THE OHIO STATE UNIVERSITY

WEXNER MEDICAL CENTER

COLLEGE OF MEDICINE

STANDARD OPERATING PROCEDURES

FOR

GOOD CLINICAL RESEARCH PRACTICE

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The Ohio State University Wexner Medical Center	OSUWMC

Glossary of Terms

The following definitions, utilized throughout the COM-CCRM SOPs, may have come from the International Conference on Harmonization E6 Good Clinical Practices (ICH E6 GCP), the Office of Responsible Research Practices (ORRP) at OSU, the Food and Drug Administration (FDA), and the Department of Health and Human Services (DHHS).

Adverse Drug Reaction (ADR): In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established, all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase "responses to a medicinal product" means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, (i.e., the relationship cannot be ruled out). Regarding marketed medicinal products: A response to a drug that is noxious and unintended and that occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function *(See the ICH guidance for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting)*.

Adverse Event (AE) (ICH): Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product *(See the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting)*.

Adverse Event (AE) (ORRP): Any undesirable and unintended (although not necessarily unexpected) effect occurring as a result of interventions, interactions, or collection of identifiable private information in research. In medical research, any untoward physical or psychological occurrence in research, including abnormal laboratory finding, symptom, or disease temporally associated with the use of (although not necessarily related to) a medical treatment or procedure. Adverse events involving drugs are also referred to as Adverse Drug Experiences.

ALCOAC -CEA criteria: Key attributes for good documentation described by the FDA and adapted by the World Health Organization (WHO). Data should meet certain fundamental elements of quality. Whether they are recorded on paper or electronically, source data should be **A**ttributable, **L**egible, **C**ontemporaneous, **O**riginal, **A**ccurate, **C**omplete **C**onsistent, **E**nduing and **A**vailable.

Applicable Regulatory Requirement(s): Any law(s) and regulation(s) addressing the conduct of clinical trials of investigational products of the jurisdiction where trial is conducted.

Applicable Clinical Trial (ACT): Registration is required for trials that meet the **FDAAA 801** or **42 CFR 11** definition of an "Applicable Clinical Trial" and were either initiated after September 27, 2007, or initiated on or before that date and were still ongoing as of December 26, 2007. Trials that were ongoing as of September 27, 2007 and reached their completion date (see **Primary Completion Date data element** on ClinicalTrials.gov) before December 26, 2007 are excluded.

Applicable Clinical Trials include the following:

1. **Trials of drugs and biologics:** Controlled clinical investigations, other than phase 1 clinical trials, of drugs or biological products subject to U.S. Food and Drug Administration (FDA) regulation.
2. **Trials of devices:** 1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies where the primary outcome measure relates to feasibility and not to health outcomes, and 2) **Pediatric Post market Surveillance** required by FDA.

Approval (in relation to Institutional Review Boards): The affirmative decision by the IRB that the clinical trial has been reviewed and may be conducted at the institutional site within the constraints set forth by the IRB, the institution, good clinical practice (GCP), and the applicable regulatory requirements.

Approval Date: The first date that research could be performed (following notification from the IRB). For research reviewed by the convened IRB, the approval date is the date that the research was approved at a convened meeting, or if modifications were required (to secure approval), the date that the IRB approved the modifications made by the Investigator. For research reviewed using expedited procedures, the approval date is the date that the research was approved by expedited review, or if modifications were required, the date that the IRB approved the modifications made by the Investigator (*See Approval Period).*

Approval Period: For research reviewed by the convened IRB, the interval that begins on the day that the research was approved or modifications were required (to secure approval) at a convened meeting; an approval period may not be longer than one year.

Approved: An IRB action taken when the required determinations are made that allow research involving human subjects to proceed consistent with federal regulations, state and local laws, and University policy.

Assent: Agreement to participate in research expressed by an individual (e.g., a child) who cannot provide informed consent to participate on his or her own behalf. Note: Failure to object does not constitute assent.

Audit: A systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory requirement(s).

Audit Certificate: A declaration of confirmation by the auditor that an audit has taken place.

Audit Report: A written evaluation by the sponsor's auditor of the results of the audit.

Audit Trail: Documentation that allows reconstruction of the course of events.

Bioequivalence: The absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.

Biological Product: Also: **Biologic**. A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the prevention, treatment, or cure of a disease or condition of human beings. Note: Biological products also include immunoglobulin products, monoclonal antibodies, products containing cells or microorganisms, and most proteins intended for therapeutic use.

Biometrics: the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action. For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of action.

Blinding/Masking: A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single blinding usually refers to the subject(s) being unaware, and double blinding usually refers to the subject(s), Investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).

Case Report Form (CRF): A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject.

Certificate of Confidentiality: Certificates of Confidentiality are issued by the National Institutes of
Health (NIH) to protect identifiable research information from forced disclosure. They allow the Investigator and others who have access to research records to refuse to disclose identifying information on research subjects in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

Certified Copy: A copy of original information that has been verified, as indicated by dated signature, as an exact copy having all of the same attributes and information as the original. Note: Only Medical Information Management (MIM) can certify the medical record at OSUWMC.

