

Institutional Review Board

[A](#) [B](#) [C](#) [D](#) [E](#) [F](#) [G](#) [H](#) [I](#) [J](#) [K](#) [L](#) [M](#) [N](#) [O](#) [P](#) [Q](#) [R](#) [S](#) [T](#) [U](#) [V](#) [W](#) [X](#) [Y](#) [Z](#)

A**AAHRPP**

Association for the Accreditation of Human Research Protection Programs

Adverse Event (AE)

Any harm or untoward medical occurrence in a research participant administered a medical product, medical treatment or procedure even if it does not necessarily have a causal relationship with the product, treatment, or procedure. An adverse event can be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medical product, medical treatment, or procedure whether or not considered to be related.

[FDA: 21 CFR 312.32]

Adverse Reaction (AR), Adverse Drug Reaction (ADR)***Pre-Approval Clinical Use of a Product***

All noxious and unintended responses to a medicinal product related to any dose.

Marketed Medicinal Product

A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function.

[FDA: Guideline for Industry, Clinical Safety Data Management: Definitions and Standards for Expedited Reporting]

Affiliated

IRB members are considered affiliated if they, their spouse, domestic partner, or dependent children are an employee, contractor, student, board member, or have any other similar affiliation with Fred Hutch, UW, or Seattle Children's.

Allegation of Noncompliance

An unproved assertion of Non-Compliance.

Alteration of HIPAA

A request to change or omit one or more of the research-related HIPAA requirements. The most common use of an alteration is to omit the HIPAA signature requirement.

Demonstrating that the "research could not practicably be conducted without the waiver or alteration" is the main obstacle to approving an alteration. If the participant is physically present, it is usually practicable to obtain written HIPAA Authorization.

[45 CFR 164.512(i)(2)(ii)]

Assent

Affirmative agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Assurance

See [Federalwide Assurance](#).

Attachment A

The internal routing and approval form submitted along with a proposal for an activity to be performed at Fred Hutch under a grant, contract, or other sponsored agreement.

Attachment B

The internal routing and approval form submitted along with a funding proposal for an activity to be performed at Fred Hutch funded by Center funds, discretionary funds, royalties, or other non-sponsored funding source.

Attachment C

The internal routing and approval form for commercial and non-commercial research agreements.

Authorization Agreement

See [IRB Reliance Agreement](#).

Autonomy

Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.

B

Belmont Report

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical Behavioral Research is a statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.

Beneficence

An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

Benefit

A valued or desired outcome; an advantage.

Benign Behavioral Interventions

Research interventions that are brief in duration (hours up to a few days only), harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on participants, and the investigator has no reason to think the participants will find the interventions offensive or embarrassing. Such interventions can only include adult participants with adequate decision-making capacity who are prospectively asked to take part. Additional criteria must be met for how the research information is collected or recorded.

In general, these do not include physical (bodily) tasks or physical manipulations (e.g., range of motion activities, physical exercise) unless these are minor activities that are incident to the behavioral intervention and do not increase risk. For example, manipulating a keyboard, doing a puzzle, or walking while listening to music would be physical activities that could be considered minor activities that are taking place incident to the benign behavioral intervention.

Physical interventions that are physically invasive; or, those that could be harmful or painful would not meet the exemption. To meet the Exempt criteria, the intervention also cannot involve the introduction or administration of instruments, substances (including food) or energy onto or into the body.

Examples of a benign behavioral intervention that may meet the criteria for an Exempt determination include having the participants play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. [45 CFR 46.104(d)(3)]

Recommendations on Benign Behavioral Intervention: SACHRP Recommendation Approved July 26, 2017]

Biologic

A biologic product means any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man.

Broad Consent

Under the 2018 requirements of the Common Rule, a type of informed consent that allows for the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. Broad consent is less specific than consent for each use, but narrower than open-ended permission without any limitations.

Business Associate (of a Covered Entity under HIPAA)

A person or entity, other than a member of the workforce of a covered entity, who performs functions or activities on behalf of, or provides certain services to, a HIPAA covered entity that involve access by the business associate to protected health information. A business associate also is a subcontractor that creates, receives, maintains, or transmits protected health information on behalf of another business associate.

See also: [Covered Entity](#)

C

Cancer Consortium

A research partnership between the institutions of Fred Hutchinson Cancer Center, the University of Washington, and Seattle Children's. Also called the Fred Hutch/University of Washington/Seattle Children's Cancer Consortium.

Cancer-Related

- Funded by NCI; or
- Primary site of a multi-site trial has classified the study as cancer or cancer-related; or
- The trial cohort will include both patients with a cancer diagnosis and others without a cancer diagnosis AND includes a primary or secondary analysis of the portion of the cohort with a cancer diagnosis; or
- Research of secondary conditions related to cancer treatment in patients with a cancer diagnosis who have received that treatment; or
- Cancer prevention studies that specifically include a primary outcome of cancer diagnosis
- BMT not related to cancer treatment

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality is a document issued by a component of HHS pursuant to The Public Health Service Act Section 301(d), 42 U.S.C. 241(d) amended by Section 2012 of the 21st Century Cures Act, Public Law 114-255, to protect the privacy of individuals who are subjects of certain specified research activities by authorizing investigators to withhold from all persons not connected with the conduct of such research the names or other identifying characteristics of such subjects. Persons so authorized to protect the privacy of such individuals may not disclose information in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

Certification

The official notification by the institution to the supporting Federal department or agency component that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Children

Persons 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. [HHS: 45 CFR 46.402(a)]
In most states, including Washington state, the legal age at which a person is able to consent to participate in research is 18 years. Investigators should check appropriate State laws and regulations before conducting research to determine the definition of a child for the purposes of participation in research studies. In the case of research studies conducted outside the United States, the relevant laws and regulations of the research participants' country of residence should be applied.

CITI

Collaborative Institutional Training Initiative (www.citiprogram.org), an online provider of research ethics, compliance, and professional development education. Fred Hutch and the University of Washington have subscriptions for a number of CITI courses available to researchers, including Human Subjects and Good Clinical Practice training.

Clinical Investigation

Any experiment that involves a test article and one or more human subjects and that is either subject to requirements for prior submission to the FDA or is not subject to requirements for prior submission but the results are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

[FDA: 21 CFR 50.3(c)]

This term is used by the FDA to describe research that is subject to FDA regulations relating to informed consent and review by an IRB. Additional information regarding FDA clinical investigation definitions for drug or device studies is found at 21 CFR 312.3(b) and 21 CFR 812.3(h), respectively.

Clinical Research Support (CRS)

The Fred Hutch Office that promotes, supports, and facilitates research trials within the Cancer Consortium. CRS supports the Cancer Consortium Data and Safety Monitoring Committee and the Scientific Review Committee.

See also: [Data and Safety Monitoring Committee](#) and [Scientific Review Committee](#).

Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

[HHS 2018: 45 CFR 46.102(b); NIH Policy: Notice of Revised NIH Definition of "Clinical Trial"]

Clinical Trial Staff

Individuals, identified by the investigator, who are responsible for study coordination, data collection and data management. The central focus of clinical trial staff is to manage participant recruitment and enrollment, to maintain consistent study implementation, data management, and to ensure integrity and compliance with regulatory and reporting requirements. These individuals may also seek informed consent from prospective participants, enroll and meet with research participants, and collect and record information from research participants. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

[NIH Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-Funded Clinical Trials]

Closure

A study is closed when accrual of research participants is complete and all research activities have ceased. This means no interaction/intervention is planned for the purpose of research with research participants and no long-term follow-up. Data collection and analysis of identifiable data and biospecimens are complete.

