TITLE: Preparation for Site Close Out		
POLICY #: RCL-100	**Page:** 1 of 4	**Effective Date:** 1/31/2020

1. POLICY STATEMENT:

Certain steps must be taken at the time or, or prior to, the termination of research at a site or IRB completion of a research protocol. These can only occur after enrollment has ceased, all subjects have completed the protocol including any follow-up activities, and all data collection is complete.

2. BACKGROUND:

Sponsors/Contract Research Organizations (CROs) will perform close out activities to ensure that all data has been collected and verified, to perform the final accounting and disposition of test articles and to verify that the site's files are complete and accurate after all subjects have completed the protocol. These activities are usually scheduled after submission of all clinical data from a site and all queries have been resolved. Sponsors may elect to conduct the final monitoring and termination during an onsite close out monitoring visit. DF/HCC sponsor-investigators are responsible for conducting close out activities with each participating site prior to completion of the protocol with the IRB.

3. RESPONSIBLE PERSONNEL:

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

4. DEFINITIONS:

4.1. **Closed Protocol:** A protocol that is permanently closed to enrollment of new subjects. The protocol remains active for treatment or long term follow up/ data analysis.

4.2. **Completed Protocol**: All subjects on protocol have completed the treatment and the follow up/data analysis phase of the trial has ended. No further research takes place (e.g. no subjects are treated or followed; no additional data are collected).

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

5. POLICY:

5.1. **Externally-Sponsored Trials:**

5.1.1. The sponsor will contact each site to schedule close out activities once the last subject has completed all scheduled visits associated with the protocol.

5.1.2. For onsite monitoring visits, the clinical trial monitor should send a close out confirmation letter describing what is expected, what needs to be accomplished before the visit takes place, and other issues that require resolution before the visit.

5.1.3. The DF/HCC Core Site must confirm with all participating DF/HCC sites that the following have occurred:

5.1.3.1. All required data entry is complete and all data queries have been answered and resolved.

5.1.3.2. All research drug, biologic or device products have been returned to the sponsor or destroyed at the site, and copies of all related documentation, including packing slips and shipment receipts, are filed appropriately.

5.1.3.3. All other protocol-related supplies, such as unused research kits or unused CRFs, have been returned or destroyed.

5.1.3.4. Any equipment on loan (i.e. EKG machines, holter monitors, blood pressure cuffs) has been returned and Biomedical Engineering has been notified.

5.1.3.5. All expected payments from the sponsor have been received.

5.1.3.6. Each site has received a final report or letter from the sponsor (or representative) stating that there are no outstanding issues and the site may complete the study with the IRB.

5.1.4. After close out activities have been completed, the PI, or designee, at each site will confirm with the sponsor the following:

5.1.4.1. When hard copies or the CD of all case report forms (CRFs) will be provided to the site.

5.1.4.2. Any ongoing responsibilities for reporting safety information after formal termination of the protocol.

5.1.4.3. The possibility of a quality assurance (QA) and/or Food and Drug Administration (FDA) audit and process to notify the sponsor should these occur.

5.1.5. Once all of the above are complete, the Core Site will submit the appropriate study completion documentation to the Institutional Review Board (IRB).

5.1.6. Once the protocol is IRB complete, no further research activities may take place. All applicable documents and files (CRFs, research charts, regulatory files and other related data) must be maintained and stored according to DF/HCC policy RCL-101.

5.2. **DF/HCC Investigator-Sponsored Trials:**

5.2.1. The DF/HCC sponsor-investigator must ensure completion of the following activities prior to IRB closure of each participating site:

5.2.1.1. All monitoring and quality control activities (including ODQ review of the data for InForm trials) are complete and all outstanding issues have been resolved.

5.2.1.2. All required data entry is complete and all data queries have been answered and resolved.

5.2.1.3. All research drug, biologic or device products have been returned or destroyed appropriately.

5.2.1.4. Any loaned equipment or devices have been returned, as applicable.

5.2.1.5. All subject registration information is up to date with final subject status.

5.2.1.6. All research samples have been shipped and received, as applicable.

5.2.1.7. All required regulatory documents have been collected and filed.

5.2.1.8. All expected payments have been received from funding collaborators and paid out to participating sites.

5.2.2. For protocols registered on ClinicalTrials.gov, the responsible party (usually the sponsor-investigator) must confirm that the ClinicalTrials.gov record is up to date, including study status and results entry (if required to report results). For clinicaltrials.gov records that are considered applicable to FDAAA-801, results must be posted and accepted without comment from the Clinicaltrials.gov QA department.

5.2.3. After all of the above are complete, the Sponsor-Investigator, or designee, will request that the Core Site submit to the necessary documentation to complete the study with the IRB. When applicable, the sponsor-investigator may also need to provide a final study report to the FDA, funding sources, etc.

5.2.4. Once the protocol is IRB complete, no further research activities may take place. All applicable documents and files (CRFs, research charts, regulatory files and other related data) must be maintained and stored according to DF/HCC policy 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 – Human Subject Protections
FDA Industry Guidelines and Information Sheets
FDA Compliance Policy Guidance Programs: 7348.809, 7348.810, and 7348.811
Clinical Trials Agreement

7. RELATED REFERENCES:

International Conference on Harmonisation – E6

8. RELATED RESOURCES:

DF/HCC Sample Research Close Out Checklist
DFCI IRB Study Completion Request Form