TITLE: Research Subject Documentation		
POLICY #: DOC-100	**Page:** 1 of 3	**Effective Date:** 1/31/2020

1. POLICY STATEMENT:

The Principal Investigator (PI) and research team members are required to prepare and maintain adequate and accurate case histories designed to record all observations and other data pertinent to the investigation on each research subject. Research subject documentation must be organized in a consistent manner to be easily located and retrieved by any authorized individual that needs to access the information.

2. BACKGROUND:

None

3. RESPONSIBLE PERSONNEL:

3.1. Principal Investigator (PI)
3.2. Subinvestigator
3.3. Research Nurse
3.4. Study Coordinator

4. DEFINITIONS:

4.1. **Source Documentation:** Original documents, data, and records in all forms, describing or recording the methods, conduct, and/or results of the research, the factors affecting the research, and the actions taken.

4.2. **Research Chart*:*** File with subsections holding essential research documentation (source data and source documents) that pertains to an individual's participation in the research.

4.3. **Note to File:** A signed and dated document on the letterhead of the organization/investigator used to explain: how information was obtained, who obtained the information, clarification of discrepancies, and missing and /or incomplete data.

4.4. **Case Report Form (CRF):** A document designed to record all of the protocol required information to be reported to the sponsor on each subject enrolled in the research. Case report form information is transcribed from source data found in source documents.

4.5. **Source Data:** All information in original records and certified copies of original records of clinical findings, observations, or other activities in a study necessary for the reconstruction and evaluation of the study. Source data are contained in source documents.

4.6. **Core Site** – The core site is the designated DF/HCC site that coordinates regulatory submissions for DF/HCC.

5. POLICY:

5.1. Source Documentation Requirements

5.1.1. The PI and research team are responsible for ensuring source documentation is sufficient to support subject participation in the research.

5.1.2. Source documents will have clear subject identifiers (i.e., screen number, randomization number, initials) to track the document to the participating subject. Recorded observations must be signed or initialed and dated. If a template does not provide a signature line, the document must still be signed or initialed and dated to be considered source.

5.1.2.1. In limited situations, the IRB may determine that confidential or sensitive information should not have subject identifiers and/or be signed or initialed by research subjects.

5.1.3. The Case Report Forms (CRF/eCRF) must only be a collection of transcribed source data (unless otherwise defined in the protocol). Source documentation must enable CRF entries to be verifiable and capture all information required in the CRFs.

5.1.3.1. The CRF/eCRF can only be used as a source document when specifically identified by the sponsor in the IRB approved protocol. When the CRF/eCRF is used as a source document, source documentation requirements in this policy apply.

5.1.4. Any change or correction to a source document or paper CRF must be dated, initialed, and explained (as necessary). A single line is made through the incorrect entry. No prior entry is ever obscured. No correction fluid or

tape is used. Amended versions of notes in the Medical Record System are acceptable.

5.1.5. If a DF/HCC study includes DF/HCC satellite sites or the Dana-Farber/Partners Cancer Care (DF/PCC) Network Affiliates, the satellite and affiliate facilities must follow the same source document and record-keeping practices as the main location.

5.1.6. Copies of source documents submitted to the IRB or an external sponsor should contain only the minimum necessary protected health information as required for the conduct and oversight of the research. The research team will redact or obliterate any unnecessary protected health information from source documents provided to the IRB and/or external sponsor.

5.2. **Medical Records and Research Charts**

5.2.1. The following documentation, as applicable, will be maintained for each subject in the research chart or medical record:

5.2.1.1. A record of the subject's participation in the research and dates of participation.

5.2.1.2.A record of the subject consenting to research participation in accordance with CON-100.

5.2.1.3. Completed eligibility checklist, when required per REGIST-100, and supporting Source documents demonstrating that the subject was eligible or ineligible, and that eligibility was determined by an appropriately qualified study team member prior to enrollment.

5.2.1.4. Confirmation of subject registration with the sponsor (e.g. industry, consortium, National Clinical Trials Network, etc.) (NCTN) and/or within OnCore, as applicable.

5.2.1.5. Case history information used to support the existence of the subject and substantiate the integrity of research data. This may include but is not limited to: progress notes, laboratory reports, serious adverse events (SAE) reported to the IRB, incidents or protocol deviations/violations reported to the IRB, treatment response assessments, and infusion or

drug administration records. The record of each visit must support all data required by the protocol and captured in the CRFs.

5.2.1.6. All deviations, exemptions, or waivers (e.g., from inclusion/exclusion criteria) must be recorded in the subject's records and have written prospective approval from the sponsor and the IRB prior to the subject's participation (or continued participation) in the protocol.

5.3. **Notes to File**

5.3.1. A Note to File may be used to provide additional information or necessary clarifications in the essential regulatory documents or subject's research chart, as appropriate. Appropriate uses of a Note to File include:

5.3.1.1. To document the reason why information is not filed and is permanently unavailable (e.g., staff have left and the original cannot be located).

5.3.1.2. To explain site practices that affect the overall conduct of the trial.

5.3.1.3. To document that certain files are maintained in a separate location.

5.3.2. A Note to File will **not** be used in the following instances:

5.3.2.1. To document the absence of something that is not expected or required (e.g., putting a Note to File in the SAE section of the regulatory binder indicating that no SAEs have occurred).

5.3.2.2. To clarify or correct information in the source documents, unless it is impossible or impractical to make the correction on the source document itself or through an addendum to a note.

5.3.2.3. To clarify or correct CRF data and/or respond to data queries.

5.3.2.4. As a corrective action or in place of a reportable deviation/violation or unanticipated problem report to the IRB.

5.3.3. A Note to File is considered source documentation and must be signed and dated by either the person making the entry or the person reviewing and/or validating information the document contains.

5.4. **Storage**

5.4.1. Research subject documentation is kept confidential and stored in a secure, limited-access location that is accessible to the research team.

5.4.2. When the research is deemed complete, research subject documentation must be maintained in accordance with RCL-101.

6. APPLICABLE REGULATIONS & GUIDELINES:

21 CFR 50 – Protection of Human Research Subjects
21 CFR 54 – Financial Disclosure by Clinical Investigators
21 CFR 56 – Institutional Review Boards
21 CFR 312 - Investigational New Drugs – Drugs for Human Use
21 CFR 812 – Investigational Device Exemptions
45 CFR 46 – Protection of Human Subjects
FDA Industry Guidelines and Information Sheets
FDA Compliance Policy Guidance Programs: 7348.809, 7348.810, and 7348.811

7. RELATED REFERENCES:

International Conference on Harmonisation – E6

8. RELATED RESOURCES:

Note to File Template
DF/HCC Guidance on Source Documents
DF/HCC Guidance on Good Study Documentation Practices