Coded

When identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code) AND a key to decipher the code exists, enabling linkage of the identifying to the private information or specimens.

[OHRP Guidance: Coded Private Information or Specimens Use in Research]

Cohort

A group of subjects initially identified as having one or more characteristics in common who are followed over time. In social science research, this term may refer to any group of persons who are born at about the same time and share common historical or cultural experiences.

Collaborative Study

A study in which two or more institutions coordinate, with each institution completing a portion of the research activities outlined in a specific protocol.

Common Rule

See [Federal Policy](#).

Confidentiality

The obligation owed to research participants and potential research participants in relation to their individually identifiable information. The term “confidentiality” relates to information about research participants whereas the term “privacy” concerns research participants or potential research participants as individuals.

See also: [Privacy](#).

Confirmed Noncompliance

A report of noncompliance that can be determined to be true without further investigation, or an allegation of noncompliance that is determined to be true after investigation by the IRB.

See also: [Noncompliance](#)

Conflicting Interest

An individual involved in research review (e.g., IRB members) is automatically considered to have a conflicting interest when the individual or the individual’s spouse, domestic partner, children, or dependents have any of the following interests in the sponsor, product or service being tested, or competitor of the sponsor:

- Involvement in the design, conduct, or reporting of the research.
- Ownership interest, stock options, or other ownership interest of any value, excluding interests in publicly-traded, diversified mutual funds.
- Compensation of any amount in the past year or of any amount expected in the next year, excluding compensation for costs directly related to conducting research.
- Proprietary interest including, but not limited to, a patent, trademark, copyright, or licensing agreement.
- Board or executive relationship, regardless of compensation.
- Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center.
- Personal relationship (e.g., spouse, domestic partner, or immediate family member) with the principal investigator or other key personnel involved in the design, conduct or reporting of the research.
- Any other reason for which the individual believes that he or she cannot be independent.

Consent

See [Informed Consent](#).

Continuing Noncompliance

See [Noncompliance](#).

Continuing Review

The periodic IRB review of certain ongoing research at intervals appropriate to the degree of risk, but not less than once per year, to evaluate whether the research continues to satisfy the criteria for IRB approval.

Control (Subjects) or Controls Subject(s)

A group of subjects used for comparison who are not given a treatment under study or who do not have a given condition, background, or risk factor that is the object of study. Control conditions may be concurrent (occurring more or less simultaneously with the condition under study) or historical (preceding the condition under study). When the present condition of subjects is compared with their own condition on a prior regimen or treatment, the study is considered historically controlled.

Controlled-Access

Data are available to an investigator for a specific project only if certain stipulations are met.

See also: [Unrestricted-Access](#).

Cooperative Research

Projects that involve more than one institution.

Under the 2018 requirements of the Common Rule, such research projects must be approved by a single IRB for the portion of the research that is conducted in the United States.

[45 CFR 46.114]

Cooperative Review Agreement

See [IRB Reliance Agreement](#).

Coordinating Center

The central site that is responsible for organizing and managing activities and logistics, including oversight and coordination, of multi-site collaborative research. The coordinating center facilitates communication and collaboration among grantees, guides research activities, and leads data analysis efforts. Also known as an operations center.

Covered Entity

Those individuals, organizations and institutions required to comply with HIPAA with respect to the use and disclosure of Protected Health Information or PHI. Examples of covered entities include hospitals, clinics, health care professionals and health plans.

See also: [Business Associate](#)

D

Data and Safety Monitoring Board (DSMB)

A committee of scientists, physicians, statisticians, and others that collects and analyzes data during the course of a clinical trial to monitor for adverse effects and other trends (such as an indication that one treatment is significantly better than another, particularly when one arm of the trial involves a placebo control) that would warrant modification or termination of the trial or notification of subjects about new information that might affect their willingness to continue in the trial.

Data and Safety Monitoring Committee (DSMC)

A Cancer Consortium committee of scientists, physicians, statisticians, and others that performs ongoing review and monitoring throughout the accrual life of Cancer Consortium intervention studies.

Data and Safety Monitoring Plan (DSMP)

A plan for appropriate oversight and monitoring of the conduct of a research study involving human subjects to help ensure the safety of the research participants and the validity and integrity of the research data.

dbGaP (Database of Genotypes and Phenotypes)

A central data repository at the National Center for Biotechnology Information (NCBI), a branch of the National Library of Medicine.

See also: [NIH GWAS data repository](#).

De-identified Information

Information relating to individuals that has been de-identified according to the following criteria: the identities of subjects cannot be readily ascertained or otherwise associated with the data by the repository staff or secondary data users as described at HHS Pre-2018: 45 CFR 46.102(f), or HHS 2018: 45 CFR 46.102(e)]; a statistical expert has determined that the risk or re-identification is small as described at 45 CFR 164.514(b)(1) (the HIPAA Privacy Rule); the 18 identifiers enumerated at 45 CFR 164.514(b)(2) (the HIPAA Privacy Rule) are removed; and the submitting institution has no actual knowledge that the remaining information could be used alone or in combination with other information to identify the subject of the data. Note that this definition is specific to NIH's Genomic Data Sharing policy.

Declaration of Helsinki

A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries. It was revised in 1975 and 1989.

Delayed Onset Research

Research for which funding applications may be submitted to a sponsoring agency with the knowledge that human subjects will be involved during the period of support, but definite plans for this involvement are not yet known and so cannot be described in the application.

Department of Defense (DoD) Component

Department of Defense components include, but may not be limited to:

- Department of Defense
- Navy
- Office of Naval Research
- Naval Academy
- U.S. Naval Observatory
- Army
- U.S. Army Corps of Engineers
- Military Academy (West Point)
- Air Force
- Air Force Academy
- Marines
- Coast Guard
- Coast Guard Academy
- National Guard
- Missile Defense Agency
- Defense Advanced Research Projects Agency (DARPA)

- Pentagon Force Protection Agency
- Defense Intelligence Agency
- National Geospatial-Intelligence Agency
- National Security Agency
- National War College
- Other DoD facilities

Designated Government Department or Agency

The federal department or agency that conducts, supports, or otherwise has regulatory oversight over human subjects research to which Reportable Incidents must be reported under this policy and applicable federal regulations. If there is more than one Designated Government Department or Agency the reports will be made to all Designated Government Departments or Agencies. This may include, but is not limited to:

- The Office for Human Research Protections (OHRP) in accordance with federal regulations and the institution’s Federalwide Assurance.
- The appropriate institute at the National Institutes of Health (NIH) if the research is conducted, funded, or overseen by the NIH.
- The Department of Defense (DOD) if the research is conducted, funded or otherwise subject to regulatory oversight by the DOD and/or one of its components in accordance with federal regulations and the institution’s Federalwide Assurance DOD addendum.
- The FDA for research regulated by the Food and Drug Administration (FDA).
- Other departments or agencies conducting, funding, or overseeing research that are signatories to the Common Rule.

Designated Reviewer

The IRB chair or an Experienced IRB Member designated by the IRB chair to conduct Non-Committee Reviews.

Detainee

A detainee is defined as any individual captured by, or transferred to the custody or control of, DoD personnel pursuant to the law of war. This does not include persons being held solely for law enforcement purposes, except where the United States is the occupying power.

Also known as: Prisoner of War

Disaster

Any natural or human-caused event that places life, property, or the environment in danger and that includes and goes beyond the regular 911 police/fire/medical response for greater than 24 hours.

DoD-Affiliated Personnel

Service members, Reserve Service members, National Guard members, DoD civilians, and DoD contractors.

Double-Blind

A study design in which neither the investigators nor the subjects know the treatment group assignments of individual subjects. Sometimes referred to as “double-masked.”

