University of Nebraska Medical Center

**Center for Clinical and Translational Research Standard Operating Procedure**

Nebraska Medicine

Section: **Clinical Research Center**

Title: **Specimen Kit Prep and Destruction**

SOP Number: **CO41**

Date Created: **August 16, 2016**

Version Date: **August 16, 2023**

**PURPOSE:** The purpose of this standard operating procedure (SOP) is to outline how research specimen collection kits should be prepped for use in the Clinical Research Center and disposed of if they are expired or unused at the end of a clinical trial.

**SCOPE:** This SOP applies to all specimen collection kits for clinical research in the Clinical Research Center (CRC).

**PERSONNEL RESPONSIBLE:** CRC staff involved in specimen collection kit management - Study Coordinators, Clinical Research Associates, Laboratory Personnel, and Administrative Personnel.

**PROCEDURES:**

**Lab Kit Preparation**

Proper specimen lab kit preparation is vital to ensuring safe clinical trial conduct. If utilizing CRC clinical services, lab kits must be prepped by study coordinators or other study specific personnel.

1. Review study patient schedule of activities to ensure appropriate kit is prepared.
2. Review lab kit materials against schedule of activities to ensure all required specimen collection contains are included in the lab kit.
3. Review lab kit materials to ensure all are within the expiration date.
4. Label the individual samples containers as required by the sponsor (e.g., with subject ID and date).
5. Complete the requisition form in its entirety except for collection data and time of sample collection.
6. Provide the specimen lab kit to the CRC Clinical Research Associates on the day of the visit, or at a predetermined time prior to the visit.

**Lab Kit Destruction**

Specimen collection kits, whether expired or unused at the end of a clinical trial, must be disposed of properly. Disposal may include returning kits to a sponsor, if requested.

If a sponsor does not require returning expired or unused kits, then the staff at the CRC will dispose of the items as follows:

1. Any glass or sharps items are placed in a sharps container.
2. All documents, labels, or paperwork with confidential information will be shredded.
3. All other items are discarded appropriately.
4. Any items that can be repurposed will be used if appropriate (e.g., pipettes).

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## Department Approval

Signed Serena Gaines
Research Nurse Manager

Signed: 10/1/2024

Signed
Assistant Vice Chancellor for Clinical Research

Signed: 10/13/2024