



Definitions for the HRPP

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1. Overview

This document establishes the definitions followed by the Drexel Human Research Protections Office. This is a non-exhaustive list. Please reference regulations and other documents (e.g., guidance documents issued by federal agencies) when applicable. These definitions are interpretations of current practices under the Drexel University HRPP and may differ from other institutional policies, unless otherwise specified.

2. Definitions

2.1 Access

The mechanism of obtaining or using information electronically, on paper, or other medium for the purpose of performing an official function.

2.2 Accounting of Disclosures

Information that describes a covered entity's disclosures of PHI other than for treatment, payment, and health care operations; disclosures made with Authorization; and certain other limited disclosures. For those categories of disclosures that need to be in the accounting, the accounting must include disclosures that have occurred during the 6 years (or a shorter time period at the request of the individual) prior to the date of the request for an accounting. However, PHI disclosures made before the compliance date for a covered entity are not part of the accounting requirements.

2.3 Adverse Event

For the purposes of these policies and procedures, an adverse event (AE) is any untoward medical occurrence in a study participant undergoing intervention which does not necessarily have a causal relationship with the intervention. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the study intervention, whether or not related to the study intervention. Adverse events encompass both physical and psychological harms.

2.4 Allegations of Noncompliance

An unproven assertion of Noncompliance.

2.5 Anonymized Data

Data are anonymous if no one, not even the researcher or a third party entity (e.g., Qualtrics), can connect the data to the individual who provided it through direct identifiers such as name, address, IP address or any type of identification number or indirect identifiers (i.e., other unique individual characteristics like age, race, socioeconomic level, etc.) that might make it possible to identify an individual from a pool of subjects.

2.6 Authorization Agreement/Reliance Agreement (also known as Institutional Authorization Agreement (IAA))

Documents respective authorities, roles, responsibilities, and communication between an institution/organization providing the ethical review of research and a participant institution relying on the institution/organization.



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2.7 Authorization

An individual's written permission to allow a covered entity to use or disclose specified PHI for a particular purpose. Except as otherwise permitted by the Privacy Rule, a covered entity may not use or disclose PHI for research purposes without a valid Authorization.

2.8 Benign Behavioral Intervention

A behavioral intervention which is brief in duration, harmless, painless, not physically invasive, not likely to have a significant lasting adverse impact on the subject, and the investigator has no reason to think the subject will find the intervention offensive or embarrassing.

2.9 Biologic

Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, nucleic acids, or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources - human, animal, or microorganism - and may be produced by biotechnology methods and other technologies. In general, the term "drugs" includes therapeutic biological products.

2.10 Case Series

The external reporting (e.g., publication, poster or oral presentation) of an interesting clinical situation or medical condition in a **series** of patients (i.e., more than one patient). Case series usually contain detailed information about each patient and may include demographic information and information on diagnosis, treatment, response to treatment, follow-up after treatment, as well as a discussion of existing relevant literature. The information used in the report must have been originally collected solely for non-research purposes as the result of a clinical experience.

2.11 Children

Persons who have not attained the legal age for consent to treatments or procedures involved in clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted.

According to Pennsylvania (PA) State Law, minors are persons under the age of eighteen. The general rule is that a person may consent for his or her own medical care at the age of eighteen. Therefore, the Drexel University IRB defines children as persons who are under eighteen years of age. Certain statutes and case law, however, provide minors with "majority" status in some circumstances, giving them the right to consent to their own medical care. For example: emancipated minors. Drexel University will review issues of consent related to enrollment of these children in research on a case-by-case basis.

NOTE: For research conducted in jurisdictions other than PA, the research must comply with the laws regarding the legal age of consent in the relevant jurisdictions. Drexel University's Legal counsel should be consulted with regard to the laws in other jurisdictions.



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2.12 Clinical Research

The scientific study of human health and disease to develop new medical treatments, interventions, and health practices. It involves the systematic study of drugs, medical devices, behavioral interventions, and public health strategies to assess their safety, efficacy, and impact on individuals and populations.

