University of Nebraska Medical Center

Center for Clinical and Translational Research Standard Operating Procedure

Nebraska Medicine

Section **Clinical Research Center**

Title: **Specimen Labeling**

SOP Number: **SOP-37**

Date Created: **May 13th, 2011**

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Version Number: **3**

PURPOSE: The purpose of this standard operating procedure (SOP) is to outline how to accurately label research specimens collected and stored in the Clinical Research Center (CRC), so that stored specimens can easily be retrieved, and/or inventoried.

SCOPE: This SOP applies to all specimens collected for clinical research.

PERSONNEL RESPONSIBLE: All CRC staff involved in specimen collection or storage, including - Study Coordinators, Clinical Research Associates, Laboratory Personnel, Administrative Personnel.

PROCEDURES:

Impeccable clinical practice must be utilized when obtaining specimens from research participants, as these specimens represent important data required by the investigator or sponsor. Specimens collected and/or stored must be labeled so that they can be uniquely identified and retrieved for testing.

At least two patient identifiers (patient's name and date of birth - room number cannot be used) are to be used whenever taking blood samples per Nebraska Medicine policy (RI10). Collect and label the specimen in the presence of the patient and after specimen collection. The responsibility for labeling the specimen resides with the person who obtains the specimen. If labeling is delegated, the person collecting the specimen must verify correct labeling before the specimen is sent.

1. All specimens collected and/or stored should be labeled securely
    - Labels will be affixed directly to the primary specimen container, and anything printed should be in black permanent ink.
    - If using a self-adhesive label on a specimen to be frozen, wrap the label around container in such a way that the ends of the label overlap. This will ensure that the label will remain intact when frozen. Reinforce with tape all the way around the tube when unsure.
2. Each specimen will be labeled consistently with adequate information to identify the specimen by using by following the protocol specific instructions including the date and time of the collection and other specified identifiers such as:
    - Subject unique identifier
    - Study name
    - Sponsor-designated Study ID
    - Locally assigned Study ID

- Barcode that matches a sample collection requisition form that contains appropriate patient identification

3. During the planning stages of a study, CRC staff consult the study protocol, operations manual, or the central lab regarding special requirements for specimen labeling or storage. This information will be documented in the nursing guidelines and laboratory manual and communicated to all appropriate CRC staff.

RESOURCES:

Nebraska Medicine:

- TX06 Laboratory Specimen Labeling
- RI10 Patient Identification

Staff Accountability:

Developed By: Director of Clinical Operations, Clinical Research Center
Associate Vice Chancellor for Clinical Research, Clinical Research Center
Reviewed By: Clinical Research Associates, Clinical Research Center

Department Approval

Signed _____
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Signed _____
Medical Director of Clinical Research Center