Participant Recruitment and Screening	CR-302
Clinical Research Standard Practices	**Effective Date:** August 2022

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

Roles:

[X]	Principal Investigator
[X]	Sub-Investigators
[X]	Study Coordinators/Associates
[X]	Data Specialist
[X]	Financial Analyst
[X]	Key Study Ancillary Personnel

The recruitment phase of a clinical study is frequently difficult and challenging. Successfully recruiting participants involves the development and implementation of a well-coordinated plan that may require the efforts of the entire research team. Once in place, participant recruitment efforts must be constantly assessed, with new strategies implemented as necessary. After potential participants have been identified through recruitment efforts, the process of participant selection begins.

This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and clinical requirements involved in participant recruitment and selection.
This SOP applies to the activities involved in recruiting and screening participants for all clinical studies involving human participants in research during all investigational phases of development.

POLICY AND PROCEDURE STATEMENTS

1. Develop and implement an overall recruitment plan
    a. Based upon the specific inclusion/exclusion criteria for a study, identify the target population for potential study participants.
    b. Establish a recruitment timeline
    c. Determine recruitment methods (e.g., StudyFinder, print media/radio ads, letters, community talks, patient support groups, Internet).
    d. Project costs associated with each recruitment strategy.

e. Obtain sponsor approval for all materials to be used.
f. Submit to the IRB as appropriate for approval.
g. Identify sources of potential participants:
    i. Chart review – determine if a HIPPA Waiver of Authorization is required – See Clinical Research Guidebook
    ii. phone contacts;
    iii. referrals from other physicians/clinics;
    iv. advertisements.

2. Assess the effectiveness of the recruitment plan
    a. Monitor progress and assess results of the recruitment strategy. Develop appropriate alternative strategies, if necessary.
    b. Institute alternative strategies if enrollment projections lag.
    c. Evaluate final results.

3. Initiate screening procedures
    a. Develop a screening log based upon the study inclusion/exclusion criteria to collect screening information on all potential participants. A Screening and Enrollment Log is available on the CTO Website.
    b. Note if individuals went on to enroll in the study; if they were not enrolled, document the reason.
    c. Obtain informed consent per Institutional Review Board standard operation procedure *Informed Consent Process for Research* (HRP-090).
    d. It is recommended to maintain a log of when informed consent was obtained from each participant as well has when each participant is reconsented. A participant Informed Consent Tracking Log Template is available on the CTO website.
    e. Retain all signed informed consent forms from participants who terminate their participation in the study during the screening process.

RELATED POLICIES AND REFERENCES

Code of Federal Regulations: Protection of Human Subjects (21 CFR 50.20)

Code of Federal Regulations: Institutional Review Board (21 CFR 56.109)

Code of Federal Regulations: Investigational New Drug Application (21 CFR 312.60,62)

International Conference on Harmonization Good Clinical Practice E6(R2)

Investigator Manual (HRP-103)

Screening Tests Prior to Study Enrollment: Guidance for Institutional Review Boards and Clinical Investigators; U. S. Food and Drug Administration; January 1998

APPROVALS

Authorized:	Kevin Gardner, Jr., MS, BSN, RN, CCRC Director, College of Medicine Clinical Trials Office Adam McDowell, BA, JD, CRA Director, Office of Research Affairs, Contracts Thomas Brydebell Director, Office of Research Affairs, Grants Elizabeth Galgocy, MEd, RN, CIP Director, Research Quality Assurance, Human Research Trials
Approved:	Neal Thomas, MD, MSc Associate Dean of Clinical Research Sheila Vrana, PhD Associate Dean of Research

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CONTENT REVIEWERS AND CONTRIBUTORS

Director, College of Medicine Clinical Trials Office

Director, Office of Research Affairs, Contracts

Director, Office of Research Affairs, Grants

Director, Research Quality Assurance, Human Research Trials