

University of New Mexico Cancer Center / New Mexico Cancer Care Alliance



STANDARD OPERATING PROCEDURE



Clinical Research Office

Title: STUDY TERMINATION (CLOSE OUT) VISIT
(Please note this is pharmaceutical trial specific)

SOP No.: 3.4

Version No.: 4

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NMCCA Clinical Research Supervisor

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INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the processes followed at UNM Cancer Center (UNM CC) and New Mexico Cancer Care Alliance (NMCCA) sites when an industry trial has come to a close and the sponsor monitor conducts a study termination visit (also known as a Close out Visit, or COV) in order to:

Review all regulatory files for completeness;

Complete the verification of all data in case report forms (CRFs) against source documentation;

Meet with the research team to discuss the results of:

- the final audit of the regulatory files,

- the final source data verification,

- the reconciliation of the study drug shipment and receipt records with drug accountability records,

- the possibility of a quality assurance and/or FDA audit,

- the requirements for long term data storage.

SCOPE

This SOP applies to the procedures for conducting the study termination visit for all industry-sponsored clinical studies subject to investigational new drug (IND) regulations for drugs and biologics or investigational device evaluation (IDE) regulations for devices during all investigational phases of development. It describes the steps followed by this clinical research site from the time the study monitor schedules the study termination visit until all follow-up activities associated with the visit have been completed.

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50	General responsibilities of sponsors
21 CFR 312.56	Review of ongoing investigations
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 HRRC review
21 CFR 312.68	Inspection of investigator's records and reports
January 1988	Guidelines for the Monitoring of Clinical Investigations
May 1997	International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline
SOP 3.8	Long Term Storage

REFERENCES TO OTHER APPLICABLE SOPs

All SOP's are applicable to this SOP.

RESPONSIBILITY

This SOP applies to those members of the regulatory and clinical research teams involved in arranging, managing, participating in or following up after the study termination visit. This includes the following:

- Principal investigator
- Sub-investigator
- Research manager
- NMCCA CRS
- Research coordinator
- Regulatory coordinator
- Data coordinator
- Study pharmacist
- Research technician
- Patient services assistant
- Data manager
- Information specialists
- Administrative assistant
- Clinical trials assistant

PROCEDURES

Scheduling the study termination visit -

Owner	Criteria / Steps
PI Research Coordinator Regulatory Coordinator	As soon as possible 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 termination visit.

Preparing for the study termination visit

Owner	Criteria / Steps
Research Manager NMCCA CRS	Ensure that all regulatory documentation and case report forms not previously monitored are complete, up to date and available for review. For patient related materials, this may include documentation at multiple clinical sites within the NMCCA network.
Research / Data/ Regulatory Coordinator	Ensure that all data queries received to date have been resolved to the extent possible.

Research Manager Research Coordinator Regulatory Coordinator Data Coordinator Study Pharmacist	<p>Ensure that the appropriate patient medical records will be available for review at the time of the study termination visit.</p> <p>Ensure that all study and patient data have been updated in the electronic database system. All clinical sites must be closed to the IRB of record, and all patients must be confirmed off study (treatment and follow up activities complete).</p> <p>Inform the study pharmacist of the scheduled visit so that study drug can be inventoried and drug accountability records can be completed.</p>

Managing the study termination visit

Research Coordinator Regulatory Coordinator Data Coordinator Pharmacist	<p>Ensure that the study monitor is provided all documents required to complete the termination visit. Provide the monitor with an update on any study-related issues.</p>
PI or Sub-Investigator Research Coordinator Regulatory Coordinator Research Manager NMCCA CRS Pharmacist	<p>At the conclusion of the visit, meet with the study monitor to discuss any issues related to:</p> <ul style="list-style-type: none"> Final audit of regulatory files, Final source data verification, Study drug reconciliation, The possibility of a quality assurance and/or FDA audit, Requirements for data retention and storage.
PI or Sub-Investigator and assigned Research Staff	<p>If data were entered by computer, determine when hard copies of all CRFs will be provided to the site.</p> <p>Review with the monitor the sponsor's requirements for protecting the integrity of the electronic data.</p> <p>Discuss with the monitor the sponsor's requirements for patient follow-up for serious adverse events after formal termination from the study, if applicable.</p>

Following-up after the study termination visit

Regulatory Coordinator	<p>Ensure that the study drug is either prepared for return to the sponsor/CRO or disposed of at the site at the sponsor's written request.</p> <p>File copies of study drug packing slips and shipment receipts appropriately.</p>
Research Coordinator	<p>OR</p> <p>Provide sponsor with documentation of the previously authorized study drug disposal and file site copy appropriately.</p>
Research Manager	<p>If the randomization code on any study drug was broken for any reason, ensure that complete documentation is available.</p> <p>Ensure return or destruction of all other study-related materials.</p>
Study Pharmacist	<p>Ensure that any equipment on loan is returned.</p> <p>Request a letter from the sponsor stating that the study activities have been completed, including return of study drug and any equipment and that the study is terminated</p>
Regulatory Coordinator	<p>Submit required study closure report to the IRB. Provide the study sponsor with a copy of the correspondence.</p>
Research Coordinator Regulatory Coordinator Data Coordinator Administrative Assistant Clinical Trials Assistant	<p>After all data queries have been resolved, check study files for completeness. Arrange for transfer of study documents to secure storage, noting storage location at the site.</p> <p>Scan/upload IRB Close out letter and Long Term Storage List in Velos Study Close out Documentation File</p> <p>The responsible Regulatory Coordinator will e-mail all individuals who were part of the research team (including the NMCCA Business Manager, CRO Program Manager and website administrators for NMCCA and UNMCC) when the study is closed.</p>