E

Elements of Consent

By regulation, the information to be provided to each prospective research participant. Basic and additional elements of consent are listed at 45 CFR 46.116 and 21 CFR 50.25.

Emancipated Minor

A legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law (for such purposes as consenting to medical care), but who are entitled to treatment as if they had by virtue of assuming adult responsibilities such as being self-supporting and not living at home, marriage, or procreation.

Emergency Use

The use of a test article on 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. "Not sufficient time" is defined by Fred Hutch as seven (7) business days or less.

[FDA: 21 CFR 56.102(d)]

Engaged in Research

In general, 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.

[OHRP Guidance: Engagement of Institutions in Human Subjects Research (2008)]

Epic

A University of Washington Medicine medical records system for registration, scheduling, financial clearance, charge capture and billing.

Equitable

Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed.

Exempt

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| HHS Pre-2018 Requirements of the Common Rule | Certain human subjects research that is excepted from the requirements of the Common Rule because it falls within one or more categories of research described in 45 CFR 46.101(b). |
| HHS 2018 Requirements of the Common Rule | Certain human subjects research that is excepted from the requirements of the Common Rule because it falls within one or more categories of research described in 45 CFR 46.104. |
| FDA | Certain clinical investigations that are excepted from the requirements of IRB review as described at 21 CFR 56.104. |

Expedited Review

A review procedure conducted by either the IRB chairperson or by one or more IRB members designated by the chairperson, rather than by the full IRB committee, for certain kinds of research involving no more than minimal risk, for minor changes in approved research, or for research for which limited IRB review is a condition of exemption (i.e., HHS 2018: 45 CFR 46.110(b)(1)(iii)).

Experienced IRB Member

An IRB member is considered experienced if the IRB chair considers the IRB member to have sufficient experience in and knowledge of conducting IRB reviews.

Experimental

Term often used to denote a therapy (drug, device, procedure) that is unproven or not yet scientifically validated with respect to safety and efficacy. A procedure may be considered "experimental" without necessarily being part of a formal study (research) to evaluate its usefulness.

Expiration Date

The first date that the protocol is no longer approved. The date after the end date of the approval period.

E

FDA

United States Food and Drug Administration, an agency of the federal government established by Congress in 1912 and presently part of the Department of Health and Human Services.

FDA-Regulated Research

Research that is subject to the oversight of the U.S. Food and Drug Administration. The following activities are FDA-regulated research:

- Any use of a drug other than the use of a marketed drug in the course of medical practice. (Clinical investigations subject to requirements for prior submission to the FDA under section 505(i) of the Federal Food Drug and Cosmetic Act.)
- Any use of a device to evaluate its safety or efficacy. (Clinical investigations subject to requirements for prior submission to the FDA under section 520(g) of the Federal Food Drug and Cosmetic Act.)
- Any collection of data to submit to FDA or hold for inspection by FDA in support of a marketing application.

Federal Policy for the Protection of Human Subjects

Also known as the "Common Rule," the federal policy codified by Health and Human Services at 45 CFR 46 provides regulation for the involvement of human subjects in research. The Federal Policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that takes appropriate administrative action to make the Policy applicable to such research. Nineteen federal agencies adopted or follow the pre-2018 Federal Policy. 19 federal agencies adopted or follow the 2018 Federal Policy.

Pre-2018 Requirements of the Common Rule

The term used to describe the Federal Policy in effect August 19, 1991 through January 21, 2019. All research with an initial approval before January 21, 2019 is subject to the requirements of this version of the Common Rule, unless ongoing research is re-reviewed and approved under the 2018 Requirements of the Common Rule.

2018 Requirements of the Common Rule

The term used to describe the Federal Policy in effect beginning July 19, 2018, with a compliance date of January 21, 2019. All research with an initial approval or *de novo* review approval on or after this date is subject to the requirements of this version of the Common Rule.

Federalwide Assurance (FWA)

A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

[HHS: 45 CFR 46.103]

Fetus

The product of conception from implantation until delivery.

[HHS: 45 CFR 46.202(c)]

Fred Hutch Personnel

Individuals directly employed by Fred Hutch, non-employee volunteers performing similar research functions as a Fred Hutch employee, or those designated in Fred Hutch PeopleSoft system as 'non-employee' but who are performing similar research functions as a Fred Hutch employee (e.g., interns, visiting fellows).

Full Committee Review

Review of proposed research at a convened IRB meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas and who represents the perspective of participants and the community. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

Funding Source Document (FSD)

The grant, contract, agreement, or other document that describes the scope of work supported by the funding.

G

Gateway

Gateway is a database repository of mostly hematopoietic stem cell transplant (HSCT) patient data managed by Fred Hutch. It contains data originating from LabVision, UW, Seattle Children's, and various Fred Hutch departments.

Gene Therapy

The treatment of genetic disease accomplished by altering the genetic structure of either somatic (nonreproductive) or germline (reproductive) cells.

Generalizable Knowledge

A term that means the information is expected to expand the knowledge base of a scientific discipline or other scholarly field or study and yield one or both of the following:

- Results that are applicable to a larger population beyond the site of data collection or the specific subjects studied.
- Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.

Genotype

An individual's collection of genes.

GOG

Gynecological Oncology Group

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.

Grant

Financial support provided for research study designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant.

Guardian

An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care.

[HHS: 45 CFR 46.402(e)]

H

HIPAA

The federal law called the Health Insurance Portability and Accountability Act that regulates, among other things, the disclosure of protected health information (“PHI”) about patients treated by most health care providers, third-party payors and related organizations in the United States (“Covered Entities”). In the context of human subjects research, HIPAA establishes a federal standard for the manner in which the confidentiality and security of PHI will be maintained by Covered Entities and prescribes a process through which researchers can obtain PHI about patients who are sought by researchers to be research participants or potential research participants.

HIPAA Identifiers

Health information linked by one or more of the following 18 identifiers is considered protected health information under HIPAA:

1. Names;
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census:
 - a) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
 - b) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Telephone numbers;
5. Fax numbers;
6. Email addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

If a communication contains any of these identifiers, or parts of the identifier, such as initials, the data is to be considered “identified”. To be considered “de-identified”, all of the 18 HIPAA Identifiers must be removed from the data set. This includes all dates, such as surgery dates, all voice recordings, and all photographic images.

For information regarding de-identification of protected health information, see: <https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html>

See also: [HIPAA](#) and [Protected Health Information](#)

HRPP

Human Research Protection Program

Human Research

Any activity that satisfies one or more of the following criteria:

- It is a "clinical investigation" involving "human subjects" as defined in United States Food and Drug Administration regulations (21 CFR Section 50.3);
- It is "research" involving "human subjects" as defined in United States Department of Health and Human Services regulations or other Common Rule regulations (45 CFR Section 46.102);
- It is funded by the Department of Defense and DOD regulations for the protection of human subjects (32 CFR Part 219) apply;
- It is research involving "health care information" of a "patient" under the Washington Uniform Healthcare Information Act (see Revised Code of Washington Chapter 70.02); or
- It is research involving human subjects under any other applicable state or local laws or regulations.

Human Subject

Also known as Human Research Participant.

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| HHS Pre-2018 Requirements of the Common Rule | A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. [45 CFR 46.102(f)] |
| HHS 2018 Requirements of the Common Rule | 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. [45 CFR 46.102(e)] |
| FDA | An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. [21 CFR 50.3(g)] For research involving medical devices, a human subject is also an individual on whose specimen an investigational device is used or as a control. [21 CFR 812.3(p)] When medical device research involves in vitro diagnostic and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects. |
| Department of Defense (DoD) | A living individual about whom an investigator (whether professional or student) conducting research: Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or Obtains, uses, studies, analyzes, or generates identifiable private information, personally identifiable information, or identifiable biospecimens. [DoD Directive 3216.02 G.2.] |

Human Subjects Protection (HSP) Training

Training that covers, at a minimum, the history of human subjects research, ethical principles, HHS and FDA regulations, IRB structure and function, and the protection of vulnerable populations of research. Also called human subjects training.

