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Center for Clinical and Translational Research Standard Operating Procedure

Section: **Clinical Research Center**

Title: **Using CRC Space**

SOP Number: **CO31**

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

Version Date: **March 26, 2024**

PURPOSE: The purpose of this standard operating procedure (SOP) is to set guidelines for the use of Clinical Research Center (CRC) space by individuals from other University of Nebraska Medical Center (UNMC) or Nebraska Medicine (NM) departments, and outside sponsor organizations.

SCOPE: This SOP applies to all UNMC or NM study personnel wanting to use the CRC for their clinical research. This SOP also applies to all sponsor representatives or Contract Research Organizations (CRO) personnel working on site.

PERSONNEL RESPONSIBLE: Principal Investigator--and when delegated by the principal investigator-- Sub-investigators, Study Coordinator and/or other pertinent staff.

DEFINITIONS:

- **Contract Research Organization (CRO) -** A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's research-related duties and functions.
- **Sponsor -** An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of the research.

PROCEDURES:

General Guidance – The CRC clinical space is available for use by UNMC and Nebraska Medicine faculty and staff. Regular CRC hours are Monday-Friday, 0800-1630. Requests for use of the CRC space and services outside of regular CRC business hours will be considered on a case-by-case basis and require approval from Clinical Research Center leadership.

1. Use of the CRC space and resources can be requested through the Study Intake Process.
2. The arrangements will be documented in writing prior to use of services.
3. All UNMC/NM study personnel using CRC space will comply with the Code of Conduct for Use of Space:
   - Coordinator will make an appointment in CRC following CO33 guidance.
   - Coordinator will ask Clinical Research Center (CRC) personnel for a room assignment upon arrival.
   - Coordinator will bring their own supplies unless permission is granted to use CRC supplies.
   - Coordinator will comply with all policies especially when it comes to patient safety policies.

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- Coordinator will clean up any space used after using it including being responsible for terminal cleaning if a participant is infected and considered contagious in any way.
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- Any staff performing procedures in the CRC space must be credentialed by Nebraska Medicine.
- If non-CRC staff are performing any invasive non-nursing procedures, including phlebotomy, a basic life support (BLS) certified CRC staff member must also be present in the CRC, in case of an emergency.
- For all nursing procedures and medication monitoring periods, at least two nurses must be present in the CRU.
- It is at the discretion of CRC Leadership whether outside coordinators can perform clinical procedures in the CRC. If outside coordinators plan to perform clinical procedures in the CRC, this must be noted in the Study Intake Form for review by staff and leadership.
- If a non-CRC coordinator will perform clinical services in CRU space, that coordinator must complete the applicable CRC Competency Checklists prior to the subject's first appointment. All non-CRC coordinators involved in the service must complete this checklist (e.g., backup coordinators).

4. Sponsor representatives or CRO personnel, (i.e., study monitors) are only permitted during regular CRC business hours when CRC staff are present. CRC personnel will assign sponsor representative/study monitors a work area in the designated monitor spaces in Eppley Cancer Institute and make sure they have access to only requested study subject information for their visit.

Report suspicious activity or problems to security by calling 402-559-5111. Study coordinators from other UNMC/NM departments are not to leave their subjects unattended unless it was arranged for CRC personnel to be back-ups for the study and CRC personnel are notified that they will be leaving the area.

Resources:
Study Intake Process: https://www.unmc.edu/cctr/resources/crc/intakeform.html

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Department Approval

Signed Serena Gaines _____ Signed: 3/26/2024 _____

Research Nurse Manager

Signed _____ Signed: 3/26/2024 _____

Assistant Vice Chancellor for Clinical Research