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

STANDARD OPERATING PROCEDURE

Clinical Research Office

Title: LONG TERM STORAGE

SOP No.: 3.8	Version No.: 6	Effective Date: 9-2008

Owner: NMCCA Clinical Research Manager

Name: Leslie Byatt

Leslie Byatt
Signature

3/19/18
Date

Authorized / Approved by:

Name: Oliver Rixe, MD, PhD

Title: NMCCA Medical Director

Signature

3/28/2018
Date

INTRODUCTION AND PURPOSE

This standard operating procedure provides guidance required to assure that the long term record retention requirements are met for clinical trials. The length of time for storage is determined by the type or sponsor of a specific trial.

SCOPE

This SOP applies to the clinical trials conducted at the University of New Mexico, through the New Mexico Cancer Care Alliance or Affiliate Sites for the MBCCOP

APPLICABLE REGULATIONS AND GUIDELINES

Regulation/Guideline	Specific Section
21 CFR 312.60	General responsibilities of investigators
Manual For Conducting Human Subject Research the University of New Mexico Health Sciences Center	10.1 Investigator Records
Study Protocol & Contract if applicable	Storage guidance.

An investigator is required to retain records for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and the FDA is notified. Additionally, signed HIPAA Authorizations and documentation of HRRC granted waivers of HIPAA authorization must be retained for 6 years from the date of creation or the date it was last in effect, whichever is later. Finally, for non FDA studies, records will be kept for at least three years. If the study protocol has specific record retention requirement, those must be followed in conjunction with this SOP. In no case should treatment related records be destroyed before ten years.

REFERENCES TO OTHER APPLICABLE SOPs

SOP 3.4	Study Termination (Close Out) Visit

RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in arranging, managing, or participating in the audit at this research site. This includes the following:

Principal Investigator

Research Nurse Manager

Research Coordinator

NMCCA CRS

Regulatory Coordinator

NMCCA Clinical Trials Assistant

Study Pharmacist

Administrative Assistant

GUIDANCE ON LENGTH TO STORE BY STUDY TYPE IF NOTHING SPECIFIED IN PROTOCOL

Type of Study/Sponsor	Length of storage	Comments
Cooperative Group Trials	Three years from study closure date and at least 6 years from date last subject signed HIPAA authorization	Subject treatment related records must be retained for 10 years from study close
Investigator Initiated Trials	Three years from study closure date and at least 6 years from date last subject signed HIPAA authorization	Subject treatment related records must be retained for 10 years from study close
Pharmaceutical Sponsored, multi-center trials	According to Clinical Trial Agreement specific for each study	Subject treatment related records must be retained for 10 years from study close

PROCEDURES

Implementing record storage

Owner	Criteria / Steps
CROM, NMCCA CRM	Determines if study materials need to be retained and stored. Also notified prior to any destruction of records
Regulatory Coordinator	Determines if the long term storage documents are to be retained by NMCCA or UNM CCC, based upon the sponsor and contractual agreements.

Preparing the records for storage at UNM

Owner	Criteria / Steps
Data Coordinator	Retrieve shadow charts/CRF's from file cabinets Take the study information out of the binders and place in a folder and secure with a rubber band. Email NMCCA Clinical Trials Assistant the appropriate (completed) forms (Appendix A). Refer to Appendix A-UNM for complete instructions.
NMCCA Clinical Trials Assistant (CTA)	Notify Site(s) of Study Closed to IRB All regulatory related records need to be transferred to storage box along with the completed long term storage form. Deliver the prepared materials to the Administrative Support Office. Refer to Appendix A-UNM for complete instructions
NMCCA CTA	Check all materials for appropriate preparation for storage. Assign Box Number from log. Set up the transfer to the storage unit and record date it is sent. Refer to Appendix A-UNM for complete instructions

Preparing the records for storage at Alliance/Affiliate Sites

Owner	Criteria / Steps
Data Coordinator Nurse, Clinical Trial Coordinator or Designee	Retrieve shadow charts/CRF's from file cabinets Take the study information out of the binders and place in a folder and secure with a rubber band. Email NMCCA Clinical Trials Assistant the appropriate (completed) forms See Appendix B-Alliance/Affiliate Sites for complete instructions.
NMCCA Clinical Trials Assistant	Notify Site(s) of Study Closed to IRB All regulatory related records need to be transferred to storage box along with the completed long term storage form. Deliver the prepared materials to the Administrative Support Office. Refer to Attachment B-Alliance/Affiliate for complete instructions.

NMCCA Clinical Trials Assistant	Check all materials for appropriate preparation for storage. Set up the transfer to the storage unit and record the date it is sent. Iron Mountain 555 Gallatin Pl NW Albuquerque, NM 87121 (505) 224-2897 See Appendix B-Alliance/Affiliate for complete instructions