Documentation of Informed Consent Process	CR-301
Clinical Research Standard Practices	**Effective Date:** December 2023

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:

Roles:

X	Principal Investigators	X	Regulatory Specialists
X	Sub-Investigators	X	Key Study Ancillary Personnel
X	Study Coordinators/Associates	X	Financial Analyst/Research Accountants
X	Data Specialists	X	Central Research Office Personnel

The ethical conduct of clinical investigations is based upon the voluntary consent of the participant who has been appropriately informed about a study's risks and benefits. It is the responsibility of the investigator to ensure that all federal and state regulations have been met through the language of the informed consent document, and that informed consent itself has been properly obtained from the participant or the participant's legally authorized representative (LAR).

Documentation of the informed consent process is required to establish that the participant was accurately and adequately informed and that no study-related procedures were initiated prior to obtaining informed consent.

This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and ethical requirements for documenting the informed consent process.
This SOP may be shared with Sponsors and/or CROs upon request.

POLICY AND PROCEDURE STATEMENTS

1. General principles
    a. As defined by the Penn State University (PSU) Institutional Review Board (IRB) and Penn State Human Research Protections Program (HRPP), an "investigator" means a principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific study. Such individuals include, but not limited to, sub-investigators, research assistants, or coordinators.
    b. Investigators may be delegated on the study sponsor's delegation log to participate in the informed consent process without being approved by the IRB to obtain consent, unless otherwise specified by the Penn State College of Medicine Conflict of Interest Committee.
        i. Such an example would be a physician investigator with a conflict of interest management plan might be involved in the explanation of the

protocol and its risks and benefits, answering participants' questions, and confirming that participants meet the study's eligibility criteria.

c. Participants, or LARs, will be consented in a private location after having adequate time to review the study's consent form, and have had all questions answered.
d. While the consent form lists the person obtaining consent first, it is acceptable for the participant, or LAR, to sign the consent form first. Additionally, absent HRPP instructions, the participant's name may be printed by either the participant or a study team member.
e. Participants, or LARs, will be consented using the current IRB-approved informed consent form. Study teams may choose to utilize either the Sponsor's consent template or the PSU IRB consent template to create the consent form used for the study.
    i. Once consented using the PSU IRB consent template, participants do not sign a full informed consent for protocol changes or changes to the consent form. Such changes to the consent form will be presented to currently enrolled participants using a consent addendum. The consent addendum will state what the changes are to the previous version of the consent.
        - When possible and appropriate, changes to the consent language would be presented in such a way that the original paragraph/section will appear with added text being in bold and removed having a strikethrough.
        - The consent addendum will include a statement that explicitly indicates that all other sections of the consent remain the same.
f. Participants who screen fail and re-screen later will sign the current IRB-approved informed consent form at the time of re-screening.
g. Maintain the original consent per sponsor's guidelines/federal regulations.

2. Documentation of informed consent process
    a. Document the informed consent process (regardless if required to obtain written consent or permitted to obtain verbal consent) by providing the following information:
        i. Form of consent obtained (e.g., written, verbal, or implied)
        ii. Date and time the consent was obtained;
        iii. Informed consent was obtained prior to participation in the study and before any study related procedures were performed;
        iv. Any questions or concerns raised by the participant, LAR, and/or others present during discussions;
            - It is preferred that the actual questions or concerns that were raised and the responses that were provided be documented
        v. Note that participant had an opportunity to review the document;
        vi. The participant or legal authorized representative were given a copy of the relevant consenting materials,
            - If written consent was obtained, a copy of the signed, dated, and timed consent form is to be given

- If verbal or implied consent was obtained, any applicable written IRB-approved materials used during the consenting processes should be provided, including but not limited to, summary explanations of research, etc.

b. Revisions to the informed consent form
    i. Review changes to the protocol and investigator's brochure as well as IND safety reports, to assess the need for revising the informed consent form.