Hutch IRB

A secure, web-based, end-to-end, electronic IRB system used for submissions to the Fred Hutch IRB.

HVTN

HIV Vaccine Trials Network

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Identifiable Biospecimen

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

[HHS 2018: 45 CFR 46.102(e)(6), FDA: proposed rule to amend part 50, Protection of Human Subjects, and part 56, Institutional Review Boards (87 FR 58733, September 28, 2022)]

Identifiable Private Information

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| HHS Pre-2018 Requirements of the Common Rule | Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. [45 CFR 46.102(f)] |
| HHS 2018 Requirements of the Common Rule | Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. [45 CFR 46.102(e)(5), FDA: proposed rule to amend part 50, Protection of Human Subjects, and part 56, Institutional Review Boards (87 FR 58733, September 28, 2022)] |

Identifiable, Sensitive Information

Information about an individual that is gathered or used during the course of biomedical, behavioral, clinical, or other research, where the following may occur:

- An individual is identified; or
- For which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

[NIH Policy for Issuing Certificates of Confidentiality]

Immediate Family

Spouse, domestic partner; and dependent children.

Impartial Witness

A person independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent discussion if the participant or the participant's legally authorized representative cannot read.

Family members of the participant or participant's legally authorized representative are considered independent of the trial and may serve as impartial witnesses.

See also: [Witness](#).

Independent Ethics Committee (IEC)

An independent review panel that is responsible for ensuring the protection of the rights, safety, and well-being of participants involved in a clinical investigation and is adequately constituted to ensure that protection. An IEC is similar to an IRB but is generally the term for such a panel outside the United States.

[FDA: 21 CFR 812.3(t)]

Individual Investigator

An investigator at an institution which does not hold a Federalwide Assurance who is collaborating and engaged in research overseen by Fred Hutch IRB.

Individual Investigator Agreement (IIA)

See [IRB Reliance Agreement](#).

Individuals with Impaired Decision-Making Capacity

Persons whose decision-making capacity is restricted, wholly or in part, due to illness, mental disability, or other circumstances.

Individually Identifiable Health Care Information

Any information that identifies or can readily be associated with a patient and directly relates to the patient's health care. Individually identifiable health care information is the term generally used to describe information subject to protection under the Uniform Health Care Information Act which has been adopted in many states, including Washington State.

Industry Contract

Any agreement involving a commercial entity and either Fred Hutch or another organization that describes support for the research being provided by the commercial entity. This support is typically monetary, but it can also include provision of study drug, equipment, facilities, or other non-monetary research support.

Informed Consent

A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution, or agents thereof from liability for negligence.

[HHS: 45 CFR 46.116; FDA: 21 CFR 50.20 and 50.25]

Institutional Biosafety Committee (IBC)

A body established under NIH Guidelines to provide local review and oversight of nearly all forms of research utilizing recombinant or synthetic nucleic acid molecules. Over time, many institutions have chosen to assign their IBCs the responsibility of reviewing a variety of experimentation that involves biological materials (e.g., infectious agents) and other potentially hazardous agents (e.g., carcinogens).

Institutional Official / Organizational Official (IO/OO)

- **Institutional Official (IO):** Term utilized by DHHS.
 - The Institutional Official (IO) is the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance. The IO is responsible for ensuring that the Human Research Protection Program ([HRPP](#)) functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents the institution named in the Federalwide Assurance (FWA). The IO at Fred Hutch is the Executive Vice President.
[<https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-september-18-letter-attachment/index.html>]
- **Organizational Official (OO):** Term utilized by AAHRPP.
 - An identified, knowledgeable leader of the HRPP who is responsible for the program and has the authority to implement the program. This individual may rely on others for the interpretation of laws, regulations, codes, and guidance and the day-to-day operations of the [HRPP](#), and should have a basic understanding of the relevant laws, codes, regulations, and guidance that govern research involving human participants, the responsibilities of an organizational official, and the responsibilities of the IRB or EC and researchers and research staff in protecting research

participants. This individual should be directly involved in the allocation of resources to the HRPP. In some circumstances, more than one individual serves in this capacity. The OO at Fred Hutch is the Vice President and Chief Compliance Officer, who has overall responsibility for Fred Hutch's HRPP in close coordination with the IO.

Institutional Profile

A record of information an institution keeps about another collaborating institution/organization for one or more Collaborative Studies or Multi-Site Studies.

Institutional Review Board (IRB)

A review body established by the organization to protect the rights and welfare of research participants recruited to participate in research activities. An IRB is organized in accordance with the Department of Health and Human Services (DHHS) at 45 CFR 46 and for studies involving products regulated by the Food and Drug Administration (FDA), the IRB complies with the requirements set forth in 21 CFR 50, 21 CFR 56, 21 CFR 312, and 21 CFR 812.

Interaction

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|---|---|
| HHS: Pre-2018 Requirements of the Common Rule | Includes communication or interpersonal contact between investigator and subject. [45 CFR 46.102(f)] |
| HHS: 2018 Requirements of the Common Rule | Includes communication or interpersonal contact (e.g., questionnaires, interviews) between investigator and subject. [45 CFR 46.102(e)(3)] |

Interpretation

Facilitating oral communication in more than one language; performed by an interpreter.

Interpreter

A person who translates orally for individuals conversing in different languages.

Intervention

| | |
|---|---|
| HHS: Pre-2018 Requirements of the Common Rule | Includes both 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. [45 CFR 46.102(f)] |
| HHS: 2018 Requirements of the Common Rule | Includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. [45 CFR 46.102(e)(2)] |

Investigation

A searching inquiry for facts; detailed or careful examination.

Investigational Device Exemption (IDE)

An action taken by the Food and Drug Administration (FDA) to permit the investigational use of a Medical Device in a clinical study in order to collect safety and effectiveness data.

[FDA: 21 CFR Part 812]

Investigational Drug or Biological Product

A drug or biological product that has not yet been determined to be safe and effective for a particular use in the general population and not yet approved by the Food and Drug Administration (FDA) for commercial marketing.

[FDA: 21 CFR Part 312]

Investigational New Drug Application (IND)

A request for Food and Drug Administration (FDA) authorization to administer an Investigational Drug or Biological Product to humans.

[FDA: 21 CFR Part 312]

Investigator

| | |
|---------------------|--|
| FDA – Drug Trials | An individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. “Subinvestigator” includes any other individual member of that team. [21 CFR 312.3(b)] |
| FDA – Device Trials | An individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. [21 CFR 812.3(i)] |
| NIH | The individual responsible for the conduct of the clinical trial at a trial site. If a clinical 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. [NIH Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials] |
| OHRP | An individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB. For the purposes of the HHS regulations, OHRP interprets an “investigator” to be any individual who is involved in conducting human subjects research studies. Such involvement would include: <ul style="list-style-type: none">• obtaining information about living individuals by intervening or interacting with them for research purposes;• obtaining identifiable private information about living individuals for research purposes;• obtaining the voluntary informed consent of individuals to be subjects in research; and• studying, interpreting, or analyzing identifiable private information or data for research purposes. [OHRP: Investigator Responsibilities FAQ] |

See also: [Principal Investigator](#) and [Subinvestigator](#).