2.13 Clinical Significance

Of practical importance.

2.14 Coded Data

Data are coded when a link will exist between a unique code and individual subjects' identifiers such as name, medical record number, email address or telephone number. Generally, the data is collected with a "Study ID," and a linkage file is maintained where the Study ID is associated with the subject's identifiers.

The code should not be a combination of information related to the individual, such as initials, date of birth, etc. It can be sequential numbers and/or letters, such as ST01, ST02, ST03, and so on.

2.15 Commercial IRB

Independent, pay-for-services IRB that provides regulatory and ethical review services.

2.16 Common Rule

The Common Rule refers to the "Federal Policy for the Protection of Human Subjects," adopted by a number of federal agencies. Although the Common Rule is codified by each agency separately, the text is identical to DHHS regulations in 45 CFR 46 Subpart A.

2.17 Complaint

A concern expressed by subjects or others about the conduct of the study or a subject's participation.

2.18 Confidentiality

Methods used to ensure that information obtained by investigators about subjects is not improperly divulged.

2.19 Conflict of Interest

A situation in which financial or other personal considerations may compromise, may involve the potential for compromising, or may have the appearance of compromising an individual's objectivity in meeting University duties or responsibilities, including research activities.

2.20 Corrective and Preventive Action (CAPA) Plan

The plan that is submitted in response with a Reportable New Information (RNI) report as it outlines what corrective actions will be taken to act on the event or problem that has already occurred and what preventive actions are being taken to eliminate the root cause of a potential problem.

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2.21 Court-Appointed Legal Guardian

(except to the extent any appointed health care agent has authority, unless the health care agent's authority has been suspended by a court order) is a court appointed guardian granted "general" guardianship or "guardian of the person" may provide surrogate consent for all activities of the individual; therefore, this guardian may provide surrogate consent for research participation of the individual.

2.22 Covered Entity

A health plan, a health care clearinghouse, or a health care provider who transmits health information in electronic form in connection with a transaction for which DHHS has adopted a standard.

2.23 Data Use Agreement

An agreement into which a covered entity enters with the intended recipient of a limited data set that establishes the ways in which the information in the limited data set may be used and how it will be protected.

2.24 Dead Fetus

A fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

2.25 De-identified Data

Data are considered de-identified when any direct or indirect identifiers or codes linking the data to the individual subject's identify are destroyed or there is no potential for deductive disclosure. De-identification can occur by removing the code from the dataset or destroying the linkage file. At this point, no data can be linked back to an individual.

2.26 Delivery

A delivery is a complete separation of the fetus from the woman by expulsion or extraction or any other means.

2.27 Designated Record Set

A group of records maintained by or for a covered entity that includes

1. medical and billing records about individuals maintained by or for a covered health care provider;
2. enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or
3. used, in whole or in part, by or for the covered entity to make decisions about individuals. A record is any item, collection, or grouping of information that includes PHI and is maintained, collected, used, or disseminated by or for a covered entity.

2.28 Dietary Supplement

A dietary supplement is a product taken by mouth that is intended to supplement the diet and that contains a dietary ingredient. The dietary ingredients in these products can include vitamins, minerals, herbs and other botanicals, amino acids, other dietary substances intended to

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supplement the diet, and concentrates, metabolites, constituents, extracts, or combinations of the preceding types of ingredients. See section 201(ff) of the FD&C Act [21 U.S.C. 321(ff)].

2.29 Disclosure

The release, transfer, access to, or divulging of information in any other manner outside the entity holding the information.

2.30 Drexel University Research Agents

Individuals who act on behalf of the institution, exercise institutional authority or responsibility, or perform institutionally designated activities. Drexel University Research agents include faculty, staff, students, contractors, and volunteers, depending upon their involvement in research, sponsored programs, or projects as determined by the applicable committees (e.g., IRB, IACUC) or ORI offices.

