DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Essential documents for the conduct of a clinical trial	Policy #: CRP-1007
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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, 03/22

Purpose:
The purpose of this policy and procedure is to indicate the essential documents to conduct clinical research in accordance with Good Clinical Practice. These documents should demonstrate the compliance of the investigator, sponsor and study monitor with the standards of Good Clinical Practice (as per ICH Good Clinical Practice Guidelines).

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:
Essential documents are those in which allow the evaluation of a clinical trial and the quality of the data generated. These documents serve to demonstrate overall study compliance by all individuals involved including the principal investigator, sponsor and monitor, as well as clinical research staff. Essential documents span the process of a clinical trial including prior to study start-up, during study, and study close out.

A. Essential documents needed prior to study startup include:
1. Investigator's brochure (if applicable)
2. Signed protocol and amendments and sample case report form
3. Information given to trial participant
    a. Informed consent (in English or Spanish)
4. Advertisement for trial participant recruitment (if any)
5. Financial implication of trial (Budget)
6. Signed clinical trial agreement between involved parties (Institution and Sponsor and/ or Institution and Clinical Research Organization)
7. Approval from DHR Health Institute for Research & Development and the Institutional Review Board (IRB).
8. Approval from external/central IRB
9. Current CV from investigators and study personnel
10. Certificate indicating successful completion of the Human Subject Research Protection, Conflict of Interest, and Good Clinical Practice (if applicable) training from CITI.

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B. Essential documents needed during the study:
1. Any updates on documents submitted in Section A

C. Essential documents after completion or termination of study.
1. Investigational product accountability at investigational site (i.e. DHR)
2. Documentation of sponsor recommended disposal of investigational product.
3. Final trial close-out monitoring report.
4. Report of notification to all review committees including internal and external.

Procedure
Effort must be made to obtain and file all documents listed above and maintained in the regulatory binders for each and every study.