DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Clinical Trial Personnel Qualifications	Policy #: CRP-1036
	PAGE: 1 OF: 2
DEPARTMENT: DHR Health Institute for Research & Development	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

Purpose:
The purpose of this document is to describe how the DHR Health Institute for Research & Development handles the qualifications of personnel involved in research.

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:

References

- Curriculum Vitae
- Human Subjects Protection Training
- Good Clinical Practice Training
- Professional Licenses, if applicable
- Delegation Log

Policy:
This SOP is meant to be followed without deviation. However, it is an allowable exception to follow procedures specified in a protocol that may deviate from this SOP.

Procedure:

Procedures

1. The Study Coordinator, under Principal Investigator oversight, helps to ensure all personnel directly involved in participant contact should be qualified by education, training and experience to perform delegated tasks, and that the qualifications are documented in Curriculum Vitae, Professional Licenses and training certificates that will be filed in the regulatory binder.
2. Principal Investigator is ultimately responsible for ensuring personnel is qualified by education, training and experience to perform delegated tasks.
3. All study personnel should be in compliance with the following qualifications:
   a. Curriculum Vitae (CV) summarizes education, skills and experience. Should be signed/dated and updated at least every two years or with changes.

All documentation of personnel qualifications will be filed in the regulatory binder. **SUBJECT:** Clinical Trial Personnel Qualifications	Policy #: CRP-1036
	PAGE: 2 OF: 2
DEPARTMENT: DHR Health Institute for Research & Development	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

   b. Professional licenses are required according to practice scope and tasks assigned on the delegation log. Licenses should be reviewed for expiration and kept up to date.
   c. Good Clinical Practice and Human Subjects Protection training documentation should be current within the last 3 years or by the expiration date listed on the certificate.
4. The responsibilities of the research staff is describes in the Delegation Log.

Training

1. Each staff member receives or has direct access to applicable Standard Operating Procedures (SOPs).
2. Each staff member reviews the applicable SOPs if there is any significant change.
3. All SOP training is documented and tracked Training Record Log located in the Regulatory Binder.
4. New staff is trained on applicable SOPs within 10 business days of employment.
5. Staff members whose duties fall within this SOP scope are retrained within 10 business days of the approval of each SOP revision.