2.31 Durable General Power of Attorney

grants the agent whatever authority is specified in the power of attorney document and is referred to as an attorney-in fact. Where the power of attorney includes a specific provision stating that it shall survive any period of incapacity or mental incompetence of the principal it is considered a “durable” power of attorney, and the person holding power of attorney may provide surrogate consent for research participation **unless** the research participation includes an activity expressly excluded from the power of attorney. *NOTE that a general power of attorney is only valid when registered with the register of deeds in either the county named in the power of attorney or the county in which the principal resides. Before relying on the decision of a person holding a general power of attorney, investigators should require proof that the power of attorney has been registered and should examine the document to ensure that it expressly survives any period of incapacity or mental incompetence of the principal. For assistance with these determinations, please contact the Office of General Counsel.*

2.32 Emergency Test

The use of an investigational product with a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval. [21CFR 56.102(d)]

2.33 Engaged Institution

An institution is considered *engaged* in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. Employees and agents are individuals acting on behalf of the institution and are further defined in ORI-004 Drexel Research Agent Eligibility and Responsibilities. Involvement in human research activities by Drexel agents does not guarantee the institution is engaged.

2.34 Federalwide Assurance (FWA)

An agreement through which an institution commits to the U.S. Department of Health and Human Services (HHS) that it will comply with the requirements in the HHS Protection of Human



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Subjects regulations at 45 CFR 46. The FWA is the only type of assurance currently accepted and approved by the Office of Human Research Protections (OHRP).

2.35 Fetus

The product of conception from implantation until delivery.

2.36 Financial Interest Related to Research

Means financial interest in the sponsor, product, or service being tested. The definition is at least as stringent as the level of an investigator's financial interest that requires evaluation as a possible conflict of interest.

2.37 Generalized Knowledge

Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

2.38 Health Information

Any information, whether oral or recorded in any form or medium, that (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

2.39 Health Care Power of Attorney (HCPOA)

A health care agent pursuant to the execution of health care power of attorney document. A HCPOA document (to the extent of authority granted) grants the agent power to make health care decisions for the individual following a physician's determination that the individual lacks adequate capacity to make their own health care decisions. Therefore, if such a physician determination has been made, the agent under an HCPOA may provide surrogate consent for research participation to the extent this does not contradict the written HCPOA.

2.40 Humanitarian Device Exemption (HDE)

A 'premarket approval application' submitted to FDA pursuant to Subpart A, 21 CFR 814. HDE approval is based upon, among other criteria, a determination by FDA that the HUD will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from use of the device outweighs the risk of injury or illness from its use, while taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

2.41 Humanitarian Device Exemption (HDE)

A person who or entity that obtains approval of an HDE from the FDA.

2.42 Humanitarian Use Device

A device intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.



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2.43 Human Subject as Defined by DHHS

A human subject as defined by the Common Rule is a living individual about whom an investigator (whether professional or student) conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

2.44 Human Subject as Defined by FDA

For research covered by FDA regulations, human subject means an individual who is or becomes a participant in a clinical investigation, either as a recipient of the test article or as a control. A subject may be in normal health or may have a medical condition or disease. In the case of a medical device, a human subject also includes any individual on whose specimen an investigational device is used or tested or used as a control. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.

2.45 Human Subject Research

Any activity that meets the definition of “research” and involves “human subjects” as defined by either the Common Rule or FDA regulations.

NOTE: The terms “subject” and “participant” are used interchangeably in Drexel University HRP SOPs and have the same definition.

2.46 Incidental Findings

Unexpected imaging finding discovered in the course of conducting a research study that has a potential health or reproductive importance that are beyond the aims of the study and have not been anticipated in the study protocol. Such procedures may include MRI, CT scans, Ultrasound, PET, SPECT, arteriograms, x-rays, fluoroscopy, or other tests that produce an image.

2.47 Investigational Device Exemption (IDE)

An investigational device exemption in accordance with 21 CFR 812.

2.48 Identifiable Biospecimen

A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

2.49 Identifiable Information

Information where the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

2.50 Identifiable Private Information

Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

2.51 Immediate Family

Spouse, domestic partner, and dependent children.



