1. BACKGROUND:

There are procedures that are conducted upon formal completion of research in order to comply with IRB requirements and FDA regulations for drugs, biologics and devices during all phases of development. Study completion may only occur once all research activity has ceased, all subjects have completed the treatment and follow up, and data collection and analysis are complete.

2. ASSOCIATED DF/HCC POLICIES:

2.1. RCL-100
2.2. RCL-101

3. PROCEDURE:

3.1. Close Out Procedures

3.1.1. When necessary, sponsors will schedule a close out visit once the last subject has completed all scheduled visits associated with the protocol. During the closeout visit, sponsors will ensure that all data has been collected and verified, perform the final accounting and disposition of test articles and verify that files are complete and accurate after all subjects have completed participation in the protocol.

3.1.2. During the close out visit, the PI should review with the sponsor:

- Ongoing responsibilities for reporting serious adverse events and IND safety reports after formal termination of the protocol.
- Record retention expectations.
- The possibility of a future quality assurance (QA) and/or Food and Drug Administration (FDA) audit.

3.1.3. For DF/HCC investigator-sponsored trials, the sponsor-investigator will ensure all additional close-out requirements are met per RCL-100 for all participating DF/HCC sites.

3.1.4. The sponsor should provide a close out confirmation letter stating that there are no outstanding issues. Once received, the PI at the Core Site will notify the Institutional Review Board (IRB) that the protocol is complete by submitting a study completion request.

3.1.4.1. The study completion request may be submitted at any time or at the next continuing review. The IRB will send an approval of study completion that must be filed with essential regulatory documents.

3.1.5. Once Study Completion is approved by the sponsor and IRB, all applicable documents and files (CRFs, research charts, regulatory files and other related data) may be sent to storage per RCL-101.

3.2. **Record Retention Procedures**

3.2.1. Once the research is completed, the research teams may gather all research related records and prepare them for archival (e.g. long-term storage). Teams must comply with sponsor requirements, institutional policies, and RCL-101.

3.2.2. Once the study is completed, the Office of Data Quality (ODQ) and Research Informatics for Operations (RIO) may gather, organize and prepare any protocol-related data (hard copy or electronic) for long-term storage. For investigator-sponsored trials where RIO is hosting case report forms in InForm, they may take InForm offline but maintain research data in the database. The sponsor-investigator will be alerted when data is being sent off site for archiving.

3.2.3. Once the study is completed, the Research Pharmacy may gather all drug accountability documents and prepare them for long-term storage. The sponsor-investigator will be alerted when data is being sent off site for archiving.

3.2.1. At the end of the required period of storage, written approval from the sponsor is required prior to destroying any research related documents.