Child/Children: Person(s) who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. For purposes of OSU HRPP policy, individuals under 18 years of age are considered children in Ohio unless they meet the definition of emancipated minors.

Clinical Investigation (FDA): Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58, regarding nonclinical laboratory studies.

Clinical Trial: Also, **Research**, **Clinical Research**, **Clinical Study, Clinical Investigation**. Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. Any experiment that involves an investigational product and one or more human subjects.

Clinical Trial/Study Report: A written description of a trial/study of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report *(See the ICH Guidance for Structure and Content of Clinical Study Reports)*.

Coded: Direct personal identifiers have been removed (e.g., from data or specimens) and replaced with words, letters, figures, symbols, or a combination of these (not derived from or related to the personal information) for purposes of protecting the identity of the source(s), but the original identifiers are retained in such a way that they can still be traced back to the source(s). Note: A code is sometimes also referred to as a "key," "link," or "map."

Coercion: Persuasion (i.e., of an unwilling person) to do or agree to something by using obvious or implied force or threats.

Co-Investigator (Co-I): Also: **Sub-Investigator (Sub-I).** *See Sub-Investigator.*
Comparator (Product): An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical trial.

Compassionate Use: Use of an investigational drug or biologic or unapproved medical device for a single subject (or small group of subjects) with a serious disease or condition, who does not meet the requirements for inclusion in a clinical investigation, and for whom no standard acceptable treatment is available. Prior FDA and IRB approval are required for compassionate use. Note: The terms compassionate use and emergency use are not synonymous.

Compensation: Payment, merchandise, class credit, or other gift or service provided to research subjects or their legally authorized representatives to reimburse them for their time, effort, and/or for any out-of-pocket expenses associated with research participation. Note: Compensation is sometimes distinguished from an incentive or inducement, which is generally thought of as a payment or other offering that is "over and above" reimbursement and intended to encourage research participation.

Compliance (in relation to trials): Adherence to all the trial-related requirements, good clinical practice (GCP) requirements, and the applicable regulatory requirements.

Confidential Disclosure Agreement (CDA): Also: **Non-Disclosure Agreement (NDA)**. A document used when transferring non-PHI from one party to another for review only (no further use or dissemination), generally for the purpose of evaluating the potential for a future relationship between the parties.

Confidentiality (ICH): Prevention of disclosure, other than to authorized individuals, of a sponsor's proprietary information or of a subject's identity.

Confidentiality (ORRP): In the context of human subjects' research, the condition that results when data are maintained in a way that prevents inadvertent or inappropriate disclosure of subjects' identifiable information.

Conflict of Interest (COI): A financial interest or other opportunity for tangible personal benefit of an individual or his/her immediate family that may exert a substantial and improper influence on the individual's professional judgment in exercising any University duty or responsibility, including the review of research. Note: For IRB members and consultants, financial and non-financial interests/opportunities are included.

Continuing Noncompliance: Noncompliance (serious or non-serious) that has been previously reported, or a pattern of ongoing activities that indicate a lack of understanding of human subjects' protection requirements that may affect research subjects or the validity of the research and suggest the potential for future noncompliance without intervention. Examples of continuing noncompliance may include but are not limited to: repeated failures to provide or review progress reports resulting in lapses of IRB approval, inadequate oversight of ongoing research, or failure to respond to or resolve previous allegations or findings of noncompliance.

Contract: A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

Contract Research Organization (CRO): A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

Coverage Analysis - identifies all clinical items or services associated with a particular clinical trial, including identification of the financially accountable party, such as the trial sponsor, other funding source, patient, or a third-party payor.

Covered Entities - defined in the HIPAA rules as (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards. Generally, these transactions concern billing and payment for services or insurance coverage. (e.g., hospitals, academic medical centers, physicians, and other health care providers who electronically transmit claims transaction information directly or through an intermediary to a health plan) Covered entities can be institutions, organizations, or persons.
Researchers are covered entities if they are also health care providers who electronically transmit health information in connection with any transaction for which HHS has adopted a standard. (e.g., physicians who conduct clinical studies or administer experimental therapeutics to participants during the course of a study must comply with the Privacy Rule if they meet the HIPAA definition of a covered entity).

Custom Device: A device that necessarily deviates from devices generally available or from an applicable performance standard or pre-market approval requirement to comply with the order of an individual physician or dentist and that is:

- Not generally available or generally used by other physicians or dentists;
- Not generally available in finished form for purchase or for dispensing upon prescription;
- Not offered for commercial distribution through labeling or advertising; and

- Intended for use by an individual patient named in the order of a physician or dentist and is to be made in a specific form for that patient or is intended to meet the special needs of the physician or dentist in the course of professional practice.

Data and Safety Monitoring: The process for reviewing data collected as research progresses to ensure the continued safety of current and future subjects as well as the scientific validity and integrity of the research.

