source.
   - PI must provide and ensure that the contract employee understands the duties assigned and is qualified to conduct those specific duties.