



Clinical Research Center Space Policy	CR-501
Clinical Research Standard Practices	Effective Date: September 2024

SCOPE AND PURPOSE This document is applicable to the following roles within Penn State College of Medicine and Penn State Health entities engaged in clinical research:

<input checked="" type="checkbox"/> Principal Investigator	<input type="checkbox"/> Regulatory Specialists
<input checked="" type="checkbox"/> Sub-Investigators	<input checked="" type="checkbox"/> Key Study Ancillary Personnel
<input checked="" type="checkbox"/> Study Coordinators/Associates	<input type="checkbox"/> Financial Analyst/Contract Management Accountants
<input type="checkbox"/> Data Specialist	<input type="checkbox"/> Central Research Office Personnel

This policy describes the process for use of the shared space for conducting clinical research at the Clinical Research Center (CRC) of Penn State Health Milton S. Hershey Medical Center. It defines the process for use, sharing, and management of the CRC space to ensure a safe and compliant research environment.

This policy may be shared with Sponsors and/or CROs upon request.

POLICY AND PROCEDURE STATEMENTS

1. General

- a. The CRC website provides a list of available spaces for clinical research within the center.
- b. Badge access to the CRC is restricted to study staff necessary to complete study visits. Other authorized personnel will be determined on a case by case basis. Email a request with name and study IRB number to the central CRC email crc@pennstatehealth.psu.edu for approval.
- c. Research participants and visitors are not to be left alone in the CRC. There must be at least one staff member in the CRC if a participant is present. The following are considered staff members per this policy:
 - i. CRC staff members
 - ii. Study team members
 - iii. Clinical Research Contingency Pool personnel
 - iv. Hershey Medical Center clinical nurses
- d. Visitors must always be accompanied by authorized personnel. Refer to the *CR-501: Visitation Guidelines* regarding visitors.
- e. CRC is open with staff coverage during the following hours: Monday-Friday 7:30 a.m. to 4 p.m., excluding holidays recognized by Penn State Health.
 - i. Study visits occurring outside after Core Operation Hours require a study team member or Clinical Research Contingency Pool team member to always remain with the research participant.
 - ii. It is the study team's responsibility to provide coverage if they need to leave the unit.
 - iii. The study team must document the coverage plan. Please provide this in writing to the CRC nursing staff when scheduling visits.

- f. Use of CRC rooms for study training/education will be approved based on space availability.
 - g. Exceptions to this policy may be granted at the discretion of CRC leadership.
- 2. Approval process for use of space in the CRC
 - a. To apply to use the Clinical Research Center, please complete the application form on the CRC website. <https://research.med.psu.edu/research-support/crc/>
 - i. Click the “Complete the CRC Application Here” button, found in the “Application Process: Clinical Research Center in Hershey” section.
 - b. Applications are due the 15th of each month for review the first Wednesday of the following month. Reviews are not done in January or July.
 - c. Identify the need for the CRC: space needs, nursing time, nursing services, supplies.
 - d. Once the application is approved, a letter is sent to the Principal Investigator (PI) and study coordinator.
 - e. Schedule a startup meeting with the Clinical Staff Leader at 717-531-1642
- 3. Requesting Space in the CRC
 - a. Complete the scheduling request form and email **crc@pennstatehealth.psu.edu**
 - i. All requests must be emailed with the scheduling request form.
 - ii. Requests should be submitted as soon as possible to confirm room availability and ensure adequate staffing.
 - iii. The Scheduling Request form and the Participant Demographics form are provided to the study team at the start-up meeting.
 - b. Room assignment will be based on the needs of the project, availability of space, and compliance with regulatory requirements.
 - c. Daily room assignment will be posted at the reception office door (H4503) and the nursing station (H4515).
 - d. Study training/education room usage will be approved based on space availability.
- 4. Use of Research Space
 - a. Rooms must be kept clean and left ready for the next study team visit.
 - b. Any room related concerns, such as an equipment malfunction, should be reported to a CRC staff nurse.

RELATED POLICIES AND REFERENCES

Clinical Research Center website (<https://research.med.psu.edu/research-support/crc/>)

Clinical Research Center Visitation Guidelines (CR-502)

APPROVALS

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