3. For participants who are patients of Penn State Health
    a. The documentation of the consent process is to occur in the Penn State Health electronic medical record. The preferred method is for direct entry into the electronic medical record; however, a scanned copy of hand-written note is permissible.
    b. For locations that utilize Cerner as the electronic medical record:
        i. Documentation of consent will be entered in the participant's electronic medical record as either an Outpatient Note, Outpatient Nursing Note, Inpatient Progress Note, or in the Clinical Trials Form/Interdisciplinary Narrative Form. However, due to viewing limitation, documentation in the Clinical Trials Form and/or Interdisciplinary Narrative Form is the least preferred method, but is acceptable.
            - The subject line should be "Research Consent" for Outpatient Note, Outpatient Nursing Note, and Inpatient Progress Note for each of reference.
        ii. Study information should be entered in the Clinical Trials Form within two business days, or as soon as possible, if the participation in the research lasts more than one encounter.
    c. The requirement to document the consent process in the electronic medical record and have a copy of the signed consent form scanned into the electronic medical record may be waived if one of the two exceptions are met:
        i. The PSU IRB issues a waiver of documentation of consent, or
        ii. The participant meets ALL of the following criteria:
            - Participating in research that does NOT meet the National Institutes of Health definition of clinical trial
            - Do NOT routinely receive care at a Penn State Health facility
            - Research activities occur solely in non-Penn State Health facilities (including, not limited to, Penn State Clinical Research Center, NMR Building, etc.)
    d. Send a copy of the signed informed consent form to Health Information Services to be uploaded into the participant's medical record.

4. For participants who are NOT patients of Penn State Health
    a. The documentation of consent is to occur in the participant's study file
    b. Maintain the original consent per sponsor's guidelines/federal regulations.

RELATED POLICIES AND REFERENCES

A Guide to Informed Consent: Guidance for Institutional Review Boards and Clinical Investigators; U. S. Food and Drug Administration; January 1998

The Belmont Report; U. S. Department of Health and Human Service, Office for Human Research Protections; 18 April 1979

Code of Federal Regulations: Elements of Informed Consent (21 CFR 50.25)

Code of Federal Regulations: Institutional Review Board (21 CFR 56.109, 111)

Code of Federal Regulations: Investigational New Drug Application (21 CFR 312.54, 60, 62)

Code of Federal Regulations: General requirements for Informed Consent (45 CFR 46.116)

Compliance Program Manual, Bioresearch Monitoring Program, Clinical Investigators and Sponsor-Investigators (Program# 7348.811); U. S. Food and Drug Administration; 22 July 2020

Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects; World Medical Association; June 1964

International Conference on Harmonization Good Clinical Practice E6(R2)

Medical Care Availability and Reduction of Error (MCARE) Act [40 Pa. Stat. § 1303. 504(e)]

Penn State University Institutional Review Board Investigator Manual (HRP-103)

Penn State University Institutional Review Board Standard Operation Procedure: Written Documentation of Consent (HRP-091)

Penn State University Institutional Review Board Standard Operation Procedure: Informed Consent Process for Research (HRP-090)

Penn State University Institutional Review Board Standard Operation Procedure: Legally Authorized Representatives, Children, and Guardians (HRP-013)

APPROVALS

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History of Reviews and Revisions

November 2023	
Scope and Purpose	Removed list of Entities. Updated "Financial Analyst/**Research Accountants**" and added "Regulatory Specialists" and "Central Research Office Personnel" to list of Roles. Legal representative updated to legally authorized representative (LAR) to align to with federal regulations and international standards. Notation made that this SOP may be shared with Sponsors and/or CROs upon request.
Policy and Procedure Statements	Section 1 General principles added. Existing sections advanced by one, and referenced accordingly. Bullet 2.a.i. added, with existing bullets advanced by one, and referenced accordingly. Bullet 2.a.vii. revised to differentiate documents to be given to participants or legally authorized representative added
Related Policies and References	Added reference to Pennsylvania MCARE Act Replaced "Penn State Institutional Review Board and Human Subjects Protection Office Policy IRB Policies and Operating Procedures" with specific references. Added subsections 2.b-2.d.
Content Reviewers and Contributors	Added Executive Director, Human Research Protection Program
History of Reviews and Revisions	Section added.