Data and Safety Monitoring Board (DSMB) or Committee (DSMC) (ORRP): A group comprised of expert(s) in the field of medicine and/or science applicable to the research, statistician(s), lay representative(s), and others as necessary to monitor study progress. A data and safety monitoring board reviews study-specific data periodically throughout the research to ensure continued subject safety and scientific validity and to make recommendations whether to continue, modify, or terminate the study. Note: The following terms are interchangeable – data and safety monitoring board, data and safety monitoring committee, and data monitoring committee.

Data and Safety Monitoring Board (DSMB) (ICH): Also: **Independent Data Monitoring Committee (IDMC), Monitoring Committee or Data Monitoring Committee**. An independent data monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial.

Data and Safety Monitoring Plan: The plan for reviewing research data to ensure the safety of subjects and scientific validity of the research, including who will perform the monitoring, the type and frequency of review, and procedures for notifying appropriate entities (e.g., Investigators, sponsor, etc.) of the results. Note: Monitoring performed by a data and safety monitoring board is one type of data and safety monitoring plan.

Data Use Agreement (DUA): A document used when transferring protected health information (PHI), including limited data sets, from one party to another.

Deferred: An IRB action that specifies conditions under which research can be reconsidered for approval, pending substantive (i.e., directly relevant to the determinations required for approval by the IRB) clarifications or modifications to the protocol and/or informed consent process/document, without which, the IRB could not fully evaluate the research under review. Note: Convened IRB review of the Investigator's response(s) is required.

De-identified: Also: **Redacted**. All direct personal identifiers are *permanently* removed (e.g., from data or specimens), no code or key exists to link the materials to their original source(s), and the remaining information cannot reasonably be used by anyone to identify the source(s). Note: For purposes of OSU HRPP policy, de-identified data do not contain any of the 18 identifiers specified by the HIPAA Privacy Rule (or have been determined to be de-identified by a statistician in accordance with the standards established by the Privacy Rule).

Department of Health and Human Services (DHHS): The Department of Health and Human Services is the principal agency for protecting the health of all Americans. It is comprised of the Office of the Secretary (18 Staff Divisions) and 11 Operating Divisions.

Device: Also: **Medical Device**. Instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article (including a component part), or accessory that is recognized in the official National Formulary or United States Pharmacopoeia (or any supplement to these) and is:

- Intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease in man or other animals, or
- Intended to affect the structure or any function of the body of man or other animals, that does not achieve any of its primary intended purposes through chemical action within or on the body, and is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

Diminished Decision-Making Capacity: As it applies to informed consent, lacking the ability to provide valid informed consent to participate in research, (e.g., as a result of trauma, intellectual disability, certain mental illnesses, cognitive impairment, or dementia). Note: Diminished decision-making capacity may be temporary, permanent, progressive, or fluctuating.

Direct Access: Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsors, monitors, and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor's proprietary information.

Direct Entry: Recording data where an electronic record is the original means of capturing the data. Examples include the keying by an individual of original observations into a system, or automatic recording by the system of the output of a balance that measures subject's body weight.

Directed (For-Cause) Audit/Review: An audit of research and/or Investigators initiated at the request of the IRB or Institutional Official to obtain or verify information necessary to ensure compliance with regulations and institutional requirements and to inform decisions about the conduct of human subjects' research and/or human subjects' protection.

Disapproved: An IRB action taken when the determinations required for approval of research cannot be made, even with substantive clarifications or modifications to the protocol and/or informed consent process/document. Note: Research cannot be disapproved by expedited review.

Documentation: All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

Drug: Substance recognized in the United States Pharmacopoeia, Homeopathic Pharmacopoeia of the United States, or National Formulary (or any supplement to any of these), and is an article either intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or intended to affect the structure or any function of the body (other than food), or intended for use as a component of any substance described above.

Electronic Case Report Form (e-CRF): An auditable electronic record designed to record information required by the clinical trial protocol to be reported to the sponsor on each trial subject.

Electronic Patient Diary: An electronic record into which a subject participating in a clinical trial directly enters observations or directly responds to an evaluation checklist.

Electronic Record: Any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

Electronic Signature: A computer data compilation of any symbol or series of symbols, executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

Emergency Use: Use of an investigational drug or biologic or unapproved medical device for a human subject in a life-threatening situation for which no standard acceptable treatment is available and when there is not sufficient time to obtain IRB approval. Note: Under FDA regulations, emergency use is a category of research (e.g., clinical investigation) that is exempt from the requirements for IRB review.

Engaged: Involved in human subjects' research in such a way (or to the extent) that the ethical and regulatory requirements for human subjects' protection are applicable. An individual (or organization) becomes engaged in human subjects' research when, for the purposes of non-exempt research, the individual (or organization's employee or agent) obtains any of the following:

- Data about research subjects through intervention or interaction
- Identifiable private information about research subjects
- Informed consent of research subjects

Note: An organization is also engaged in human subjects' research whenever it receives a direct federal award to support the research.

Environmental Health & Safety (EHS): A department within OSU aimed at assisting the university community in providing and maintaining a safe, healthful work environment for students, faculty, staff, contractors, and visitors.

