TITLE: Record Retention for Completed Research		
POLICY #: RCL-101	**Page:** 1 of 5	**Effective Date:** 1/31/2020

1. POLICY STATEMENT:

The ~~Overall~~ Principal Investigator (PI) is responsible for assuring that all applicable regulations and institutional requirements are met for retaining research records once the research is completed.

Commented [SC1]: Edits throughout to remove old terminology and to clarify responsibilities of the PI or designee at each participating DF/HCC site, as well as the DF/HCC Sponsor-Investigator where applicable.

2. BACKGROUND:

Research documentation must be maintained and archived for purposes such as establishing patent rights, supporting published results, demonstrating compliance with regulatory requirements, and by providing evidence of data integrity and subject safety.

3. RESPONSIBLE PERSONNEL:

3.1. ~~Overall~~ Principal Investigator (PI)
3.2. Study Coordinator
3.3. Office of Data Quality (ODQ)
3.4. Research Informatics Office (RIO)
3.5. Research Pharmacy Personnel
3.6. Institutional Disease Program Personnel

4. DEFINITIONS:

4.1. **Completed protocol:** All research activity has ceased (e.g. no subjects are treated or followed; data collection and analysis are complete). If required, a study completion report has been submitted and approved by the IRB.

4.2. **Sponsor:** An individual, company, institution, or organization that takes responsibility for the initiation and management of the research.

4.3. **Sponsor-Investigator:** An individual who both initiates and conducts an investigation, and when applicable, under whose immediate direction the investigational drug is administered or dispensed is referred to as a sponsor-investigator. This individual is acting as both the Sponsor and an Investigator on the same protocol.

~~4.3.~~4.4. **Inspection**: The act by a regulatory authority of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority to be related to the research and that may be located at the site of the research, at the sponsor's and/or contract research organization's (CRO)

facilities or at other establishments deemed appropriate by the regulatory authority.

5. POLICY:

5.1. ~~Investigator~~ PI (or designee) **Responsibilities**

5.1.1. Once the research is completed, gather all research related records and prepare them for archival (e.g. long-term storage).

5.1.2. Ensure compliance with storage and documentation requirements (see 5.6).

5.1.3. Alert and obtain approval from the sponsor to archive research related documents.

5.1.4. Ensure that logs for off-site record storage are maintained and available for inspection.

5.1.5. Ensure that long-term storage of electronic materials is maintained and available for inspection.

~~5.1.5.~~5.1.6. At the end of the required period of storage, contact the sponsor in writing and obtain approval prior to destroying any research related documents.

5.2. **ODQ Responsibilities** (paper CRF trials)

5.2.1. Once the research is completed, gather, organize and prepare the forms/data for long-term storage.

5.2.2. Alert the ~~Overall PI~~Sponsor-Investigator that the forms/data are being sent off-site.

5.2.3. Ensure compliance with storage and documentation requirements (see 5.6).

5.2.4. At the end of the required period of storage, contact the ~~Overall PI and sponsor~~Sponsor-Investigator in writing and obtain approval prior to

destroying any forms/data.

5.3. **RIO Responsibilities** (InForm EDC trials)

5.3.1. Once the research is completed, lock InForm. Take InForm offline but keep the research data in the database.

5.3.2. Ensure compliance with storage and documentation requirements (see 5.6).

5.3.3. At the end of the required period of storage, contact the ~~Overall PI and sponsor~~Sponsor-Investigator in writing and obtain approval prior to destroying any forms/data.

5.4. **Research Pharmacy Responsibilities**

5.4.1. Once the study is completed, gather all drug accountability documents and prepare them for long-term storage.

5.4.2. Ensure compliance with storage and documentation requirements (see 5.~~6~~5).

5.4.3. At the end of the required period of storage, contact the sponsor in writing and obtain approval prior to destroying any research related documents.

5.5. **Storage and Documentation Requirements**

5.5.1. Long Term Storage of Hard Copy Materials

5.5.1.1. Boxes are stored in a secure location that is fireproof, waterproof and readily accessible, should you need to retrieve the items within 48 business hours for audit or inspection.

5.5.1.2. Document the storage of archived research materials. At minimum, documentation must include:

- DF/HCC protocol number
- Date of the shipment
- Long-term storage facility box identification
- Storage facility address and fire safety information
- Procedures for Retrieval of Hard Copy Materials

5.5.2. Long Term Storage of Electronic Materials:

5.5.2.1. Electronic media must be stored in a manner consistent with institutional policies and procedures. The following are minimal requirements.

- There must be accurate and complete records of stored information and restoration procedures.
- Electronic materials must be stored in a remote, secure location.
- Electronic materials must be available to authorized staff for prompt retrieval.
- There must be physical and environmental protection consistent with applicable laws and regulations.

5.5.2.2. Document the storage of archived research materials. At minimum, documentation must include:

- DF/HCC Protocol number
- Date of Archival
- Electronic System utilized for archival
- Contact information for Electronic System including any system requirements to access that need to be maintained.
- Procedures for Retrieval of Electronic Documents
- Retention period

5.5.3. Retention Requirements

5.5.3.1. Archive the regulatory files and research charts for the longer of the following two time frames:

- The length of time specified in the protocol; or
- Seven (7) years from the time the research was completed.

5.5.3.2. For drug or device research involving children, the minimum period is whichever is later:

- The length of time specified in the protocol; or
- Seven (7) years; or
- Until the last child in the research reaches the age of twenty-one (21).

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:

None