In Vitro

Literally, “in glass” or “test tube”; used to refer to processes that are carried out outside the living body, usually in the laboratory, as distinguished from in vivo.

In Vivo

Literally, “in the living body;” processes, such as the absorption of a drug by the human body, carried out in the living body rather than in a laboratory (in vitro).

“Involving” DoD

Research is considered to involve DoD when:

- The research is funded by a component of DoD.

- The research involves cooperation, collaboration, or other type of agreement with a component of DoD.
- The research uses property, facilities, or assets of a component of DoD.
- The subject population will intentionally include personnel (military and/or civilian) from a component of DoD.

IR

Institutional Review, as in IR File Number (e.g., IR 9999).

IRB Approval

The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

[HHS: 45 CFR 46.102(h)]

IRB Authorization Agreement (IAA)

See [IRB Reliance Agreement](#).

IRB Certification

A document used when Fred Hutch acts as the coordinating center of a multi-center study. It assures the Fred Hutch IRB that each performance site's IRB of record conducts its own review and approval of the research activity.

IRB Pre-Reviewed Source

Sources of de-identified or coded human information or biospecimen resources that have been evaluated by Institutional Review Office (IRO) Director or IRO Assistant Director, and an IRB Chair or designee to ensure they have appropriate gatekeeping procedures in place to prohibit the release of identifiable private information to the Fred Hutch investigator utilizing information or biospecimens from the source. Refer to [HRP-151 - IRB Pre-reviewed Sources of De-identified Human Specimens and/or Data](#).

IRB of Record

The IRB responsible for review and oversight of research and determining the research meets the regulatory criteria for approval at a participating site.

IRB Reliance Agreement

The agreement that documents respective authorities, roles, responsibilities, and communication between an institution/organization providing the ethical review and a participating institution relying on the ethical review.

An IRB reliance agreement is an umbrella term that encompasses individual investigator agreements, IRB authorization agreements, cooperative review agreements among IRBs of Washington state, and IRB services contracts.

Cooperative Review Agreement

A type of IRB Authorization Agreement made between Fred Hutch IRB and a partner institution in Washington State.

Individual Investigator Agreement (IIA)

An agreement used when Fred Hutch agrees to extend our FWA to cover an Individual Investigator engaged in a research project overseen by Fred Hutch IRB.

IRB Authorization Agreement (IAA)

A written agreement that establishes the relationship between two IRBs that hold Federalwide Assurances, in which one institution defers IRB review responsibility to the other institution's IRB in order to avoid dual review.

IRB Services Contract

Used to establish the reliance arrangement between Fred Hutch and an independent IRB where the independent IRB will serve as the IRB of record for certain established research projects. May also be called a master services agreement.

IRO

Institutional Review Office

IRO Staff

Staff employed within the IRO that are responsible for the IRB operations and HRPP which includes support to four IRB committees.

J

Justice

An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.

K

Key Personnel

The PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant.

[NIH Glossary of Terms]

L

Large-Scale Genomic Data

The GDS Policy applies to all NIH-funded research that generates large-scale human or non-human genomic data as well as use of these data for subsequent research. Large-scale data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomics, epigenomic, and gene expression data. Examples are included below. See Supplemental Information to the NIH Genomic Data Sharing Policy for more examples.

- Sequence data from more than one gene or region or comparable size in the genomes of more than 1,000 human research participants.
- Sequence data from more than 100 genes or region of comparable size in the genomes of more than 100 human research participants.
- Sequence data from more than 100 isolates from infectious organisms.

Legally Authorized Representative (LAR)

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| HHS Pre-2018 Requirements of the Common Rule | 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. [45 CFR 46.102(c)] |
| HHS 2018 Requirements of the Common Rule | 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 in the research context, legally authorized representative means an |

| | |
|-----|--|
| | individual recognized by institutional policy as acceptable for providing consent in the nonresearch context. [45 CFR 46.102(i)] |
| FDA | 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. [21 CFR 50.3(l)] |

Legally Effective Consent

Informed consent is legally effective if it is both obtained from the participant or the participant's legally authorized representative and involves a process that provides the prospective participant or legally authorized representative sufficient opportunity to consider whether to participate, and minimizes the possibility of coercion or undue influence; and, includes a consent discussion and/or consent document that is both (i) understandable to the participant or the participant's legally authorized representative, and (ii) free of exculpatory language. To demonstrate that legally effective informed consent has been obtained, documentation should be maintained consistent with the HHS protection of human subjects regulations and with applicable laws of the jurisdiction in which the research is conducted.

[HHS: 45 CFR 46.116; FDA: 21 CFR 50.20]

Life-threatening Adverse Event

An adverse event that places the subject, in the view of either the investigator or sponsor, at immediate risk of death. It does not include an adverse event or suspected adverse reaction that, had it occurred in a more severe form, might have caused death.

[FDA: 21 CFR 312.32(a)]

See also: [Adverse Event](#) and [Suspected Adverse Reaction](#).

Limited Data Set

Protected Health Information (PHI) that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

- Names;
- Postal address information, other than town or city, State, and zip code;
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints; and
- Full face photographic images and any comparable images.

[HHS: 45 CFR 164.514(e)(2)]

See also: [Protected Health Information](#).

Limited IRB Review

Under the 2018 requirements of the Common Rule, exempt Categories 2 and 3 include a provision for limited IRB review. Limited IRB review under **exempt categories 2(iii) and 3(i)(c)** requires the Expedited Reviewer to determine that when appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

Living and Deceased Individuals

RCW 70.02 pertains to health care information about living and deceased individuals; therefore, activities that might be considered “not human subjects” under the Common Rule because the individuals are deceased, must still be reviewed by an IRB if the research involves the use of the deceased individual’s health care information maintained by a Washington State healthcare organization.

Local Context Reviewer (LCR)

Person providing to the IRB of record the local research context regarding the relying site’s local community, geographical area, institution, and/or other factors that may influence the conduct of the proposed research, including local laws, regulations, customs, and practices.

Local Research Context

Information provided to the IRB of record by a local context reviewer, consultant, or a participating site’s IRB regarding the participating site’s local community, geographical area, institution, and/or other factors that may influence the conduct of the proposed research, including local laws, regulations, customs, and practices.

Long-Term Follow-Up

Long term follow up includes research interactions that involve no more than minimal risk to subjects (e.g., quality of life surveys); and collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol. Long term follow-up excludes research interventions that would not have been performed for clinical purposes, even if the research interventions involve no more than minimal risk.

Longitudinal Study

A study designed to follow subjects forward through time.

M

Medical Device

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 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.

[FDA: 21 USC 321(h)]

Minimal Risk

Where 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.

[HHS Pre-2018: 45 CFR 46.102(i); HHS 2018: 45 CFR 46.102(j); FDA: 21 CFR 50.3(k)]

Prisoner Research

For prisoner research, minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. [45 CFR 46.303(d)]

OHRP interprets the term “healthy persons” in this definition as referring to healthy persons who are not prisoners.

[OHRP FAQ on Prisoner Research]

Department of Defense (DoD) Research

For purposes of research Involving DoD, the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests” in the definition of minimal risk (32 CFR 219.102(j)) shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

[DoD Instruction 3216.02]

Minor Noncompliance

See [Noncompliance](#).

Modification

Any change to a research study that is made after initial IRB review and approval.

Monitoring

The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design, and subject protections.

MTA

Materials Transfer Agreement

Multi-Center Study

A study involving more than one performance site engaged in research.

Multi-Site Study

A study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol.

N

Neonate

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| HHS | A newborn. [HHS: 45 CFR 46.202(d)] |
| WA State | A newly born infant less than 28 days of age. [WAC 246-320-010(38)] |

NIH-designated Repository

Any data repository maintained or supported by NIH either directly or through collaborative.

