


<b>Standard Operating Procedures for Clinical Research at USF Health CRC</b>			
	<b>SITE CLOSE-OUT VISIT</b>		
<b>SOP#: 311</b>	<b>Effective Date: 06/01/2016</b>	<b>Version: 1.0</b>	<b>Page 1 of 4</b>

**PURPOSE:** The purpose of this SOP is to describe the procedures followed by key research personnel engaged in clinical research at the CRC during a close-out visit with a sponsor representative from the time the monitor schedules the visit until all associated follow-up activities have been completed.

**SCOPE:** This SOP applies to key research personnel involved in arranging, managing, participating in, and/or resolving outstanding items resulting from the study close-out visit.

**RESPONSIBILITY:** The Principal Investigator (PI), study coordinator, and/or other designated key personnel are responsible for study close-out visits.

**DEFINITIONS:**

**Case Report Form (CRF):** A paper or electronic questionnaire specifically used in clinical trial research. The Case Report Form is the tool used by the sponsor of the clinical trial to collect data from each participating site. All data on each patient participating in a clinical trial are held and/or documented in the CRF, including adverse events.

**Investigational Product (IP):** A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial.

**Key Personnel:** An individual designated by the principal investigator who is knowledgeable about the research study. This may include investigators, coordinators, assistants, residents, fellows, students working on the research, administrators or managers who oversee the research, and external individuals associated by agreement or contract with USF Health who are involved in conducting the research. Individuals providing services in the course of their position (e.g., pharmacist, biostatistician) are not considered key personnel unless involved in key aspects of the research such as protocol development, consenting, blinding procedures etc.


**Monitoring:** The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

**Regulatory Binder:** Method used to organize/store essential study documents. The regulatory binder is often the first document reviewed during audits and inspections.

**PROCEDURE:**

**1. Preparing the Study Close-Out Visit:**

- 1.1 After the last patient has completed all scheduled visits associated with the study, arrange a mutually convenient date and time for the study monitor to conduct the study close-out visit.

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**PROCEDURE (cont.):**


- 1.2 Request a visit agenda from the monitor describing what is expected, what needs to be accomplished before visit takes place and to ensure that key personnel (pharmacists and or PI) will be available, if applicable.
- 1.3 Complete a study close- out checklist (Appendix W)
- 1.4 Ensure that all regulatory documentation and case report forms (CRFs) not previously monitored are completed and ready for review.
- 1.5 Ensure that all data queries received to date have been resolved and that the database has been locked.
- 1.6 Inventory investigational product (IP)/ test article supply and complete final accountability records. If previously instructed, return or dispose of any unused IP in accordance with the protocol and regulations. File copies of study packing slips and shipment receipts appropriately in regulatory binder for monitor review.
- 1.7 Arrange for the monitor to meet with the PI and/or Fiscal Manager to discuss any outstanding issues.

**2. Managing the Study Close-Out Visit:**

- 2.1 Ensure all documentation is filed appropriately and ready for the monitor to review during the close-out visit. Discuss all open study-related issues and what steps will be taken to resolve them in order to satisfy the sponsor/CRO requirement(s).
- 2.2 Review with the monitor the list of outstanding issues related to regulatory documents, source data verification, test article reconciliation, and any requirements for data retention and storage.
- 2.3 Review with the monitor the responsibilities for reporting serious adverse events and IND safety reports after formal termination of the study.
- 2.4 Discuss any concerns regarding the possibility of a quality assurance (QA) audit and/or FDA audit.
- 2.5 If the study involved electronic data capture, discuss when hard copies of all CRFs will be provided to USF.
- 2.6 The PI is responsible for ensuring the appropriate follow-up, per the protocol, for any participant experiencing an ongoing unanticipated problem (e.g., serious adverse event) at study end and providing this information to the sponsor, assuring all sponsor's requirements have been met.
- 2.7 Discuss the timelines and requirements for final payments (if applicable).

**3. Follow-up after the Study Close-Out Visit:**

- 3.1 The monitor will document the visit by submitting a study termination visit report outlining what was accomplished during the visit and noting any items that need additional attention. Ensure that a copy of the report and follow-up letters are placed in the regulatory file

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**PROCEDURE (cont.):**

- 3.2 If not previously instructed, ensure that any remaining IP is either returned to the sponsor/CRO per their requirements or if the sponsor allows remaining investigational drug to be disposed of at the site following the close-out visit.
  - The authorized key personnel (with verification by a second authorized key personnel) can dispose of the drug according to the USF Environmental Health and Safety Universal Pharmaceutical Waste Program.
  - If the drug is stored in the CIRP, the Pharmacist will dispose the drug per the CIRP Disposal and Destruction of Investigational Product Policy in accordance with the pharmaceutical waste management plan. The CIRP does not destroy investigational product on-site.
- 3.3 Ensure all documentation is complete (i.e. sponsor drug accountability/ destruction logs).
- 3.4 Ensure all test article packing slips and shipment receipts are accounted for and properly filed in the regulatory binder.
- 3.5 Provide the sponsor with any documentation of previously authorized test article disposal and file site copy appropriately. If the randomization code for any test article was broken for any reason, ensure complete documentation has been filed.
- 3.6 Ensure return or destruction of all other study-related materials, such as unused lab kits and CRFs.
- 3.7 After all data queries have been resolved, check regulatory binders, subject files and other study files for completeness.
- 3.8 Arrange for transfer/ storage of study documents to secured USF approved storage location.
- 3.9 Submit the Final Report to the USF IRB. Provide the sponsor/CRO with a copy of the IRB closure letter.
- 3.10 Verify participant stipends have been distributed per the study budget, as outlined in the informed consent document.

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<b>REFERENCES:</b>	21 CFR 312.50 General Responsibilities of Sponsors; 21 CFR 312.59 Disposition of unused supply of investigational drug; 21 CFR 312.60 General Responsibilities of Investigators; 21 CFR 312.62 Investigator recordkeeping and record retention; 21 CFR 312.64 Investigator reports; 21 CFR 312.66 Assurance of IRB Review; 21 CFR 312.68 Inspection of Investigator's Records and Reports; FDA Sheet: January 1988 Guidelines for Monitoring of Clinical Investigations; May 1997 International Conference on Harmonization (ICH) Good Clinical Practices; CIRP Policy: Disposal and Destruction of Investigational Product USF HRPP Policy and Procedure Manual: Records Retention and Accessibility	
<b>RELATED POLICIES:</b>	SOP #201: Regulatory Documentation	
<b>APPENDICES:</b>	Appendix W: Site Close-Out Checklist	
<b>REVISION HISTORY:</b> Keep a running history of all revision dates.		
<b>Approval Date</b>	<b>Effective Date</b>	<b>Review/Revision Date</b>
01/01/2015	01/01/2015	06/01/2016