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2.52 Investigational New Drug (IND)

An investigational new drug application in accordance with 21 CFR Part 312.

2.53 IND Safety Report

The sponsor must notify the FDA and all participating investigators (i.e., all investigators to whom the sponsor is providing drug under its INDs or under any investigator's IND) in an IND safety report of potential serious risks, from clinical trials or any other source, as soon as possible, but in no case later than 15 calendar days after the sponsor determines that the information qualifies for reporting as defined in [21 CFR 312.32](#). In each IND safety report, the sponsor must identify all IND safety reports previously submitted to the FDA concerning a similar suspected adverse reaction and must analyze the significance of the suspected adverse reaction in light of previous, similar reports or any other relevant information. Such reports must be accompanied by confirmation that the sponsor has submitted the report to the FDA.

2.54 Individually Identifiable Health Information

Information that is a subset of health information, including demographic information collected from an individual, and (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; and (a) that identifies the individual; or (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

2.55 Institutional, Investigator, or Sponsor Hold

A voluntary action by the institution, investigator, or sponsor of the study to place some or all research activities associated with the study on hold.

2.56 Institutional Review Board (IRB)

A board designated by Drexel University to review, approve the initiation of, and conduct period review of research involving human participants. The primary purpose of such review is to assure the protection of the rights and welfare of the human participants. The IRB may be assigned other review functions as deemed appropriate by the Drexel University.

2.57 Intervention

Physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

2.58 Interactions

Communication or interpersonal contact between investigator and subject.

2.59 Investigational Device

A device (including a transitional device) that is the object of an investigation. Investigation, as it pertains to devices, means a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device.



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2.60 Investigational Drug

A drug that has not yet been approved by the FDA or an approved drug that is being studied in a clinical investigation.

2.61 In Vitro Diagnostic (IVD) Product

Those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. [21 CFR 809.3(a)]

2.62 Legally Authorized Representative (LAR)

An individual or 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. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

2.63 Limited Data Set

Refers to PHI that excludes 16 categories of direct identifiers and may be used or disclosed, for purposes of research, public health, or health care operations, without obtaining either an individual's Authorization or a waiver or an alteration of Authorization for its use and disclosure, with a data use agreement.

2.64 Local Consideration

Requirements of any applicable state or local laws, regulations, institutional policies, standards or other factors, including local ancillary reviews, relevant to research.

2.65 Man-made Disaster

A disaster caused by acts of man, including but not limited to acts of war, terrorism, chemical spills, power shortages, cyber-attacks.

2.66 Minimal Risk

The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

2.67 Minimum Necessary

The standard that uses the least information reasonably necessary to accomplish the intended purpose of the use, disclosure, or request. Unless an exception applies, this standard applies to a covered entity when using or disclosing PHI or when requesting PHI from another covered entity. A covered entity that is using or disclosing PHI for research without Authorization must make reasonable efforts to limit PHI to the minimum necessary. A covered entity may rely, if reasonable under the circumstances, on documentation of IRB or Privacy Board approval or other appropriate representations and documentation under section 164.512(i) as establishing that the

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request for protected health information for the research meets the minimum necessary requirements.

2.68 Minor Change

A minor change is one which, in the judgment of the IRB reviewer, makes no substantial alteration in:

1. The acceptability of the risk-to-benefit analysis or increases the level of risks to subjects
2. The research design or methods (adding procedures that are not eligible for expedited review would be considered more than a minor change)
3. The number of subjects enrolled in the research (usually not greater than 10% of the total requested locally)
4. The qualifications of the research team
5. The facilities available to support safe conduct of the research

Any other factor which would warrant review of the proposed changes by the convened IRB

2.69 Natural Disaster

A major adverse event resulting from natural earth processes, such as floods, earthquakes, volcanic eruptions, and other geologic processes.

2.70 Neonate

A neonate is a newborn.

