Clinical Research Locations	CR-107
Clinical Research Standard Practices	**Effective Date:** July 2023

SCOPE AND PURPOSE The document is applicable to the people and processes of the following Penn State College of Medicine and Penn State Health entities specified below engaged in clinical research:
Entities:

	Penn State Health Shared Services	X	Penn State College of Medicine
X	Milton S. Hershey Medical Center	X	Medical Group – Academic Practice Division
X	St. Joseph Medical Center	X	Medical Group - Community Practice Division
X	Holy Spirit Medical Center	X	Penn State Health Life Lion, LLC
X	Hampden Medical Center	X	Lancaster Medical Center

Roles:

X	Principal Investigator	X	Regulatory Specialist
X	Sub-Investigator	X	Key Study Ancillary Personnel
X	Study Coordinators/Associate	X	Financial Analyst/Research Accountant
	Data Specialist	X	Central Research Office Personnel

This policy describes the appropriateness of locations across all campuses for the conduct of clinical research. This policy applies to the written procedures followed by the research team as it conducts all clinical studies involving human participants in research, including all interventional and observational human research. This policy only relates to Penn State University and Penn State Health spaces. Approval for use of other spaces (e.g., parks, schools, restaurants, public spaces, etc.) are at the discretion of the IRB and the party/ies who have ownership/oversight of said spaces.

POLICY AND PROCEDURE STATEMENTS

1. Clinical researchers are encouraged to utilize presently approved locations to conduct human participants research. However, prior approval from the unit director or manager of the presently approved locations is required through the accepted process for that space (will differ for clinical space vs dedicated clinical research space). In addition, the PI and study team must adhere to all the applicable procedures for each location.
    a. The presently approved locations for human participants research comprise all Department of Health and Joint Commission clinical locations which includes inpatient units, outpatient clinics and ancillary clinical services. In addition, other presently approved locations specific for clinical research are:
        i. Clinical Research Center
        ii. NMR Facility
        iii. Penn State Exercise Research Unit (HCAR)
        iv. Penn State Cancer Institute Exercise Unit (PSCI)
        v. Dermatology clinical research space (UPC II 2010/B)

vi. Neurology clinical research space (C2852/A, C3522, C5518, and H5508)
vii. Neuroscience clinical research space (East Campus 1302)
viii. Ophthalmology clinical research space (UPC I 501 A/B)
ix. Special Hematology (C6608)

b. A comprehensive list of all approved locations shall be maintained on the Clinical Trials Office (CTO) website and linked to from the Penn State Clinical Research Guidebook. The list of approved locations in this policy document will be updated biennially when this policy is reviewed to include any additional locations that are approved through the process outlined in this policy.

2. Any human research study that requires collecting biospecimens, or performing any clinical assessment or intervention, including (e.g., vital signs, walk tests, physical examinations, procedures that would normally be performed in a clinical area, etc.) is allowable only in the approved locations for clinical research.
    a. Walk tests must take place in a hallway of a hospital or clinic with the following conditions being met:
        i. A code cart or code button is readily accessible (within 2 minutes' walk/run);
        ii. Study team has cell reception and/or a second team member present who can activate emergency response system;
        iii. Temporary barriers can be deployed to limit interference of the participant performance without obstructing foot traffic; and
        iv. All life safety and other regulatory requirements are met.

3. Any human research that involves conversations, surveys, questionnaires, focus group, etc., and does not require clinical assessment or intervention, as described above, may be performed at approved alternative locations, such as conference rooms. Alternative locations may be used after prior approval as defined below.
    a. With approval, the following clinical assessments may occur in alternative locations:
        i. Vital signs
        ii. Visual skin assessments that require minor adjustment of the participant's clothing to perform such an inspection

4. Requests to conduct human participants research in places other than those on the approved location list require approval through the following process. Approval is granted to a specific study and does not imply approval for another study.
    a. Request for the approval of an alternative location is available on the CTO website and linked to the Penn State Clinical Research Guidebook.
    b. The process for obtaining approval is as follows:
        i. Approval from the director that maintains oversight of the proposed alternative location
            - For clinical space, the person granting approval must be the clinic's medical director or practice site manager
            - For non-clinical space, the person supporting approval must be the operations director or operations manager of the department assigned to the proposed alternative location

ii. Approval from Research Quality Assurance to address biosafety matters, if the study involves the collection, procession, and/or shipping of biospecimens.
iii. Approval from CTO to address billing compliance and clinical operation matters.
iv. Approval from Facilities Management to confirm that the proposed alternative location meets applicable regulations, including accessibility and space assignment.

RELATED POLICIES AND REFERENCES

Clinical Research Guidebook (https://research.med.psu.edu/research-support/guidebook/)

International Conference on Harmonization Good Clinical Practice E6(R2)

APPROVALS

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DATE OF ORIGIN AND REVIEWS

Date of origin: May 2023

Review Date(s):

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