Essential Documents: Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

Exculpatory Language: As it applies to informed consent, any written or verbal communication through which a research subject (or his/her legally authorized representative) is asked to waive or appear to waive any of the subject's legal rights or to release (or appear to release) the Investigator, sponsor, or institution or its agents from liability for negligence.

Exempt Research: Research that involves human subjects that is not subject to regulations requiring IRB review and approval. Categories of research activities that may be determined to be exempt from review by the IRB are defined by federal regulations and University policy. Note: Investigators performing exempt research must comply with the requirements of the OSU HRPP even when the research is exempt from IRB review.

Experiment: Any use of a drug (except for the use of a marketed drug) in the course of medical practice, or any evaluation of the safety and efficacy of a medical device.

Feasibility Committee: A group of persons with experience and knowledge on the protocol study area, the services necessary to execute the protocol, and the research area that will oversee and provide these services.

Finding of Noncompliance: An occurrence or determination of noncompliance that does not require further confirmation or investigation (e.g., failure to respond to the IRB within established deadlines, allegation of noncompliance determined by the IRB to be true).

Food and Drug Administration (FDA): Federal agency responsible for monitoring trading and safety standards in the food and drug industries.

Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

HRPP Policies and Procedures: Policies and procedures of the Office of Research, IRBs, and ORRP that apply to the conduct, review, and oversight of human subjects' research and describe the roles and responsibilities of those involved in these activities.

Human Subject (DHHS): A living individual about whom an Investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information. Note: See the FDA definition of human subject for FDA regulated research.

Human Subject (FDA): An individual who is or becomes a subject in research, either as a recipient of a test article or as a control. A subject may be either a healthy human or a patient. For research that involves medical devices, a human subject also includes an individual on whose specimen an investigational device is used. Note: See the DHHS definition of human subject for DHHS-regulated research.

Human Subject Radiation Committee (HSRC): A subcommittee of The Ohio State University Radiation Safety Committee responsible for the review and approval of the research use of radiation in research involving human subjects. Note: The Medical Use Subcommittee of the University Radiation Safety Committee serves as the Human Subject Radiation Committee.

Humanitarian Device Exemption (HDE): An application that permits the marketing of a Humanitarian Use Device.

Humanitarian Use Device (HUD): A device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect (or are manifested in) fewer than 8000 individuals in the US per year.

Indemnification - a promise made by one party to another that it will cover any loss suffered by the other party. Clinical trials sites take out insurance or indemnity arrangements to protect them against liabilities that may arise of part of their clinical trials activities.

Impartial Witness: A person who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally authorized representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

Informed Consent (ORRP): Agreement to participate in research expressed by an individual (or his/her legally authorized representative) authorized under applicable law to make such decisions, based on sufficient information (i.e., regarding possible risks and benefits of the research) and adequate opportunity to consider voluntary participation.

Informed Consent (ICH): A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.

Inspection: The act by a regulatory authority of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authorities to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organization's (CROs) facilities, or at other establishments deemed appropriate by the regulatory authorities.

Institution (medical): Any public or private entity or agency or medical or dental facility where clinical trials are conducted.

Institutional Review Board (IRB): An independent body constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

IRB of Record: An IRB is considered the IRB of record when it assumes IRB responsibilities for another institution. A Memorandum of Understanding is required designating the relationship.

sIRB or Single IRB: An IRB of record that oversees all clinical trial sites participating in a multi-site study.

Interim Clinical Trial/Study Report: A report of intermediate results and their evaluation based on analyses performed during the course of a trial.

International Committee of Medical Journal Editors (ICMJE): A group of general medical journal editors and representatives of selected related organizations working together to improve the quality of medical science and its reporting.

International Conference on Harmonization (ICH): International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use is a joint initiative involving both regulators and research-based industry focusing on the technical requirements for medicinal products containing new drugs.

Investigational Device: A device (including a transitional device) that is the object of an investigation *(See Investigational Device Exemption and Investigational Product)*.

Investigational Device Exemption (IDE): An application that permits a device that would otherwise be required to comply with a performance standard (e.g., 510(k) submission) or to have pre-market approval by the FDA to be legally shipped for a clinical investigation.

Investigational Drug: A new drug or biologic (i.e., not approved for marketing by the FDA) used in a clinical investigation, including a biological product used in vitro for diagnostic purposes *(See Investigational New Drug Application and Investigational Product)*.

Investigational Drug Service (IDS): A department within OSU Wexner Medical Center Department of Pharmacy that assists with the management of study drug. Operational activities performed by IDS include drug acquisition, inventory management, investigational drug distribution, and investigational drug accountability records. Investigational drug supplies are handled and dispensed in accordance with applicable legal, institutional, professional, and sponsor requirements.

Investigational New Drug Application (IND): An application that permits an investigational drug that would otherwise be required to have pre-market approval by the FDA to be legally shipped for a clinical investigation.

Investigational Product: A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use. Also, a device, including a transitional device that is the object of an investigation.

