THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

SOP-11: Obtaining Informed Consent

1. Objective

To ensure that the Principal Investigator (PI) and all research team members assisting in the conduct of clinical research are informed about their obligations and responsibilities as they pertain to Good Clinical Practices (GCP), the investigational plan, applicable regulations, guidance, and institutional policies. This Standard Operating Procedure (SOP) applies to the written procedures followed by all members of a clinical research team involved in the conduct of human subjects' research at The Ohio State University Wexner Medical Center (OSUWMC), hereafter called the investigational site. These detailed instructions promote compliance in conducting clinical research.

SOP-11 describes the process for obtaining informed consent of subjects for clinical research. Attachment templates include:

A: Consent Documentation Note
B: Consent Process Checklist (Not Subject to Edit)

2. Responsibility

The College of Medicine Center for Clinical Research Management (COM-CCRM) develops, implements, and maintains SOPs. The need to write a new or revise an existing SOP is based upon changes to federal regulations, guidelines, institutional policies, or procedures. These documents will be provided to departments and research teams conducting human subjects' research. Departments or research teams may develop additional research SOPs or a Research Procedure Addendum (RPA) to expand on an existing SOP, however this need should be limited.

The PI is ultimately accountable for all clinical research activities and is responsible for the appropriate delegation of tasks to individuals with adequate training and education to perform such tasks. It is the responsibility of all members of the clinical research team involved in supervising, managing, or conducting study-related activities to follow the SOPs. The clinical research team may include but is not limited to the following members:

Research Team Members

Principal Investigator (PI)	Clinical Research Coordinator (CRC)
Sub-Investigator or Co-I (Sub-I or Co-I)	Clinical Research Assistant (CRA)
Clinical Research Manager (CRM)	Other Research Staff as appropriate
Clinical Research Specialist (CRS)	Administrative and Support Staff

3. Definitions

Please refer to the SOP Glossary document for detailed definitions of commonly used clinical research terminology.

4. Procedures

Informed consent will be obtained by the PI or a delegated research team member only under circumstances that provide the prospective subject or the Legally Authorized Representative (LAR) sufficient opportunity to consider whether or not to participate, and that minimize the possibility of coercion or undue influence.

LAR will be identified pursuant to the laws of the State of Ohio.

The PI and delegated research team member should comply with the applicable regulatory requirements, institutional policies, and to the ethical principles of human subjects' protection when obtaining and documenting informed consent of research subjects.

At a minimum, individuals obtaining informed consent should be listed as key personnel with Buck-IRB, as well as listed on the Delegation of Authority log. In cases where OSU is not the IRB of record, please refer to the specific requirements of that IRB (e.g., WCG, Advarra, etc.) These individuals will have appropriate training and education to perform such tasks.

The IRB application will clearly state whether or not a LAR will be allowed to sign the consent on behalf of the prospective subject under acceptable circumstances as defined by Office of Responsible Research Practices (ORRP), IRB of record, and medical center policies.

The IRB application will clearly identify whether subjects recruited to the study represent a vulnerable population for which additional protections may need to be implemented as outlined by ORRP and the IRB of record policies.

Prior to implementing the research study, the investigator will have the IRB approval of the informed consent document, the method(s) of the consent process, and any other information provided to subjects. Subjects will not be screened, recruited, or consented until final IRB approval of these documents has been received.

The approved documents will be updated to reflect approval date and document version by the research team members, if not updated by the IRB of record. This will allow for version control to ensure the most recently approved consent form, HIPAA authorization, consent addendums, assent form and parental permission forms are used when consenting research subjects to the IRB approved research study.

Special Considerations
Planned emergency research and emergency use of investigational drugs, biologics, or devices for life-threatening conditions have special institutional requirements and processes that will be followed outside of the scope of this SOP, if applicable. Please refer to the reviewing IRB's policy on Emergency use of Investigational Drugs, Biologics or Devices.

Waiver of written informed consent and short form consent for non-English speaking individuals have special institutional requirements and processes that will be followed outside of the scope of this SOP, if applicable.

A. Obtaining Consent

The PI or delegated research team member will review and discuss details of the research study using the consent form as a guide. All basic elements of the consent form document, HIPAA authorization, consent

addendums and any additional relevant information will be presented in detail to the prospective subject or the subject's LAR, if applicable.

