**DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT**
**POLICY AND PROCEDURE**

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| **SUBJECT:** Source Documentation | Policy #: CRP-1018 |
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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 |

**Purpose:**
Documentation of source data is necessary for the reconstruction, evaluation, and validation of clinical findings, observations, and other activities during a clinical trial. Source documentation serves to substantiate the integrity of trial data, confirm observations that are recorded, and confirm the existence of subjects. This SOP also serves to ensure data quality by creating audit trails and enabling verification that the data is present, complete, and accurate. Each specific research task lists the requirements that act to assure quality data. These requirements are applicable to all research trials funded by the Federal government.

Common requirements for all research tasks source documentation are:

- All data must be verifiable and all documentation needs an audit trail.
- Always refer to local, state, institution, institutional review board (IRB)/independent ethics committee (IEC) policies and procedures and follow them if they are more stringent.
- To achieve data quality, all data must be:
    - Attributable - Is it obvious who wrote it?
    - Legible - Can it be read?
    - Contemporaneous - Is the information current and in the correct time frame?
    - Original - Is it a copy? Has it been altered?
    - Accurate - Are conflicting data recorded elsewhere?
    - Complete – Is any information missing or unclear?
    - Consistent – Does information correlate across all records?
    - Enduring – Is the data dependable and long lasting?
    - Available – Is there an audit trail available of who made original entries or changes and when?

**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:**

**A. Source Documents:** Source documents are used to record all original data from participants that support and verify information recorded on the Case Report Form. Information subject to source documentation includes information from screening visits, telephone conversations, screening and study procedures, diagnostic and study related data, and study visits.

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**Policy:**
This SOP has been created for all clinical research studies at DHR Health Institute for Research & Development. This SOP is based upon: 1) the Code of Federal Regulations (CFR), 2) guidance that apply to the involvement of human subjects in clinical research, and 3) standards for good clinical practice (GCP).

**Responsibility:**
The Principal Investigator is responsible and accountable for assuring that source documentation is accurate and complete. The PI may delegate responsibility for source documentation to another qualified researcher involved in the study, but may not delegate accountability.

**Procedure:**
1. The IRB approved protocol describes the information to be obtained from each participant during screening and study visits. This information may be obtained by a variety of means including interviewing, assessment procedures and performance of study-specific diagnostic and laboratory tests.
2. Original documentation, containing the subject's health information and medical test results, must be retained in the subject's medical/study record. This information may include the clinical medical report, laboratory results, laboratory notes, copies of hospital charts, primary physician or other related consultations, communication between study team, subject diaries, questionnaires, check lists, photographs, negatives, drug records, X-rays, EKGs and electronic data. Documentation should also note if a procedure was not performed and should be accompanied by an appropriate explanation e.g. subject refused, subject had to leave before test could be performed.
3. At the start of the study, the collection of source documentation begins. Once each participant has signed the approved informed consent form, a HIPAA authorization should be obtained from the participant outlining all potential disclosures of the participant's private health information and if necessary, so that medical record information may be obtained from and disclosed by the participant's physicians and other providers, as necessary. Documentation, outlining any issues associated with a specific participant's involvement in the research study, should be updated as necessary at each subsequent study visit with any new medical conditions or with any past medical history that becomes known to the research team.
4. When possible, source documents should not identify patients by name but by identifiers such as study subject number, or initials. Such identifiers facilitate cross-indexing of a subject's data while protecting the subject's privacy.
5. Source documentation should be completed and filed at the end of study visit. All source documentation must be in compliance with sponsor/CRO specified recommendations.
6. Case Report Forms and source data are maintained separately, but source documents should accompany the case report form for sponsor verification.