Investigator: A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the Investigator who is the responsible leader of the team and may be called the Principal Investigator (PI) *(See Principal Investigator and SubInvestigator)*.

Investigator's Brochure (IB): A compilation of the clinical and nonclinical data on the investigational product(s) that is relevant to the study of the investigational drug in human subjects.

Investigator-Initiated Trials (IIT) are studies developed, initiated and managed by a non-pharmaceutical company researcher (e.g., individual investigators, institutions, collaborative study groups or cooperative groups), where the investigator serves as the Sponsor-Investigator.

Legally Authorized Representative (LAR): An individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. For purposes of OSU HRPP policy, the following are recognized in Ohio as legally authorized representatives:

- Persons appointed as health care agents under an Ohio Durable Power of Attorney for Health Care,
- Court-appointed guardians,
- Next of kin in the following order: spouse, adult child, parent, and adult sibling.

Life-Threatening: Refers to diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted; also, diseases or conditions with potentially fatal outcomes.

Life-Threatening Adverse Drug Experience: Any adverse drug experience that places the patient, in the view of the Investigator, at immediate risk of death from the reaction as it occurred, (i.e., it does not include a reaction that, had it occurred in a more severe form, might have caused death).

Manual of Procedures (MOP): Also: **Manual of Operating Procedures, Manual of Operations.** A MOP is a handbook that details a study's conduct and operations as well as facilitates consistency in protocol implementation and data collection across study participants and sites. It transforms the study protocol into a guideline that describes each step of the study and how it is to be executed. A copy of the MOP should be provided to each member of the Study Team. Ideally, the MOP would contain an adequate amount of detail that an individual(s) at all site(s) could run the study consistently with only the information contained in the MOP and its appendices.

Material Transfer Agreement (MTA): A contract that allows one party to perform research using the materials (e.g., data, specimens, etc.) of another party.

Minimal Risk: The probability and magnitude of physical or psychological harm that is normally encountered in daily life or in the routine medical, dental, or psychological examination of healthy persons. Note: The regulatory definition of "minimal risk" for research involving prisoners differs from the definition of minimal risk for research involving subjects who are not prisoners.

Minor Changes: Changes to research that in the judgment of the IRB do not affect assessment of the risks and benefits of the study by substantially altering any of the following: research aims or methodology, nature of subject participation, level of risk, proposed benefits, subject population, qualifications of the research team, or the facilities available to support the safe conduct of the research. Note: A minor change does not increase risk more than minimally or add procedures in research categories other than those that qualify for expedited initial review.

Modifications Required: Also: **Contingent Approval.** An IRB action that specifies conditions under which research can be approved, pending the completion of minor, non-substantive (i.e., not directly relevant to the determinations required for approval by the IRB) clarifications or modifications to the protocol and/or informed consent process/document. Note: Review of the Investigator's response(s) may be performed by expedited review.

Monitoring: The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), GCP, and the applicable regulatory requirement(s).

Monitoring Plan: document that details the monitoring policies and procedures, and the proposed frequency of on-site monitoring visits across the trial sites, for a particular trial. The following details should be included in the monitoring plan, but is not limited to: monitoring strategy and its rationale, responsibility matrix or a breakdown of who is responsible for the monitoring activities, procedures, which includes site feasibility and initiation, schedule for on-site monitoring visits and site close-out, procedures for protocol deviation, noncompliance, Adverse Event (AE) and Serious Adverse Event (SAE) reporting, activities or operational processes that will be monitored, and how.

Monitoring Report: A written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor's SOPs.

Multicenter Trial: A clinical trial conducted according to a single protocol but at more than one site, and, therefore, carried out by more than one Investigator.

Nonclinical Study: Biomedical studies not performed on human subjects.

Noncompliance: Failure (intentional or unintentional) to comply with applicable federal regulations, state or local law, the requirements or determinations of the IRB, or University policy regarding research involving human subjects. Noncompliance can result from action or omission. Noncompliance may be non-serious (minor) or serious, and may also be continuing.

Non-Serious or Minor Noncompliance: Noncompliance that does not increase risk to research subjects, compromise subjects' rights or welfare, or affect the integrity of the research/data or the human subjects protection program. Examples of minor noncompliance may include, but are not limited to: lapses in continuing IRB approval, failure to obtain exempt determination before exempt research involving human subjects is conducted, minor changes in or deviations from an approved protocol, or administrative errors.

Non-Significant Risk (NSR) Device: An investigational device that does not meet the definition of a significant risk device.

Office of Responsible Research Practices (ORRP): The Office of Responsible Research Practices provides administrative support to The Ohio State University research community and the review boards responsible for research oversight. The ORRP staff helps OSU faculty, staff, and student researchers navigate regulations governing research in a way that fosters ethical conduct, ensures compliance, and minimizes administrative burden.

Parent: A child's biological or adoptive mother or biological or adoptive father.

Permission: The agreement of a parent(s) or legal guardian to the participation of his/her child or ward in research.