The information given to the subject or the representative shall be in a language understandable to the subject or the representative. No informed consent, whether oral or written, will include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The information presented will not include complex, technical, highly specialized language or medical jargon that would not be understandable to the potential subject or the subject's LAR. The PI and delegated research team member will not coerce or unduly influence a subject to participate or to continue to participate in a research study. All consent discussions will take place in a private area with respect to the potential subject's privacy.

Before informed consent may be obtained, the PI or delegated research team member will provide the subject or the subject's LAR ample time and opportunity to read, inquire about the details of the study, and decide whether or not to participate in the study. All questions about the study will be answered to the satisfaction of the subject.

Prior to any study related procedures, the PI or delegated research team member will obtain informed consent which will be documented by the use of a written consent form unless a consent waiver or waiver/alteration of documentation of consent has been previously approved by the IRB of record. The consent form document approved by the IRB will be signed and dated by the subject or the subject's LAR (if previously approved by the IRB). Subjects/LARs who cannot write can indicate their consent by "making their mark" on the consent form, when consistent with applicable state law. In this situation, a progress note in the subject's case history should indicate the reason for the lack of a signature. This form will also be signed and dated by the person obtaining consent and, if necessary, an impartial witness to the consent process.

All blanks on the consent form, consent addendum forms (if applicable) and HIPAA authorization form (if applicable) for subject name, subject initials, dates, signatures, yes/no check boxes for optional research procedures *must* be completed by the subject themselves or by the subject's LAR, if previously approved by the IRB. Delegated research team members ***may not*** complete these blanks for the subject.

The PI or delegated research team member will ensure the subject or the subject's LAR expresses understanding of information presented on the clinical research study, that their participation is voluntary, and that the subject can withdraw at any time without penalty or loss of benefits to which they are otherwise entitled. They will ensure that all of the subject's questions have been answered.

A short form written consent document stating that the elements of informed consent, required by the FDA and institutional polices, may be presented orally to the subject or the subject's LAR if the ICF was not written in a language understandable to the subject or subject's LAR. When this method is used, there should be an impartial witness to the oral presentation. Please refer to *OSU ORRP (or IRB of record) Short Form Informed Consent Policy.*

By signing the consent form, the witness attests that the information in the consent form, and any other written information, was accurately explained to and understood by the subject or the subject's LAR, and that informed consent was freely given by the subject or the LAR.

The PI or delegated research team member will provide a copy of all signed forms to the subject or LAR.

The investigational site should ensure the subject or the subject's LAR understands that, in order to participate in the clinical research study, the subject must be eligible per the protocol's inclusion and exclusion criteria.

B. Documentation of the Informed Consent Process

A copy of the signed informed consent, HIPAA authorization form (if applicable), and consent addendum forms (if applicable) will be kept in the subject medical record if deemed necessary by the research team to ensure subject safety and communication for continued care. If the research team deems it necessary to include the consent form in the patient's medical record (e.g., therapeutic/interventional trials), it must be stated in the IRB approved consent and communicated to the subject. The original forms will be kept by the PI and delegated research team members, preferably in a binder or chart.

The informed consent process will be documented by the PI or delegated research team member in a source document *(See Attachment A: Consent Documentation Note)*. The source document will outline the informed consent discussion with the subject or the subject's LAR. At a minimum it will have the consent process documentation elements outlined in *Attachment B: Consent Process Checklist.* The person obtaining the informed consent will sign and date the Consent Process Checklist at the time of consent. The PI or Sub-I will review and confirm the consent process, on paper and/or in the EMR, in a timely manner by signing and dating the paper checklist and/or reviewing the checklist in the EMR.

All signed informed consent forms, HIPAA authorization forms (if applicable), and consent addendum forms (if applicable) of all subjects regardless of whether they are enrolled in the clinical research study will be kept in conjunction with the clinical research study essential documents and retained according to ORRP or IRB of record policy.

C. Revisions to the Informed Consent Form

The informed consent form, and any other written information provided to subjects, may be revised whenever important new information becomes available or when administrative changes or general edits are needed. Revised informed consent forms and written information given to subjects must receive IRB approval prior to use.

The subject or the subject's LAR will be notified of changes in a timely manner if new information becomes available that may be relevant to the subject's willingness to continue participation in the research study. The communication of the changes in the consent form will be documented in the subject's research chart and/or medical record, if appropriate. If the new information raises awareness of an unacceptable increase in risk to the subject or eliminates an *immediate* hazard to the subject, the PI may deviate from the protocol and consent form document prior to review and documented IRB approval.