2.71 Noncompliance

Any failure to follow:

- Applicable federal regulations, state or local laws, or institutional policies governing human subject protections, or
- The requirements or determinations of the IRB, including the requirements of the approved investigational plan (i.e., protocol deviations).

Noncompliance can result from performing an act that violates these requirements or failing to act when required. Noncompliance may be minor or sporadic or it may be serious or continuing.

A. Continuing Noncompliance

A pattern of repeated noncompliance which continues after it has been determined that noncompliance occurred, including inadequate effort to take corrective actions or comply with IRB requirements within a reasonable timeframe.

B. Serious Noncompliance

Noncompliance that increases risk of harm to subjects; adversely affects the rights, safety, or welfare of subjects; or adversely affects the integrity of the data or the research.

2.72 Non-Significant Risk (NSR) Device

An investigational device that does not meet the definition of a significant risk device.

2.73 Nonviable Neonate

A nonviable neonate means a neonate after delivery that, although living, is not viable.



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2.74 Personally Identifiable Information

Any information collected or maintained about an individual, including but not limited to, education, financial transactions, medical history and criminal or employment history, and information that can be used to distinguish or trace an individual's identity, such as the individual's name, Social Security number, date and place of birth, mother's maiden name, biometric data, and any other personal information that is linked or linkable to a specific individual.

2.75 Pilot Study

Typically defined as an initial or smaller-scale investigation or a study to either test out new experimental designs (including survey or instrument development) or methods of treatment; synonymous with feasibility study

2.76 Pregnancy

A pregnancy encompasses the period of time from implantation until delivery. A person will be assumed to be pregnant if they exhibit any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

2.77 Prisoner

A prisoner is any individual involuntarily confined or detained in a penal 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.

2.78 Privacy

Having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. It is the state or condition of being free from unauthorized intrusion, being observed or disturbed by other people.

2.79 Privacy Board

A board that is established to review and approve requests for waivers or alterations of Authorization in connection with a use or disclosure of PHI as an alternative to obtaining such waivers or alterations from an IRB. A Privacy Board consists of members with varying backgrounds and appropriate professional competencies as necessary to review the effect of the research plan on an individual's privacy rights and related interests. The board must include at least one member who is not affiliated with the covered entity, is not affiliated with any entity conducting or sponsoring the research and is not related to any person who is affiliated with any such entities. A Privacy Board cannot have any member participating in a review of any project in which the member has a conflict of interest. At Drexel University, the IRB serves as the Privacy Board.

2.80 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, and information which has been provided for



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specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

2.81 Professional Conflict of Interest

Exists when an IRB Member or consultant is a key member of the research team for the protocol under review. This includes the Principal Investigator, Co-investigator, and Study/Project coordinator and any individual that is listed on a grant application or FDA 1572 form.

Professional COIs may also exist for IRB Members or consultants who have a professional interest in a competing protocol or for individuals whose employment or job performance is contingent on successful approval of grants and contracts, who have an employment supervisory or reporting role to the person whose work the IRB is examining, or have a relationship with an entity that grants the Member a non-financial benefit, such as a voluntary professional leadership role.

2.82 Protected Health Information (PHI)

PHI is individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. PHI excludes individually identifiable health information in education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g, records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer.

2.83 Public Health Crisis

Any crisis or serious incident arising from human, animal, plant, food or environment original, which has an adverse health impact, and which requires action by authorities.

2.84 Quorum

A quorum of the IRB consists of a majority (more than half) of the voting membership, including at least one member whose primary concern is in a non-scientific area.

2.85 Related

There is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.

2.86 Relying Site/Institution

An institution or site engaged in human subjects research that has agreed to cede the ethical review of the research to an external IRB.

2.87 Repository

A collection of data or biological specimens whose organizers:

- Receive data or specimens from multiple sources;
- Maintain the data or specimens over time; and
- Control access to and use of data or specimens by multiple individuals and/or for multiple purposes, which may evolve over time.

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A. Non-research Repository

Created and maintained for purposes that are totally unrelated to research. Such purposes may include diagnosis, treatment, billing, marketing, quality control, and public health surveillance.