Personal Protective Equipment (PPE): In research facilities, PPE is used to help prevent employee exposure to hazards; this includes physical, chemical, and biological hazards. PPE is not a substitute for engineering controls, administrative controls, or safe operating procedures, but is used in conjunction with these controls. Common examples of PPE include chemical resistant gloves, latex gloves, chemical splash goggles, safety glasses, lab coats, aprons, face shields, respirators, and hearing protection. For more information on PPE, see the OSU Environmental Health & Safety website.

Planned Emergency Research: Research involving human subjects who are in need of emergency medical intervention (i.e., comparison of methods for providing cardiopulmonary resuscitation), but who cannot give informed consent because of their life-threatening medical conditions and who do not have an available legally authorized representative to provide consent.

Policy: Formal statement of principles on which action(s) for a specific issue are based.

Predicate Rule: An FDA regulation that requires the submission to and/or inspection by the FDA of certain data and information relevant to FDA-regulated investigational and/or marketed products. Examples include clinical trial data to support a New Drug Application or device Premarket Approval application.

Principal Investigator (PI): A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the Investigator is the responsible leader of the team and may be called the Principal Investigator *(See also Sub-Investigator and Investigator).*

Prisoner: An individual involuntarily confined or detained in a penal institution (e.g., prison, jail, or juvenile offender facility), with restricted ability to leave the institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Privacy: The state of being free from the observation, intrusion, or attention of others.

Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Examples of private information include medical or academic records or personal journals.

Procedure: A series of actions conducted in a certain order or manner; an operational method by which policy is put into practice.

Protected Health Information (PHI): Information that is created or received by a health care provider, health plan, employer, or health care clearinghouse; relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; the past, present, or future payment for the provision of health care to an individual; identifies the individual; when there is a reasonable basis to believe the information can be used to identify the individual. [Under HIPAA regulations at 45 CFR 164, PHI (*Protected Health Information*) *also includes*: Individually identifiable health information that is: (i) Transmitted by electronic media;
(ii) Maintained in any medium described in the definition of *electronic media* at §162.103, or (iii) Transmitted or maintained in any other form or medium.]

Protocol: A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents.

Protocol Amendment: A written description of a change(s) to or formal clarification of a protocol.

Protocol Registration and Results System (PRS): Website for entering and updating ClinicalTrials.gov records. https://register.clinicaltrials.gov/

Quality Assurance (QA): All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with GCP and the applicable regulatory requirement(s).

Quality Control (QC): The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled.

Quality Improvement: A process initiated to develop/enhance a practice or procedure and to institutionalize the practice or procedure.

Randomization: The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

Record Owner: This individual may be the Principal Investigator or a designated research team member that is responsible for updating the ClinicalTrials.gov record and ensuring that it is updated in a timely manner. The owner must maintain communication so that the protocol record is released by the PI (Responsible Party) in the required time frame *(See Responsible Party)*.

Recruitment Materials: Announcements; advertisements; flyers; posters; scripts for telephone or other oral communication; letters or email messages; bulletin board tear-offs; Internet postings; newspaper, radio, television, or video broadcasts, or other media used to attract potential subjects for research.

Recruitment Methods: Materials, compensation, and other practices or procedures used to inform potential subjects about research. Note: Methods for recruiting research subjects are generally distinguished from those of marketing, advertising, or public relations' efforts, which have promoting a product, service, or idea as goals.

Regulatory Authorities: Bodies having the power to regulate. In the ICH GCP guidance, the expression "Regulatory Authorities" includes the authorities that review submitted clinical data and those that conduct inspections.

Related: Associated or having a timely relationship with; a reasonable possibility exists that an outcome may have been caused or influenced by the event in question (e.g., administration of a study drug), although an alternative cause/influence may also be present. Related events may be *definitely*, *probably*, or *possibly* related.

Repository: Collection of data and/or specimens obtained and stored for future research use and/or distribution, including a collection not originally or primarily obtained for research purposes.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge *[See Clinical Investigation (FDA)]*.

Responsible Party: The individual with complete access to trial data and rights to publish. The Responsible Party may designate individuals to help complete the ClinicalTrials.gov record, however, the final responsibility of review and approval lies with the Responsible Party *(See Record Owner)*.

Routine (Not-for-Cause) Review: An assessment or examination of something (e.g., a practice or procedure) with the possibility or intention of instituting change, if necessary.

Serious Adverse Event (SAE): An adverse event that is fatal or life threatening, permanently disabling, requires or prolongs hospitalization, or results in significant disability, congenital anomaly, or birth defect.

Serious Noncompliance: Noncompliance that has the potential to increase risk to research subjects, compromise subjects' rights or welfare, or affect the integrity of the research/data or the human subjects protection program. Examples of serious noncompliance may include, but are not limited to: conducting or continuing non-exempt human subjects' research without IRB approval; lack of informed consent from research subjects; failure to report or review serious adverse events, unanticipated problems, or substantive changes in research; or inappropriate oversight of the research to insure the safety of human subjects and the integrity of the research/data.

Severely Debilitating: Refers to diseases or conditions that cause major irreversible morbidity (e.g., blindness, loss of limb, loss of hearing, paralysis, or stroke).