The PI or delegated research team members may implement a deviation from, or a change in, the protocol to eliminate an immediate hazard to clinical research study subjects without prior IRB approval. The implemented deviation or change should be submitted to the IRB for review and approval, to the sponsor for agreement, and (if required) to the appropriate regulatory authorities within the required timeframe.

All above procedures and processes followed for obtaining initial consent apply to re-consenting subjects with a revised informed consent form.

Informed consent is an ongoing process. Even in the absence of new information or changes to research procedures, periodic review or confirmation of a subject's consent should be assessed by the PI and research team members.

D. Special Consent Circumstances

The PI and delegated research team members will refer to ORRP's OSU Human Research Protection Program (OSU HRPP) and the IRB of record's Policies for details on how to handle the following special consent circumstances where potential subjects may be deemed vulnerable, or the type of research requires additional protections and processes:

Assent and Parental Permission
Short Form Informed Consent
Vulnerable Populations
Research Involving Prisoners
Research Involving Children
Research Involving Pregnant Women, Fetuses or Neonates
Vulnerable Populations: Student, Employees and Adults Unable to Provide Consent
Planned Emergency Research
Emergency Use of Investigational Drugs, Biologics or Devices Human
Gene Transfer

5. Applicable Regulations, Guidances and Policies

Regulation/ Guidance/Policy	Title
21 CFR 50	Protection of Human Subjects
21 CFR 56	Institutional Review Boards
21 CFR 312	Investigational New Drug Application
21 CFR 812	Investigational Device Exemptions
45 CFR 46	Protection of Human Subjects
45 CFR 160	HIPAA Privacy Rule
45 CFR 164 Subparts A and E	HIPAA Privacy Rule
42 CFR 50 Subpart F	Responsibility of Promoting Objectivity in Research (Research COI)
45 CFR 94	Responsible Prospective Contractors
OSU Office of Responsible Research Practices HRPP	Additional Requirements for Clinical Research: ICH GCP

OSU Office of Responsible Research Practices HRPP	Assent and Parental Permission
OSU Office of Responsible Research Practices HRPP	Documentation of the Informed Consent Process
OSU Office of Responsible Research Practices HRPP	Emergency Use of Investigational Drugs, Biologics or Devices
OSU Office of Responsible Research Practices HRPP	Informed Consent Process and the Elements of Informed Consent
OSU Office of Responsible Research Practices HRPP	Planned Emergency Research
OSU Office of Responsible Research Practices HRPP	Privacy and Confidentiality Practices
OSU Office of Responsible Research Practices HRPP	Recruiting Methods, Recruitment Materials, and Participant Compensation
OSU Office of Responsible Research Practices HRPP	Research Involving Children
OSU Office of Responsible Research Practices HRPP	Research Involving Data and or Biological Specimens
OSU Office of Responsible Research Practices HRPP	Research Involving Human Subjects
OSU Office of Responsible Research Practices HRPP	Research Involving Investigational Drugs
OSU Office of Responsible Research Practices HRPP	Research Involving Medical Devices
OSU Office of Responsible Research Practices HRPP	Research Involving Pregnant Women, Fetuses or Neonates
OSU Office of Responsible Research Practices HRPP	Research Involving Prisoners
OSU Office of Responsible Research Practices HRPP	Research Involving Radiation
OSU Office of Responsible Research Practices HRPP	Responsibilities of Principal Investigators, Co-Investigators and Key Personnel
OSU Office of Responsible Research Practices HRPP	Short Form Informed Consent
OSU Office of Responsible Research Practices HRPP	Vulnerable Populations: Students, Employees, and Adults Unable to Provide Consent
OSU Office of Research Compliance	Human Gene Transfer
OSUWMC	Use of Patient Information by Hospitals and Medical Staff
OSUWMC	Patient Information & HIPAA Requirements

ICH GCP E6 (R2)	Guidelines for Good Clinical Practice E6 Integrated Addendum
FDA Guidance for Industry	Investigator Responsibilities- Protecting the Rights, Safety, and Welfare of Study Subjects, October 2009
FDA Guidance for Industry	A Guide to Informed Consent- Information Sheet
FDA Guidance for Industry	Recruiting Study Subjects- Information Sheet
FDA Guidance for Industry	Screening Tests Prior to Study Enrollment- Information Sheet

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