NIH GWAS Data Repository

Also known as the “Database of Genotype and Phenotype (dbGaP)”, the NIH Genome-Wide Association Studies (GWAS) Data Repository is a database developed by the National Center for Biotechnology Information (a division of the National Library of Medicine) to archive and distribute the results of studies that have been investigated.

Non-Committee Review

A review procedure conducted outside the full committee, either by an IRB Chair or a member designated by the Chair, or by IRB staff. [Expedited reviews](#) and [Exempt](#) reviews are conducted by an IRB Chair or designated reviewer. Reviews of Not Research, Not Human Research, and Not Engaged are generally conducted by IRB staff.

Nonaffiliated Member

Member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community (e.g., minister, business person, attorney, teacher, homemaker).

Noncompliance

An intentional or unintentional action or activity relating to human subjects research by a person subject to the human research protection program of Fred Hutch ([HRPP](#)) that violates or otherwise fails to adhere to one or more of (i) the requirements or determinations of the IRB, (ii) the HRPP, or (iii) laws or regulations governing the conduct of human subjects research, including applicable FDA, DHHS, and DoD regulations.

“Noncompliance” does not include protocol deviations that are beyond the immediate control of the Principal Investigator and his or her study staff (e.g., delays caused by weather, the acts or omissions of third parties such as outside labs, or scheduling changes not caused by the Principal Investigator or his or her staff). However, this type of protocol deviation may constitute an unanticipated problem involving risks to research subjects or others that still must be reported to the IRB.

Serious Noncompliance

Noncompliance that materially increases the risks to or otherwise seriously jeopardizes the rights and welfare of human research participants or materially impairs the integrity of the study data.

Continuing Noncompliance

A pattern of repeated noncompliance that continues after initial discovery, including inadequate efforts to take corrective actions within a reasonable timeframe. Examples include a pattern of behavior that evidences a lack of attention to or knowledge of the HRPP, or the protection of research participants, or that is likely to continue without intervention.

NOTE: Continuing noncompliance generally does *not* apply if the PI discovers non-compliance and undertakes an audit or other investigation that uncovers additional incidents of the same or very similar kind—because these are considered to be part of the same “discovery”. Continuing noncompliance instead generally applies when noncompliance has been discovered and addressed with a corrective and preventive action (CAPA) plan, but then that CAPA is ineffective such that additional incidents of the same kind occur.

Minor Noncompliance

Noncompliance that does not meet the definition of serious or continuing noncompliance.

Normal Volunteers

Volunteer subjects used to study normal physiology and behavior or who do not have the condition under study in a particular protocol, used as comparisons with subjects who do have the condition. “Normal” may not mean normal in all respects. For example, patients with broken legs (if not on medication that will affect the results) may serve as normal volunteers in studies of metabolism, cognitive development, and the like. Similarly, patients with heart disease but without diabetes may be the “normals” in a study of diabetes complicated by heart disease.

Not Human Subjects (NHS) Research

Research that does not involve human subjects. This is an institutional determination made by IRO staff or a member of the IRB for research projects that exclusively evaluate de-identified or coded information or biospecimens derived from humans. It is a determination recognized by the Office for Human Research Protections of DHHS but is not recognized by the FDA.

Also known as research not involving human subjects.

Nuremberg Code

A code of research ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects.

O

OnCore

This Clinical Trial Management System (CTMS) is managed by the Cancer Consortium and serves as a single, centralized, web-based enterprise resource to support clinical research studies conducted within or across the three institutions.

Operations Center

See [Coordinating Center](#).

OWL

Optical Web Library (OWL) is a web-based application maintained by Fred Hutch Clinical Research Division that houses scanned images of certain information from patients medical records and long-term follow-up, including consents

P

Parent

A child's biological or adoptive parent.
[HHS: 45 CFR 46.402(d)]

Participating Site (pSite)

A performance site in a multi-site or collaborative human research study that will rely on the IRB of record for the study. Such deferment of IRB review is documented and agreed upon in a reliance agreement.

Performance Site

A site whose staff, facilities or private records of identifiable individuals are engaged in the conduct of research; or a site that receives HHS funds. The performance site is the actual place where the research activity takes place (e.g., clinic or hospital). The performance site's location may be different from the location where the IRB review takes place.

Permission

The agreement of parent(s) or guardian to the participation of their child or ward in research.
[HHS: 45 CFR 46.402(c)]

Phase 1, 2, 3, 4 Drug Trials

Different stages of testing drugs in humans, from first application in humans (Phase 1) through limited and broad clinical tests (Phase 3), to postmarketing studies (Phase 4).

Phase 1 Drug Trial

Phase 1 trials include the initial introduction of an investigational new drug into humans. These studies are typically conducted with healthy volunteers; sometimes, where the drug is intended for use in patients with a particular disease, however, such patients may participate as research participants. Phase 1 trials are designed to determine the metabolic and pharmacological actions of the drug in humans, the side effects associated with increasing doses (to establish a safe dose range), and, if possible, to gain early evidence of effectiveness; they are typically closely monitored. The ultimate goal of Phase 1 trials is to obtain sufficient information about the drug's pharmacokinetics and pharmacological effects to permit the design of well-controlled, sufficiently valid Phase 2 studies. Other examples of Phase 1 studies include studies of drug metabolism, structure-activity relationships, and mechanisms of actions in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. The total number of research participants involved in Phase 1 investigations is generally in the range of 20-80.

Phase 2 Drug Trial

Phase 2 trials include controlled clinical studies conducted to evaluate the drug's effectiveness for a particular indication in patients with the disease or condition under study, and to determine the common short-term side effects and risks associated with the drug. These studies are typically well-controlled, closely monitored, and conducted with a relatively small number of patients, usually involving no more than several hundred research participants.

Phase 3 Drug Trial

Phase 3 trials involve the administration of a new drug to a larger number of patients in different clinical settings to determine its safety, efficacy, and appropriate dosage. They are performed after preliminary evidence of effectiveness has been obtained and are intended to gather necessary additional information about effectiveness and safety for evaluating the overall benefit-risk relationship of the drug, and to provide an adequate basis for physician labeling. In Phase 3 studies, the drug is used the way it would be administered when marketed. When these studies are completed and the sponsor believes that the drug is safe and effective under specific conditions, the sponsor applies to the FDA for approval to market the drug. Phase 3 trials usually involve several hundred to several thousand patient-subjects.

Phase 4 Drug Trial

Concurrent with marketing approval; FDA may seek agreement from the sponsor to conduct certain post-marketing (Phase 4) studies to delineate additional information about the drug's risks, benefits, and optimal use. These studies could include, but would not be limited to, studying different doses or schedules of administration than were used in Phase 2 studies, use of the drug in other patient populations or other stages of the disease, or use of the drug over a longer period of time.

[FDA: 21 CFR 312.85]

Phenotype

The physical manifestation of a gene function.

PI Proxy

An individual designated by the study PI who has the ability to make submissions to the IRB on the behalf of the PI.

Placebo

A chemically inert substance given in the guise of medicine for its psychologically suggestive effect; used in controlled clinical trials to determine whether improvement and side effects may reflect imagination or anticipation rather than actual power of a drug.

Pregnancy

Encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

PRIM&R

Public Responsibility in Medicine and Research

Primary Activities

Activities associated with conducting the ethical review of the proposed research protocol that will be carried out at all of the participating sites and the review of the template informed consent document describing the study.

[NIH Scenarios to Illustrate the Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-site Research]

See also: [Secondary Activities](#).

Principal Investigator (PI)

The scientist or scholar with primary responsibility for the design and conduct of a research project.

