Participant Management While on Study	CR-303
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
[ ]	Financial Analyst
[ ]	Key Study Ancillary Personnel

The safety and well-being of participants is of paramount concern to the research team. This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and clinical requirements to ensure adherence to study procedures for the evaluation of a participant's response to the investigational article. Through close monitoring and careful assessment of participants, adverse events can be detected early and treated appropriately. By following these procedures, close attention is paid to participants well-being and to integrity of the data.

This SOP applies to the activities involved in managing participants on clinical studies involving human subjects in research during all investigational phases of development.

POLICY AND PROCEDURE STATEMENTS

1. General
    a. Consenting of participants must be recorded in STAR within 24 hours, regardless if the patient screen failed during the initial visit. This ensures the research bill hold is entered for this participant.
    b. All research participant visits must be recorded in STAR within two business days
    c. A visit-specific list of protocol directed tests/procedures can be found in STAR. Please reference the budget document titled "BGRID" or "Budget Worksheet Final."

2. Enrollment assessments and management

a. Participant management Forms are available on the CTO Website
b. Elicit and document the participants medical history.
c. Perform a complete or directed physical examination, as per protocol
d. Establish the participants baseline signs and symptoms.
e. Review with the participant the use of any current medication.
f. Inform the participant about the required study procedures and visits.
g. Collect specimens as directed by the protocol
h. Provide contact information to the participant
i. Schedule the follow-up visit.
j. Complete CRFs with above information as directed by protocol.
k. Randomize and dispense the test article (if applicable).
l. Review with the participant the use of any study aids, such as a diary.

3. Follow-up, completion and early termination from the study
    a. Perform a complete or directed physical examination, as required per protocol.
    b. Assess the participant for signs and symptoms of any intercurrent illness and document adverse events appropriately.
    c. Refer to Penn State University Institutional Review Board *Investigator Manual* (HRP-103) and SOP *Adverse Event Reporting* (CR-304) for reporting and documentation of any adverse events.
    d. Collect specimens as directed by the protocol.
    e. Order diagnostic tests and procedures as necessary.
    f. Institute appropriate therapy if required by the participants condition.
    g. Review any use of concomitant medication.
    h. Schedule follow-up visits per protocol.
    i. Assess the participants compliance with the test article.
    j. Collect unused test article, if appropriate
    k. Dispense additional test article, as required.
    l. Diagnose and document any intercurrent illness and endpoints.
    m. Review the participants laboratory and other test results.

4. Communication with primary or referring medical providers
    a. Inform the participants primary care provider about the participants progress while on study, if the participant agrees.
    b. Ensure that the primary care provider receives copies of the participants laboratory test results and reports of procedures, etc. if the participant agrees.
    c. Confer with the primary care provider, as appropriate.
    d. If appropriate and in consultation with the PI notify the participant of any information that may affect their safety and willingness to continue participation in the study

5. Management of ineligible participants
    a. Document the reason for ineligibility. Retain any supporting data available.
    b. Complete any clinical and laboratory assessments required by the protocol.
    c. Collect any unused test article and any used test article containers, and record data in the investigational drug log
    d. Discuss treatment alternatives with the participant. Follow the participant as required by the protocol.
    e. Notify the sponsor as required.

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)

APPROVALS

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