



THE OHIO STATE UNIVERSITY

WEXNER MEDICAL CENTER

SOP-07: Informed Consent Form Development

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, guidances, 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-07 describes the process for fulfilling the regulatory and ethical requirements for developing and writing the Informed Consent Form (ICF) for clinical research.

2. Responsibility

The Center for Clinical Research Management (COM-CCRM) Clinical Trials Management Organization (COM-CTMO) 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

A. Drafting and Developing the Informed Consent Form

Prior to implementation of a trial the PI must have IRB approval of the written informed consent form (ICF) document and any other written information which will be provided to subjects.

The PI and delegated research team members will prepare a draft ICF based upon the protocol, the Investigator's Brochure (if applicable), and templates provided by the OSU Office of Responsible Research Practices (ORRP) or alternate IRB of record and the sponsor (if applicable).

ORRP provides templates for ICFs that contain all elements required by federal regulations and university policy. The PI and delegated research team members will verify that all required and appropriate elements of the ICF are included. These templates will be used to develop the informed consent document or to adapt the sponsor's informed consent document to meet the requirements of the IRB. If it is found that changes to the ICF are necessary, sponsor and/or PI approval are required prior to submitting to the IRB.

The information that is given in the informed consent document to the subject or their legally authorized representative shall be in a language understandable to the subject or their representative. No informed consent, whether oral or written, may 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 ICF will be submitted to the IRB for review and approval along with any other required and applicable documents. The PI and delegated research team members, in collaboration with the sponsor, will make any necessary modifications to the consent form as requested by the IRB and re-submit for approval.

After the ICF has been approved by the IRB, the IRB approval letter, relevant communications, and approved ICF will be appropriately filed in the site's regulatory binder and saved electronically. Copies of the IRB approval letter and approved ICF will be sent to the sponsor for their records.

The ICF and any other written information provided to subjects will be revised whenever important new information becomes available that may be relevant to the subject's consent or that may be relevant to the subject's willingness to continue participation in the trial. Any revised written informed consent form document and written information will be submitted for IRB approval prior to use.

B. Elements of the Informed Consent Form

Both the informed consent discussion and the written ICF, provided to subjects, may include but is not limited to the following elements:

General

- A concise and focused summary of the key information that facilitates comprehension (for studies approved on/after January 21, 2019).
- A statement that the study involves research and an explanation of the purposes.
- The number of potential subjects and expected duration of subject's participation.
- A description of the procedures involved in the trial, in lay language and identification of which procedures are experimental.

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- The alternative procedures or courses of treatment that may be available to the subject.
- The compensation and/or treatment available to the subject in the event of trial-related injury (i.e., indemnification language).
- The anticipated payment, if any, to the subject for participating in the trial.
- The anticipated expenses, if any, to the subject for participating in the trial.
- For applicable clinical trials initiated on or after March 7, 2012, informed consent documents must be in compliance with the new requirement in 21 CFR § 50.25(c) and include a specific statement that refers to the trial's description on www.ClinicalTrials.gov. For clinical trials initiated on or after January 21, 2019 which are conducted or supported by a federal department or agency, the Final Rule (45 CFR 46.111, 45 CFR 46.116h) requires that one unsigned, IRB-approved consent form per study must be posted on a publicly available federal website such as ClinicalTrials.gov. The form must be posted after recruitment is complete but no later than 60 days after the last study visit is completed.

Subject's Rights and Responsibilities

- A statement that participation is voluntary; refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- The trial treatments and the probability for random assignment to each treatment.
- The subject's responsibilities.
- That the subject or the subject's legally authorized representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
- The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.
- Nothing in the regulations is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local law.
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions (for studies approved on/after January 21, 2019).

Risks and Benefits

- The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.
- The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject must be made aware of this.

Records Access and Review

- That the monitors, the auditors, the IRB, and the regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written ICF, the subject is authorizing such access.

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- That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration or other entities as applicable may inspect the records.
- One of the following statements about any research that involves the collection of identifiable private information or identifiable bio-specimens (for studies approved on/after January 21, 2019):
 - A statement that identifiers might be removed from the identifiable private information or identifiable bio-specimens and that, after such removal, the information or bio-specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative; **or**
 - A statement that the subject's information or bio-specimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
- A statement that the subject's bio-specimens (even if identifiers are removed) may be used for commercial profit and whether the subject will share in this commercial profit (for studies approved on/after January 21, 2019).
- For research involving bio-specimens, whether the research will (if known) or might include whole genome sequencing (WGS) (for studies approved on/after January 21, 2019).

C. Special Consent Circumstances

The PI and delegated research team members will refer to ORRP's OSU Human Research Protection Program Policies (OSU HRPP) as well as the policies of the IRB of record (if other than OSU IRB) for details on how to handle the following special consent circumstances:

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; Humanitarian Use Devices; Compassionate Use of Investigational Drugs or Devices; Group Consent; Electronic Consent.

5. Applicable Regulations, Guidances and Policies

Regulation/ Guidance/Policy	Title
21 CFR 50	Protection of Human Subjects
21 CFR 54	Financial Disclosure by Clinical Investigators
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
45 CFR 46.111	Criteria for IRB approved research
45 CFR 46.116h	Clinical Trial Informed Consent Form Posting
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	IRB Actions and Communications

OSU Office of Responsible Research Practices HRPP	IRB Submission and Pre-Review
OSU Office of Responsible Research Practices HRPP	Organizational Financial Conflicts of Interest
OSU Office of Responsible Research Practices HRPP	Privacy and Confidentiality
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	Research Performance Sites and Collaborative Off-Site Research
OSU Office of Responsible Research Practices HRPP	Responsibilities of Principal Investigators, Co-Investigators, and Key Personnel
OSU Office of Responsible Research Practices HRPP	Review of Research by Convened IRB

OSU Office of Responsible Research Practices HRPP	Suspension and Termination of IRB Approved Research
OSU Office of Research Compliance	Human Gene Transfer
ICH GCP E6(R2)	Guideline 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	Screening Tests Prior to Study Enrollment- Information Sheet

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