



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



Section: **Clinical Research Center**

Date Created: **January 6, 2020**

Title: **High Containment Space Utilization**

Version Date: **January 1, 2023**

SOP Number: **CO32**

PURPOSE: To ensure that all personnel with permission to utilize the Global Center for Health Security (GCHS) Clinical Research Unit (CRU) high containment space (“hot zone”) comply with appropriate workflow and participant monitoring. Appropriate donning, decontamination and doffing of personal protective equipment (PPE) standard operating procedure (CO50) should be reviewed in concert.

SCOPE: This applies to all site personnel with the potential to be involved in the implementation and coordination of any encounter in the high-risk area (“hot zone”).

PERSONNEL RESPONSIBLE: All personnel with any need to see subjects in the CRU hot zone.

PROCEDURES:

A detailed systematic procedure utilizing unidirectional flow is implemented and mandated. This described flow procedure is for single room use procedure. Dual room use procedure can be considered with appropriate double gloving and hand-hygiene procedures if subjects are known to have a common condition caused by the same pathogen and as approved by the GCHS CRU Medical Director. Attachment A details the layout of the GCHS CRU space, for reference.

DEFINITIONS:

Hot Zone: The high-risk area within the CRU with negative pressure where participants with known or suspected high risk pathogen infections are to enter, be seen, and from which exit to the outside.

Cold Zone: The low-risk area within the CRU where subjects without a known communicable condition are to enter, be seen, and from which exit to the outside.

Unidirectional Flow Procedure:

1. Visualize and verify in the decontamination and doffing area (RM 2035) that the necessary supplies and arrangement are present for appropriate decontamination and doffing of PPE for safe exit from the hot zone, to include the presence of exit facemasks immediately outside the door.



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2. Identify the team member that will remain in the cold zone and conduct 1:1 monitoring of the entire period that the team member and/ or the participant are present in the hot zone.
3. Verify the mode of verbal (telephone, mobile device, etc.) and visual monitoring (in room camera monitor, etc.) to be used.
4. Gather all supplies and equipment necessary for completion of visit, to include the preparation of collection and delivery materiel, for instance, phlebotomy supplies, medications for administration, and labels. Handling of sharps and other preparations that may be conducted in the cold zone prior to entry should be done there so that time in the hot zone is time focused on the participant.
5. Don appropriate PPE to include but not limited to gown, eyewear/face shield, gloves (layering of gloves allowed), and mask in the donning room (RM 2028; blue square). Following PPE donning protocol. Attachment B. Preparation for entry should be verified by the team member monitoring the encounter from the cold zone.
6. Exit donning area (RM 2028) and swipe badge to enter the hot zone hall (2029).
7. Place visit supplies in the exam room (RM 2032 or 2033).
8. Identify (see subject identification workflow below) and escort subject through the open "green dot" door and assure closure after subject has entered.
 - a. Subject will call CRU front desk to verify arrival in parking lot.
 - b. CRU front desk staff will communicate with study coordinator.
 - c. Study coordinator will contact subject and note to remain in car until "green dot" door is opened.
9. Announce to subject that exam rooms (RM 2032 & 2033) are monitored (both via audio and visual technologies) for safety purposes even if discussed prior to visit.
10. Proceed directly into an exam room (either RM 2032 or 2033; red squares) and close door after entry.
11. Perform clinical exam/procedures as directed by symptoms and/or protocol.
 - a. If necessary, escort subject to and from the bathroom (RM 2036) for testing procedures (i.e., urinalysis) or changing into gown for physical exam.
 - b. If necessary, examination of sensitive body regions (females: breasts/genitalia & males: genitalia) should be discussed with the subject prior to the visit (if possible) in order to discuss mode of visual monitoring (camera monitoring or second staff presence) to be followed.
 - i. Visual monitoring may be interrupted if examination of sensitive body regions is occurring.



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1. Cold zone staff either disconnects, turns off screen or closes laptop until verbally directed by hot zone staff to return to visual monitoring.
 - i. Audio capabilities between cold and hot staff will remain available AT ALL TIMES during visits.
12. At the end of visit, escort the subject to and from the bathroom (RM 2036), if necessary, to return to street clothes.
13. Conduct hand hygiene, change exterior gloves (or sanitize gloves if wearing a single pair of gloves), then proceed with the participant directly from the exam room out through the “green dot” door. Ensure closure of the “green dot” door.
14. With appropriate cleaning product, cleansed all high touch surfaces in hall (RM 2009E).
15. Enter the room that was utilized (either RM 2032 or 2033) and with appropriate cleaning product cleanse all high touch surfaces.
16. Alert verbally and/or visually to the cold zone staff member that you are proceeding to the decontamination and doffing area. Notify cold staff member if cleansing of bathroom (RM 2036) will be done prior to decontamination and doffing to note anticipated delay in exiting.
17. Proceed to cleanse high touch areas in hall (RM 2099N) and bathroom (RM 2036) if utilized during visit.
18. Verify that sufficient space exists in trash can in hallway and in decontamination and doffing area for appropriate exit (less than (2/3 full). If necessary, change trash bags and set closed bags in designated holding area in rear hallway.
19. Proceed to decontamination and doffing area (RM 2035) and ensure that the door is completely closed. Follow NMC decontamination and doffing steps for high-risk pathogens. Attachment B
 - a. Eyewear/face shield and mask may remain in place after doffing gown/gloves if proceeding directly back to donning area (RM 2028) for a subsequent hot zone visit.
20. Exit doffing area (RM 2035) after donning appropriate cold zone PPE (if not proceeding immediately back for donning with the same face shield and respirator), the hot zone staff member provides a debriefing of visit face to face with cold zone staff member to ensure closure of the encounter.



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RESOURCES:

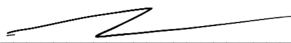
Nebraska Medicine:

- [IC01 – Standard Infection Control Practices for All Patient Care Areas](#)
- [IC04- Transmission-based Precautions/Isolation Precautions Policy](#)
- [IC02 – Hand Hygiene](#)
- **Nebraska Medicine PPE Guidelines found on Nebraska Medicine webpage.**

Department Approval

Signed *Serena Gaines*
Research Nurse Manager

Signed: 2/9/2023

Signed 
Assistant Vice Chancellor for Clinical Research

Signed: 2/7/2023



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Attachment A