Short Form: A written document stating that the elements of informed consent required by regulation have been presented orally to the subject or the subject's legally authorized representative. The short form consent document must be written in a language understandable to the subject or the subject's legally authorized representative. **Significant Risk (SR) Device:** An investigational device that is:

- Intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- For use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject;
- For a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- Otherwise presents a potential for serious risk to a subject.

Site Initiation Visit (SIV): It is a visit that happens after the study sponsor has already selected the site for participating in a clinical trial. This visit ensures that all required trial authorizations and documentation are in place and that the protocol and trial procedures are reviewed with the Investigator and the Investigator's research team in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirement prior to the start of enrollment.

Site Qualification Visit: Also: **Site Selection Visit, Pre-Site Visit.** A meeting between the site and sponsor to assess if the site has the qualifications and facilities to execute all elements of the protocol. This visit occurs after the site has decided to participate in a trial and prior to receiving a site selection letter.

Source Data: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

Source Documents: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).

Specimen: Also: **Sample**. Human biological material, including solid material (e.g., tissue, organs) body fluid (e.g., blood, urine, saliva, semen, cerebrospinal fluid), and cells.

Sponsor: An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.

Sponsor-Investigator (ICH): An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (i.e., it does not include a corporation or an agency). The obligations of a Sponsor-Investigator include both those of a sponsor and those of an Investigator.

Sponsor-Investigator (ORRP): An individual who initiates (i.e., obtains an IND or IDE) and conducts an investigation and under whose immediate direction an investigational drug or device is administered, dispensed, or used. Note: The regulatory requirements applicable to a Sponsor Investigator include those applicable to both an Investigator and a sponsor.

Standard Operating Procedures (SOPs): Detailed, written instructions to achieve uniformity of the performance of a specific function.

Statement of Investigator: The Statement of Investigator, Form FDA 1572 (1572), is an agreement signed by the Investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic.

Sub-Investigator (Sub-I): Also: **Co-Investigator (Co-I)**. Any individual member of the clinical research team designated and supervised by the Investigator at a trial site to perform critical trialrelated procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows) *(See also Investigator and Principal Investigator)*.

Subject/Trial Subject: An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control. Also known as Participant.

Subject Identification Code: A unique identifier assigned by the Investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the Investigator reports adverse events and/or other trial-related data.

Summary Document: A written version of the full information presented to a subject or the subject's legally authorized representative during the informed consent process, used in conjunction with a short

form consent document. For non-English speaking individuals, the IRB approved English language consent form may serve as the summary when an appropriately translated document is not available.

Termination (in relation to Institutional Review Boards): An action taken by the convened IRBs to permanently withdraw approval for all research activities (except for those follow-up procedures that may be necessary to protect the health and/or welfare of subjects).

Test Article: Any drug (including a biological product) or medical device for human use, human food (including dietary supplements), food or color additive, infant formula, electronic product, or any other article subject to regulation by the FDA.

Translational Research: Also: **Translational Science.** Translation is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes. Translational science is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.

Transitional Device: A device subject to section 520(l) of the Food, Drug, and Cosmetic Act; a device that the FDA considered to be a new drug or an antibiotic drug before May 28, 1976.

Trial Site: The location(s) where trial-related activities are conducted.

Unanticipated Adverse Device Effect: Any serious adverse effect on health or safety, or any life-threatening problem or death caused by (or associated with) a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application; any other unanticipated, serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

Unanticipated Problems Involving Risks to Subjects or Others: Unforeseen events (given the nature of the research procedures and subject population) that suggest subjects, research staff, or others are placed at greater risk by the research than previously expected. Unanticipated problems involving risks to subjects or others may be medical or non-medical in nature, and include, but are not limited to, serious, unexpected, and related adverse drug events and unanticipated adverse device effects.

Unapproved Medical Device: A device used for a purpose or condition for which the device would require but does not have pre-market approval or an approved investigational device exemption (IDE) from the FDA.

Undue Influence: Excessive or inappropriate reward or other incentive in which a person is induced to act otherwise than by their own free will or without adequate consideration of the consequences.

Unexpected Adverse Drug Reaction: An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product) *(See the ICH Guidance for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting)*.

Unexpected Adverse Event: An adverse event that has not been previously observed or is not consistent in nature, severity, or frequency with existing risk information, such as in the Investigator's Brochure, research protocol, consent form, or other available information (e.g., IND application for an investigational drug).

Unrelated: Unassociated or without a timely relationship; evidence exists that an outcome is definitely related to a cause other than the event in question.

Vulnerable Subjects: Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

Well-being (of the trial subjects): The physical and mental integrity of the subjects participating in a clinical trial.

