



Clinical Research Center Visitation Guidelines	CR-502
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 guideline aims to support and promote the integrity of the research participants visit. The objective is to help protect the community, staff, visitors and participants by defining guiding principles for the research participant and their visitor(s) occurring in the Clinical Research Center (CRC) unit of Penn State Health Milton S. Hershey Medical Center.

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

POLICY AND PROCEDURE STATEMENTS

1. General Standards

- a. No more than two adult visitors can accompany a research participant to their visit. Exceptions will be reviewed on a case-by-case basis with the decision made based on a holistic approach to the participant's needs and the requirements of the research study.
- b. Some research visits will occur in a smaller size room and may only be able to accommodate one visitor. A waiting room is available for additional visitors outside of the CRC unit.
- c. Any visitor under the age of 18 may be permitted if coordinated with the CRC unit staff in advance of the visit.
 - i. Children visiting the CRC must always remain under the direct supervision of the adult research participant or an adult accompanying the participant. The responsibility for the child's safety and behavior lies solely with the adult participant or the other accompanying adult. The need for an accompanying adult should be based on the child's age, developmental level, and the research activities to be performed. The research participant should be able to completely focus on the activities being performed as part of the study visit.
 - ii. Children visiting the CRC may not stay overnight in the CRC.
 - iii. Children should be capable of entertaining themselves with minimal need for engagement from research staff, the research participant, or visitors of

other research participants. It is recommended that the research participant bring appropriate activities, such as books, toys, or electronic devices, to keep the child occupied.

- iv. The CRC must maintain a quiet and focused environment. Children must engage in quiet activities and avoid behaviors that may disrupt research activities.
- v. Due to space and safety considerations, children should remain in designated spaces (i.e., waiting areas, specified areas in CRC room, etc.) unless otherwise permitted by research staff. They should not enter areas where clinical procedures or research activities are taking place.
- vi. Children must exhibit appropriate behavior at all times. Any disruptive or unsafe behavior will result in the adult participant being asked to remove the child to awaiting room available outside the of the CRC.
- d. All visitors, including children, must comply with the health and safety protocols of the facility. This includes any requirements for health screenings, hygiene practices, and wearing appropriate protective equipment if necessary.
 - i. Due to the nature of the activities occurring in the CRC, it may be necessary to temporarily restrict visits from the participant's room in the CRC for health and safety reasons. If this is necessary, visitors will be brought back from the waiting area to rejoin the participant at the earliest feasible time.
- e. No visitor or unattended child is permitted to linger in the hallways.

2. Child Research Participant

- a. Parent(s), family member(s), or caregiver(s) of the research participant are encouraged to accompany the child to their research visit.
- b. Due to the nature of the research activities to be conducted, it may be necessary for a second adult to attend to accompany any children visitors so that one adult is able to support the child research participant.
An adult visitor is required to stay with a child research participant who is required to stay overnight in the CRC
- c. The CRC staff may grant an exception for a responsible older child to serve as the "second adult visitor."

3. Service Animals and Pets

- a. Service Animal is defined as either a dog or a miniature horse (typically 70-100 pounds), which is individually trained to work or perform tasks for the benefit of an individual with a disability (including intellectual and mental disabilities) or health condition.
- b. Support Animal or Pet is any animal which is not a Service Animal. Support Animals often provide emotional support, well-being, comfort or companionship. Other terms used to describe a Support Animal include therapy animal or

emotional support animal. For the purposes of this policy, support animal and pet are considered separately from Service Animals.

Service Animals are generally permitted as it aligns with Penn State Health Policy (A-04). [Policy Manager - MCN Healthcare \(ellucid.com\)](#) Support Animals are not permitted in Penn State Health facilities.

- c. Infection Prevention Procedure
 - i. Hand hygiene must be performed after contact with any animal, its equipment, or any other item in direct contact with the animal.
 - ii. If the Service Animal contaminates the area with urine, feces, vomitus, blood or other fluid or substance, Environmental Health Services will be notified promptly. The cleanup procedures must be performed using the appropriate personal protective equipment (PPE) which would include gloves as a minimum protection. Organic debris should be bagged in a plastic bag and then the area cleaned with the hospital-approved disinfectant.

RELATED POLICIES AND REFERENCES

Penn State Health Service Animals and Pets Policy (A-04)

Visitation Guidelines for Family/Support Person(s) and Visitors

APPROVALS

Approved:	Christine Capper, BSN, RN Clinical Staff Leader, Clinical Research Center
Authorized:	Neal Thomas, MD, MSc Associate Dean of Clinical Research Sheila Vrana, PhD Associate Dean of Research Jennifer Kraschnewski, MD, MPH Director, Penn State Clinical and Translational Science Institute Richard Legro, MD Clinical Services Core Leader, Penn State Clinical and Translational Science Institute

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CONTENT REVIEWERS AND CONTRIBUTORS

Clinical Staff Leader, Clinical Research Center