B. Research Repository

Created and maintained specifically for research purposes. Such purposes may include databases to identify prospective subjects, patient outcome information to evaluate treatment effectiveness, and tissues samples for future research. Non-research repositories that are altered to facilitate research (e.g., through the addition of data fields not necessary for the core purpose of the repository) are considered research repositories.

2.88 Research

The Common Rule defines research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

The following activities are deemed not to be research under the Common Rule:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

The FDA defines “research” as any experiment that involves a test article and one or more human subjects, and that meets any one of the following:

- Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act means any use of a drug other than the use of an approved drug in the course of medical practice. [21 CFR 312.3(b)]

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- Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act means any activity that evaluates the safety or effectiveness of a device. [21 CFR 812.2(a)]
- Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research. [21 CFR 50.3(c), 21 CFR 56.102(c)]

2.89 Reviewing IRB

The selected IRB of record that conducts the ethical review of research for sites participating in a multi-site study (also referred to as the IRB of record, central IRB, or single IRB (sIRB)).

2.90 Rights

The entitlement of human subjects for adequate protections based on the ethical principles and regulations underpinning human subjects research.

2.91 Root Cause

The initiating, most basic cause of a problem that may or may not lead to a chain of causes or other problems. If the root cause is identified and resolved, it should prevent recurrence. The root cause of an event or a problem must be identified to establish an appropriate Corrective and Preventive Action Plan. Root Cause Analysis (RCA) is a formal process for identifying and documenting the root cause and the downstream effects.

2.92 Sensitive Information

Data or information, on any storage media or in any form or format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, unauthorized access, misuse, alteration, or loss or destruction of the information (e.g., could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation).

2.93 Serious Unexpected Suspected Adverse Reaction (SUSAR)

For clinical trials subject to the FDAs IND regulations, a Serious Unexpected Suspected Adverse Reaction refers to an adverse event or suspected adverse reaction which is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization,
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.
- Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an



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emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

2.94 Significant Risk (SR) Device

Significant risk device means 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; or
- Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- Is 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 the health, safety, or welfare of a subject.

2.95 Single Case Report

The external reporting (e.g., publication, poster or oral presentation) of an interesting clinical situation or medical condition of a **single** patient. Case reports normally contain detailed information about an individual patient and may include demographic information and information on diagnosis, treatment, response to treatment, follow-up after treatment, as well as a discussion of existing relevant literature. The patient information used in the report must have been originally collected solely for non-research purposes as the result of a clinical experience.

2.96 Study Deviation Log

A record of all deviations, events or issues that occur at a study site for both observational and interventional clinical research studies. This log should be maintained with the Study Records (e.g., study binder, regulatory binder, study file) and should be made available upon request for review by ORI, the IRB, and the Sponsor's monitor.

2.97 Suspension of IRB Approval

A directive of the IRB to temporarily stop some or all previously approved research activities and/or a temporary withdrawal of approval by the IRB of some or all research activities associated with a study. Suspensions may be enacted by a Chair or the convened IRB. Research activities that may be suspended include but are not limited to recruitment, screening, enrollment, research intervention/interaction, and follow-up. Suspended research studies remain open and require continuing review. Investigators must continue to provide reports on adverse events and unanticipated problems to both the IRB and sponsors just as if there had never been a suspension (i.e., all events that need to be reported during a study need to continue to be reported during the suspension period). If a suspension is lifted and IRB approval of the suspended research study has expired, a continuing review is required before the study may resume.

2.98 Sponsor

The company, institution, individual donor, or organization responsible for the initiation, management or financing of a research study.



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2.99 Sponsored Research

Research funded by external entities (public, industry, or private) through a grant or contract that involves a specified statement of work (e.g., the research proposal), including clinical trials involving investigational drugs, devices or biologics.

2.100 Systemic Investigation

An activity that involves a prospective study plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a study question.

