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

STANDARD OPERATING PROCEDURE

Clinical Research Office

Title: SPECIMEN COLLECTION, HANDLING & DISPOSAL

SOP No.: 4.5	Version No.: 4	Effective Date: 2-26-04

Owner: UNM CCC Clinical Research Operations Manager

Name: Ebany Martinez-Finley, PhD

Signature 12/19/2017 **Date**

Authorized / Approved by:

Name: Olivier Rixe, MD, PhD

Title: NMCCA Medical Director

Signature 9/28/2018 **Date**

INTRODUCTION AND PURPOSE

The proper collection, processing, and disposal of specimens and supplies obtained from study subjects are part of the data collected in a clinical trial. The specimens provide important information about the drug's action within the body and the subject's biologic and clinical response. To ensure accurate data, specimens must be collected at the specified time points, processed, possibly preserved, and then shipped appropriately. This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and clinical requirements involved in specimen collection, handling, and disposal of specimens and supplies. In addition, also describes the maintenance of lab equipment (refrigerator(s), freezer(s) and centrifuge(s)), for temperature and calibration.

SCOPE

This SOP applies to the activities involved in collecting, handling, and disposal of specimens and supplies for subjects enrolled in clinical studies conducted at the University of New Mexico Comprehensive Cancer Center (UNM CCC) and the New Mexico Cancer Care Alliance (NMCCA) sites, subject to investigational new drug (IND) regulations for drugs and biologics or investigational device evaluation (IDE) regulations for devices during all phases of development. This SOP applies to the laboratory equipment used to process specimens from subjects enrolled in clinical studies, when collected at a site.

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.62	Investigator record keeping and record retention
May 1997	International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline
October 2010	WHO Good Clinical Laboratory Practice (GCLP) ISBN 978-92-4-159785-2 http://www.who.int/tdr/publications/documents/gclp-web.pdf

REFERENCES TO OTHER APPLICABLE SOPs

N/A

RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in ensuring appropriate specimen collection, handling and disposal at this research site. This includes the following:

Research Lab Technician

Regulatory Coordinator

Clinical Research Nurse

Clinical Research Coordinator

PROCEDURES

Review Clinical Protocol, Supply Maintenance & Scheduling -

Owner	Criteria / Steps
Clinical Research Nurse/Coordinator Research Lab Tech Data Coordinator	Review protocol and amendments for specimen's requirements. Lab Technician to order lab kits in preparation for patient enrollments (if study allows). Kit supply will be maintained on Lab Supplies Spreadsheet. Lab Technician will also review the protocol for special equipment needs. To Schedule study labs, notify Research Lab Technicians (to obtain specimens) by entering subject's name, study number, protocol number (arm, if applicable), and treatment visit/required time points in the Mosaiq Calendar and QCL the Research Lab Technicians, at least 72 hours prior to subject's scheduled appointment.

Collecting the specimens -

Owner	Criteria / Steps
Research Lab Tech Clinical Research Nurse/Coordinator	Observing appropriate precautions based upon OSHA guidelines, infection control manual, and the institutional procedure manual for the handling of bodily fluids, collect the appropriate specimens identified in the study protocol. In the subject's Research Chart and/or on the case report form, note the date and time of the collection as well as any relevant information pertaining to the subject's status at the time of the procedure. Label the test tubes or other containers with subject identifiers, date, time, and any other information as required by protocol.

Processing the specimens (Research Team Member who obtains specimens' from subject needs to –

Owner	Criteria / Steps
Research Lab Tech Clinical Research Nurse/Coordinator	Process the specimen according to the specifics defined in the protocol (for example, centrifuge speed, duration, temperature requirements). Transfer the specimen to the appropriate transport tube(s), as required. Label the study-specific test tubes or other containers with subject identifiers, date, time, and any other information required to prepare for storage or shipment. Complete the laboratory requisition slip. Include one copy with the specimens when shipped. Retain one copy and file in the Research Chart. If applicable, one copy for ambient and one copy for frozen specimens.

Preparing the specimens for shipment to testing laboratory –

Owner	Criteria / Steps
Research Lab Tech Clinical Research Nurse/Coordinator	Determine if the protocol requires immediate shipping or batch shipping. Prepare and package the specimens according to the shipping instructions specified in the protocol and/or central laboratory procedure manual. Complete the specimen shipping log. Retain a copy of the shipping receipt and file in the Research Chart. All specimen(s) shipped will be tracked on Specimen Tracking form and will be entered within 48 hours of shipments.

Disposal of Specimens and Laboratory Supplies-

Owner	Criteria / Steps
Research Lab Tech Clinical Research Nurse/Coordinator	Prior Approval Must Be Obtained either by P.I., IRB, Pharmaceutical Company, or Cooperative group(s) for disposal of specimens. A list of all specimen(s) to be disposed must be provided to the Research Lab Technician. Place all syringes and test tubes that have been used for blood collection, blood slides, other bloody items, into a biohazard waste container according to the UNM Hospital Infectious Waste Disposal Procedure (revised 2/2017). Items such as gloves, gauze, and Kim-wipes™ that have been in contact with blood or body fluids can go into regular trash only if they are not dripping. All used specimen containers; centrifuge tubes, applicator sticks, disposable pipettes and gloves will be placed in a proper biohazard container and stored properly until disposal. All contaminated glass tubes and microscope slides must be disposed of in a puncture resistant plastic container. Stained slides are not considered contaminated. Follow proper spill cleanup procedures as outlined in the UNM Hospital Infectious Waste Disposal Procedure (revised 2/2017) for blood or body fluid spills. All non-expired/expired laboratory supplies items, into a biohazard waste container according to the Infectious Waste Disposal Plan (revised 2/2017)..

Maintenance /Calibration of Centrifuges'

Owner	Criteria / Steps
Research Lab Tech Clinical Research Operations Manager	Centrifuge(s) need to be cleaned at the end of each day. The exterior surface will be cleaned using Caviwipes disinfecting towelettes (non-woven disposable towelettes pre-saturated with CaiCide). To calibrate the Centrifuge(s), contact ProTech Services (866) 463-7746. Must be calibrated once **every 12 months.** Post-calibration paperwork is kept in a binder labelled calibration in the Clinical Research Operations Managers Office.

Temperature Check of Refrigerator & Freezers'

Owner	Criteria / Steps
Research Lab Tech	All temperature dependent equipment will contain a thermometer with a record sheet posted on the outside door of the equipment. The temperature is recorded via probes placed in the units. Measurements are recorded every 15 minutes and are kept in a spreadsheet. To access the temperature logs please contact Stewart Livsie). Refrigerator Temperature -20°C Freezer Temperature – 80°C

NMCCA sites that do perform specimen collection and handling on site, will only utilize CLIA accredited clinical laboratories for these activities. The CLIA accreditations will be maintained by the Regulatory Staff.