See also: [Investigator](#).

Prisoner

An individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such as institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

[HHS: 45 CFR 46.303(c)]

For Department of Defense (DoD) research, the term prisoner includes military personnel in either civilian or military custody.

Prisoner of War

See [Detainee](#)

Privacy

An individual's right to be free from unauthorized or unreasonable intrusion into his/her private life and the right to control access to individually identifiable information about him/her. The term "privacy" concerns research participants or potential research participants as individuals whereas the term "confidentiality" is used to refer to the treatment of information about those individuals.

See also: [Confidentiality](#).

Private Information

Includes 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

[HHS Pre-2018: 45 CFR 46.102(f); HHS 2018: 45 CFR 46.102(e)(4)]

Prospective Studies

Studies designed to observe outcomes or events that occur subsequent to the identification of the group of research participants to be studied. Prospective studies need not involve manipulation or intervention but may be purely observational or involve only the collection of data.

Protected Health Information (PHI)

Information about a patient that is protected from unauthorized use or disclosure by a Covered Entity under the terms of the privacy regulations of the Health Insurance Portability and Accountability Act (HIPAA).

Protocol

The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or

methodology to be employed, the eligibility requirements for prospective research participants and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Q

Quorum

The minimum number and type of IRB members that must be present at a convened meeting. In order to review proposed research at a convened meeting, a majority of the members of the IRB must be present, including at least one member whose primary concerns are in nonscientific areas and who represents the perspective of participants and the community (45 CFR 46.108(b); 21 CFR 56.108(c)). If a majority of the IRB membership is not present, or if a nonscientist is not present, then quorum has not been met.

[FDA: Minutes of Institutional Review Board (IRB) Meetings, Guidance for Institutions and IRBs]

R

Recombinant DNA Technology

“The ability to chop up DNA, the stuff of which genes are made, and move the pieces, [which] permits the direct examination of the human genome,” and the identification of the genetic components of a wide variety of disorders [Holtzman (1989), p. 1]. Recombinant DNA technology is also used to develop diagnostic screens and tests, as well as drugs and biologics for treating diseases with genetic components.

Related or Possibly Related Adverse Event

An adverse event is related or possibly related to the research procedures if, in the opinion of the principal investigator, it was more likely than not caused by the research procedures.

Adverse events that are **solely** caused by an underlying disease, disorder, or condition of the subject or by other circumstances unrelated to either the research or any underlying disease, disorder or condition of the subject are not related or possibly related. If there is any question whether or not an adverse event is related or possibly related, the adverse event should be reported.

Related to the Research

A financial interest is Related to the Research when the interest is in:

- A sponsor of the research;
- A product or service being tested

Reliance Agreement

See [IRB Reliance Agreement](#).

Reportable Incident

A locally occurring incident that (i) is determined by the convened IRB to represent an unanticipated problem involving risks to research participants or others as described in *HRP-131 - POLICY - Unanticipated Problems Involving Risks to Subjects or Others*, (ii) is determined by the convened IRB to represent serious or continuing noncompliance as described in *HRP-024 - POLICY - Noncompliance* or (iii) results in termination or suspension of the IRBs approval of a study as described in *HRP-063 - POLICY - Suspension or Termination of IRB Approval*. Note: For multi-center studies, Third-Party Safety Reports deemed to be unanticipated problems involving risks to subjects or others do not otherwise constitute a reportable event. In multicenter research projects, the institution at which the participant experienced the event determined to be an unanticipated problem is expected to report the event to OHRP.

Repository

A collection of information and/or biospecimens that are specifically intended to be used, stored, and/or shared for Secondary Research purposes.

Research

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| <p>HHS Pre-2018 Requirements of the Common Rule</p> | <p>A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, 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.</p> <p>[45 CFR 46.102(d)]</p> <p>See also: Systematic Investigation and Generalizable Knowledge</p> |
| <p>HHS 2018 Requirements of the Common Rule</p> | <p>A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, 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:</p> <p>(1) 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.</p> <p>(2) 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).</p> <p>(3) 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.</p> <p>(4) Authorized operational activities (as determined by each agency) in support of intelligence homeland security, defense, or other national security missions.</p> <p>[45 CFR 46.102(l)]</p> <p>See also: Systematic Investigation and Generalizable Knowledge</p> |
| <p>FDA</p> | <p>The regulations of the United States Food and Drug Administration (“FDA”) use the term “clinical investigation” rather than the term “research.” A “clinical investigation” is defined as any experiment that involves a test article and one or more human subjects and that is either subject to requirements for prior submission to the FDA, or is not subject to requirements for prior submission but the results are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. [21 CFR 50.3(c)]</p> <p>Additional information regarding FDA clinical investigation definitions for drug or device studies are found at 21 CFR 312.3(b) and 21 CFR 812.3(h) respectively.</p> |
| <p>NIH</p> | <p>Research with human subjects that is:</p> <ol style="list-style-type: none"> 1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It |

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| | <p>includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies.</p> <ol style="list-style-type: none"> 2. Epidemiological and behavioral studies. 3. Outcomes research and health services research. <p>Studies falling under 45 CFR 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition.</p> <p>[NIH: Glossary & Acronym List]</p> |
| Washington State | <p>A planned and systematic sociological, psychological, epidemiological, biomedical, or other scientific investigation carried out by a state agency, by a scientific research professional associated with a bona fide scientific research organization, or by a graduate student currently enrolled in an advanced academic degree curriculum, with an objective to contribute to scientific knowledge, the solution of social and health problems, or the evaluation of public benefit and service programs. This definition excludes methods of record analysis and data collection that are subjective, do not permit replication, and are not designed to yield reliable and valid results.</p> <p>[RCW 42.48.010(4)]</p> |

Research Involving a Human Being as an Experimental Subject

An activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving a human being as an experimental subject is a subset of research involving human subjects. (This definition relates only to the application of Section 980 of Title 10, U.S.C.; it does not affect the application of Part 219 of Title 32, CFR.)

[Department of Defense Directive 3216.02 G.2.]

Research Not Involving Human Subjects

See [Not Human Subjects \(NHS\) Research](#).

Research Staff

Persons responsible for the design, conduct or reporting of the research.

Respect for Persons

An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

Retrospective Studies

Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case control studies are an example of this type of research.

Review (of Research)

The concurrent oversight of research on a periodic basis by an IRB. In addition to the at least annual reviews mandated by the federal regulations, reviews may, if deemed appropriate, also be conducted on a continuous or periodic basis.

Risk

The probability and magnitude of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant.

See also: [Minimal Risk](#)

Note: Federal regulations define only “minimal risk.”

S

Scientific Review Committee (SRC)

A Cancer Consortium Committee that provides the formal internal peer-review process required for Cancer Consortium intervention studies under the terms of the Cancer Consortium's Cancer Center Support Grant. The committee has a defined membership representing all of the major clinical research areas of the Consortium.

Screeners

IRO department forms used by IRO staff to process and conduct analysis on submissions for review.

Secondary Activities

Activities associated with the review of site-specific considerations for all of the participating sites, including investigator qualifications, institutional capabilities, state/local regulatory requirements, and community ethos. Following initial approval, there are additional activities associated with fulfilling IRB oversight responsibilities, including the reviewing reportable events from all participating sites, e.g., unanticipated problems, protocol deviations, and, as necessary, reporting them to the Office for Human Research Protections (OHRP) and the funding Institute or Center as appropriate; receiving and reviewing any complaints that arise with regard to the conduct of the study; notifying all participating sites of serious or continuing non-compliance and all other determinations; and communicating with participating sites on matters related to sIRB determinations.