Common Clinical Research Regulations, Guidances & Policies

Regulation/ Guidance/Policy	Title
21 CFR 11	Electronic Records; Electronic Signatures
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
42 CFR 11	Clinical Trials Registration and Results Information Submission
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
49 CFR 107	Transportation: Hazardous Materials Program Procedures
49 CFR 171	Transportation: General Information, Regulations, and Definitions
Center for Clinical and Translational Science (CCTS)	Support for ClinicalTrials.gov Compliance

ClinicalTrials.gov	Data Element Definitions for Interventional and Observational Studies
COM Office of Research Compliance	ClincalTrials.gov Compliance SOP
Declaration of Helsinki	Ethical Principles for Medical Research Involving Human Subjects
FDA Guidance for Industry	Investigator Responsibilities- Protecting the Rights, Safety, and Welfare of Study Subjects, October 2009
FDA Guidance for Industry	IRB Continuing Review after Clinical Investigation Approval, February 2012
FDA Guidance for Industry	A Guide to Informed Consent-Information Sheet
FDA Guidance for Industry	Payment to Research Subjects- Information Sheet
FDA Guidance for Industry	Recruiting Study Subjects-Information Sheet
FDA Guidance for Industry	Screening Tests Prior to Study Enrollment Information Sheet
FDA Guidance for Industry	FDA Inspections of Clinical Investigators-Information Sheet
FDA Guidance for Industry	FDA Inspections of Clinical Investigators-Information Sheet
FDA Guidance for Industry	Part 11, Electronic Records; Electronic Signatures- Scope and Application, August 2003
FDA Guidance for Industry	Current Good Manufacturing Practice for Phase 1 Investigational Drugs, July 2008
FDA Guidance for Industry	INDs for Phase 2 and Phase 3 Studies: Chemistry, Manufacturing, and Controls Information, May 2003
FDA Guidance for Industry	Adverse Event Reporting to IRBs- Improving Human Subject Protection, January 2009
FDA Compliance Program Guidance Manual	Program 7348.11 Bioresearch Monitoring: Clinical Investigators and Sponsor-Investigators
FDA Guidance for Industry	Oversight of Clinical Investigations-A Risk-Based Approach to Monitoring, August 2013

FDA Guidance for Industry	Sponsor-Investigator-IRB Interrelationship Information Sheet
FDA Guidance for Industry	Frequently Asked Questions- Statement of Investigators (Form FDA 1572), May 2010
FDA Guidance for Industry	Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials, October 2008
FDA Guidance for Industry	Electronic Source Data in Clinical Investigations, September 2013
FDA Guidance for Industry	Computerized Systems used in Clinical Investigations, May 2007
FDA Form 1572	Statement of the Investigator
Food and Drug Administration Amendments Act (FDAAA) Section 801	Expanded Clinical Trial Registry Data Bank
ICH GCP E6(R2)	Guideline for Good Clinical Practice E6 Integrated Addendum
International Committee of Medical Journal Editors	Clinical Trial Registration
NIH Policy on Clinical Trial Registration and Results Reporting	NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information
ORRP Guidance on Clinical Trials Registration	Office of Responsible Research Practices Guidance on Clinical Trial Registration
OSU Clinical References Laboratories	OSU Clinical Reference Lab Policies and Procedures
OSU Environmental Health & Safety	Research/Biosafety Programs and Services
OSU Office of Business & Finance	Petty Cash and Change Funds
OSU Office of Compliance	Conflict of Interest
OSU Office of Research	Institutional Biosafety Policy
OSU Office of Research	Research Data Policy

OSU Office of Research Compliance	Human Gene Transfer
OSU Office of Research Compliance	Research Misconduct
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	Collaborative and Off-Ste Research Tools for Investigators
OSU Office of Responsible Research Practices HRPP	Data and Safety Monitoring
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	Event Reporting
OSU Office of Responsible Research Practices HRPP	Event Report Determination Guidance
OSU Office of Responsible Research Practices HRPP	Exempt Research
OSU Office of Responsible Research Practices HRPP	Expedited Review Procedures
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	Noncompliance
OSU Office of Responsible Research Practices HRPP	Organizational Financial Conflicts of Interest

OSU Office of Responsible Research Practices HRPP	Planned Emergency Research
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	Short Form Informed Consent
OSU Office of Responsible Research Practices HRPP	Suspension and Termination of IRB Approved Research
OSU Office of Responsible Research Practices HRPP	Vulnerable Populations: Students, Employees, and Adults Unable to Provide Consent

OSU Office of Academic Affairs	Faculty Paid External Consulting Policy
OSU Office of the Chief Information Officer	Institutional Data Policy
OSUWMC	Pharmacy Hazardous Drug Reference
OSUWMC	Use of Patient Information by Hospitals and Medical Staff
OSUWMC	Patient Information & HIPAA Requirements
OSUWMC	Photography of Patients
OSUWMC	Information Security Policy
OSUWMC Investigational Drug Service	IDS Policies and Procedures
OSUWMC Office of Human Resources	Training & Assessment Requirements
OSU Office of Sponsored Programs	Policy on Payments to Research Subjects
United States Department of Labor	Occupational Safety and Health Administration (OSHA)
World Health Organization	Good Laboratory Practice
World Health Organization	International Clinical Trials Registry Platform (ICTRP)