2.101 Termination of IRB Approval

A directive of the convened IRB to permanently stop all activities in a previously IRB approved research study and/or permanent withdrawal of IRB approval of all research activities associated with a study. IRB approval may only be terminated by the convened IRB. Terminated research studies are closed and no longer require continuing review.

2.102 Test Article

The FDA defines “Test article” as meaning any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 and 354- 360F of the Public Health Service Act [42 U.S.C. 262 and 263b-263n]. [21 CFR 50.3(j)]

Test articles covered under the FDA regulations include, but are not limited to:

- **Human drugs** - The primary intended use of the product is achieved through chemical action or by being metabolized by the body. A drug is defined as a substance recognized by an official pharmacopoeia or formulary; a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; a substance (other than food) intended to affect the structure or any function of the body; a substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device. Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)
- **Medical Devices** - A device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; 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, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.
- **Biological Products** - include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources — human, animal, or



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microorganism — and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available.

- **Dietary Supplements** - A product taken by mouth that is intended to supplement the diet and that contains a dietary ingredient. The dietary ingredients in these products can include vitamins, minerals, herbs and other botanicals, amino acids, other dietary substances intended to supplement the diet, and concentrates, metabolites, constituents, extracts, or combinations of the preceding types of ingredients. [21 USC 321 (ff)]
- **Food Additives** - A food additive is defined in Section 201(s) of the FD&C Act as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use); if such substance is not Generally Recognized As Safe (GRAS) or sanctioned prior to 1958 or otherwise excluded from the definition of food additives.
- **Color Additives** - A color additive is any dye, pigment or substance which when added or applied to a food, drug or cosmetic, or to the human body, is capable (alone or through reactions with other substances) of imparting color. Color additives for use in food, drugs, and cosmetics require premarket approval. Color additives for use in or on a medical device are subject to premarket approval, if the color additive comes in direct contact with the body for a significant period of time.
- **Foods** - Foods include dietary supplements that bear a nutrient content claim or a health claim.
- **Infant Formulas** - Infant formulas are liquid foods intended for infants which substitute for mother's milk.
- **Electronic Products** - The FDA regulates certain classes of electronic products including radiation-emitting electronic products such as microwaves and x- rays.

2.103 Unanticipated Problem Involving Risks to Subjects or Others

Any incident, experience, outcome, or new information that:

- Is unexpected (in terms of nature, severity, or frequency); **and**
- Is at least possibly related to participation in the research; **and**
- Indicates that subjects or others are at a greater risk of harm (including physical, psychological, economic, legal or social harm) than was previously known or recognized.

UPIRSOs also encompass Unanticipated Adverse Device Effects and information that sponsors are required to report to the FDA in IND Safety Reports under [21 CFR 312.32](#).

2.104 Unexpected

The incident, experience or outcome is not expected (in terms of nature, severity, or frequency) given the research procedures that are described in the study-related documents, such as the IRB-approved research protocol/research plan and informed consent documents; and the characteristics of the subject population being studied.



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2.105 Use

With respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within the entity or health care component (for hybrid entities) that maintains such information.

2.106 Viable

As it pertains to the neonate, viable means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

2.107 Waiver or Alteration of Authorization

The documentation that a covered entity obtains from an investigator or an IRB or a Privacy Board that states that the IRB or Privacy Board has waived or altered the Privacy Rule's requirement that an individual must authorize a covered entity to use or disclose the individual's PHI for research purposes.

2.108 Weather Events

Meteorological conditions that cause disruptions in operations, such as tornadoes, hurricanes, and blizzards.

2.109 Welfare

A state of physical, psychological, social, economic, and legal well-being.

2.110 Workforce

Employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity, is under the direct control of the covered entity, whether or not they are paid by the covered entity.

3. Responsibilities

3.1 Office for Research & Innovation and Human Research Protections Responsibilities

The Office of Research & Innovation and Human Research Protections Office are responsible for maintaining and implementing these procedures and definitions list. For inquiries regarding these procedures, please contact the Executive Director for Human Research Protections, as part of the Office for Research & Innovation (ORI).

4. Revision

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