University of Nebraska Medical Center

Center for Clinical and Translational Research Standard Operating Procedure

Nebraska Medicine

Section: **Clinical Research Center**

Title: **Off-Site Work Activities**

SOP Number: **CO34**

Date Created: **November 1st, 2010**

Version Date: **January 1, 2023**

PURPOSE: The purpose of this standard operating procedure (SOP) is to ensure that Clinical Research Center staff and study participants and their information are safe.

SCOPE: This SOP applies to all clinical research activities performed off the University of Nebraska Medical Center (UNMC)/Nebraska Medicine (NM) campus.

PERSONNEL RESPONSIBLE: Principal Investigator and when delegated by the principal investigator, sub-investigators, study coordinator, clinical research associates and/or other pertinent staff.

PROCEDURES:

1. Should a study require off-site research activities, staff must obtain approval from Clinical Research Center leadership prior to performing any of the off-site research activities. The staff member must provide information about the purpose of the off-site activity, expected impact on time, and report when they leave and return and the exact location. Upon completion of off-site activities, staff must also report any incidents which may have occurred during the course of these activities. Reportable incidents include but are not limited to: significant protocol deviations or injury to employees or subjects.
2. If the off-site location is another institution, Clinical Research Center leadership and/or the staff will obtain documented approval and/or certification from supervisory personnel at the off-site location prior to performing the research activities.
    - The approval will be maintained in the study documents.
    - The Institutional Review Board (IRB) is kept fully informed of all research activities conducted off-site.
        - All study locations where research activities are performed are included in the IRB application.
        - Inter-institutional agreements will be obtained as needed.
3. Custody of Research Materials
    - The research coordinator establishes the study specific operations and the materials needed for off-site activities. The research coordinator maintains security and accountability for the research materials. Research materials include:
        - All study documents
        - All investigational products
        - All research supplies
        - All research specimens

- Transport of all protected health information will be in accordance with Nebraska Medicine Policy IM34.

4. Storage of Research Materials
   - All study-specific materials will be stored in secured areas when not in use, with the exception of study drug which is kept in the research pharmacy, unless specific permission is granted by the research pharmacy to store study drug outside of the research pharmacy.
   - Utilization of off-site storage will be approved by Clinical Research Center leadership on a case-by-case basis and documented accordingly.
5. Unless otherwise specified, transportation to and from the off-site locations will be via the staff members' vehicle and mileage will be reimbursed in accordance with the current Mileage Policy.

RESOURCES:

Nebraska Medicine:

- HR42 - Reporting Work-Related Incidents
- FN29 – Mileage Reimbursement
- IM34 – Transporting Protected Health Information

UNMC:

- NU Travel Policy TO-01

Department Approval

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Signed: 2/9/2023

Signed
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Signed: 2/7/2023