[NIH Scenarios to Illustrate the Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-site Research]

See also: [Primary Activities](#).

Secondary Research/Secondary Use

Future research use of information and/or biospecimens that are collected for some other primary purpose or initial activity (including non-research).

Sensitive Information

Identifiable private information or individually identifiable health care information relating to an individual's private activities or practices. Examples include sexual preferences or practices; history of treatment for use/abuse of alcohol or drugs; information relating to a person's mental health history or treatment for mental illness or disease; HIV status; financial information such as social security numbers or private health insurance; criminal history or background.

See also: [Identifiable, Sensitive Information](#)

Serious Adverse Event (SAE)

Any adverse event that results in any of the following outcomes: Death, a life-threatening adverse event (real risk of dying), inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity/or change in psychosocial status, a congenital anomaly or, requires intervention to prevent permanent impairment or damage.

[FDA: 21 CFR 312.32(a)]

Serious Noncompliance

See [Noncompliance](#)

Signing Official for Grants Administration

A Senior Official at the institution who is credentialed through NIH eRA Commons system and is authorized to enter the institution into a legally binding contract and sign on behalf of an investigator who has submitted data or a data access request to NIH. The Signing Official for Grants Administration who has the authority to provide institutional certification for data sharing under GWAS and GDS Policies is the Fred Hutch Director of the Office of Sponsored Research.

sIRB

The selected, “single,” IRB of record that conducts the ethical review for participating sites involved in a multi-site study. An sIRB may also be known as the Lead IRB.

Single IRB (sIRB) Study

A study in which two or more institutions (participating sites, or pSites) coordinate to complete the research activities, but all institutions rely on a single institution’s/organization’s IRB for ethical review. The reviewing IRB may or may not be affiliated with any of the pSites.

Special Population

A category of subjects whose inclusion in research may present ethical problems or whose exclusion from research may pose questions of equitability. The term encompasses the pre-2018 requirements of the Common Rule “vulnerable population” and, separately under the 2018 requirements of the Common Rule, pregnant women, who are not “vulnerable” but for whom safeguards must still be considered.

Sponsor (of a drug trial)

A person or entity that initiates a clinical investigation of a drug — usually the drug manufacturer or research institution that developed the drug. The sponsor does not actually conduct the investigation, but rather distributes the new drug to investigators and physicians for clinical trials. The drug is administered to research participants under the immediate direction of an investigator who is not also a sponsor. A clinical investigator may, however, serve as a sponsor-investigator. The sponsor assumes responsibility for investigating the new drug, including responsibility for compliance with applicable laws and regulations. The sponsor, for example, is responsible for obtaining FDA approval to conduct a trial and for reporting the results of the trial to the FDA.

Sponsor-Investigator

An individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., corporation or agency.

[FDA: 21 CFR 50.3(f)]

Statistical Significance

A determination of the probability of obtaining the particular distribution of the data on the assumption that the null hypothesis is true. Or, more simply put, the probability of coming to a false positive conclusion. [See McLarty (1987), p. 2.] If the probability is less than or equal to a predetermined value (e.g., 0.05 or 0.01), then the null hypothesis is rejected at that significance level (0.05 or 0.01).

Status Report

An administrative check-in that occurs annually for studies that do not require Continuing Review under the 2018 Requirements of the Common Rule.

There are three requirements for utilizing the status report process:

1. The research is not FDA-regulated; and
2. The research study was initially approved by the IRB on or after January 21, 2019; and
3. The research is eligible for expedited review, either because it was determined to be no more than minimal risk by the IRB or because the research study status is currently “closed to accrual, in [long-term follow-up](#) only” or “closed to accrual, in data analysis only.”

Subcommittee for IRB Activity Review

A subcommittee typically involves two or more IRB Members and includes the original primary reviewers of an activity.

Subinvestigator

Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).

[ICH E6 (R1)1.56]

See also: [Investigator](#)

Suspected Adverse Reaction

Any adverse event for which there is a reasonable possibility that the drug caused the adverse event. The term “reasonable possibility” means there is evidence to suggest a causal relationship between the drug and the adverse event.

[FDA: 21 CFR 312.32(a)]

Suspension of IRB Approval

An action of the IRB, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval. Suspended studies remain open and are subject to continuing review.

Systematic

Having or involving a system, method, or plan.

Systematic Investigation

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

I

Termination of IRB Approval

An action of the IRB, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review.

Test Article

Any drug for human use, 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 Federal Food Drug and Cosmetic Act or under Sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n).

Third-Party Safety Reports

A report prepared by an external sponsor or coordinating center overseeing a multi-site study describing one or more adverse events or other unanticipated problems involving risks to participants or others which have occurred at one or more of the participating sites involved in the study.

Third-Party Subjects

An informal name for living individuals about whom researchers obtain individually identifiable private information from someone else but who themselves have no interaction with the researcher. Third-party subjects are generally considered to be human subjects.

Translation

Conversion of a written document from one language to another.

U

Unanticipated Adverse Device Effect

Any serious adverse effect on health or safety, 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 (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of research participants.

[FDA: 21 CFR 812.3(s)]

Unexpected Adverse Event

Any adverse event occurring in one or more subjects in a research protocol, the nature, severity, or frequency of which is not consistent with either:

- (1) the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
- (2) the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

[OHRP Unanticipated Problems Involving Risks & Adverse Events Guidance (2007)]

Unexpected Adverse Event or Unexpected Suspected Adverse Reaction

An adverse event or suspected adverse reaction is considered "unexpected" if it is not listed in the investigator brochure or is not listed at the specificity or severity that has been observed; or, if an investigator brochure is not required or available, is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the investigator brochure referred only to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the investigator brochure listed only cerebral vascular accidents. "Unexpected," as used in this definition, also refers to adverse events or suspected adverse reactions that are mentioned in the investigator brochure as occurring with a class of drugs or as anticipated from the pharmacological properties of the drug but are not specifically mentioned as occurring with the particular drug under investigation.

[FDA: 21 CFR 312.32(a)]

Unanticipated Problems that Involve Risk to Research Participants or Others

Any incident, experience, or outcome that meets all of the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
2. related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. suggests that the research places research participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

[OHRP Unanticipated Problems Involving Risks & Adverse Events Guidance (2007)]

Unexpected Suspected Adverse Event

Any unexpected adverse event for which there is a reasonable possibility that the drug caused the adverse event.

Unrestricted-Access

Data are accessible to anyone via public website (previously referred to as “open access”).
See also: [Controlled-Access](#).

V

Vaccine

A biologic product generally made from an infectious agent or its components — a virus, bacterium, or other microorganism — that is killed (inactive) or live-attenuated (active, although weakened). Vaccines may also be biochemically synthesized or made through recombinant DNA techniques.

Validation

A process of verifying that data entered in by the IRO staff are correct and comply with applicable standards, rules, and conventions.

Voluntary

Free of coercion, duress, or undue inducement. Used in the research context to refer to a research participant’s decision to participate (or to continue to participate) in a research activity.

Vulnerable Population

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| HHS Pre-2018 Requirements of the Common Rule | A category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantaged persons. [45 CFR 46.111(3)] |
| HHS 2018 Requirements of the Common Rule | A category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. [45 CFR 46.111(3)] |
| FDA | A category of subjects such as children, prisoners, pregnant women, handicapped or mentally disabled persons, or economically or educationally disadvantaged persons, for whom the IRB should be particularly cognizant of the special problems of their inclusion in research. [21 CFR 56.111(a)(3)] |

W

Witness

A person who is present during the entire consent interview who attests to the adequacy of the consent process and to the subject’s voluntary consent.
See also: [Impartial Witness](#).

WSIRB

Washington State Institutional Review Board