

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.

**AAS.** Approved as Submitted.

**AE. Adverse Event.** 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.

**Allegations of non-compliance:** An assertion that non-compliance has or may have occurred that requires further investigation to determine whether non-compliance has in fact occurred.

**Assent.** Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research.

**Assurance.** 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 [Federal Policy §\_\_\_\_.103].

**Attachment A:** The internal routing and approval form submitted along with a proposal for an activity to be performed at FHCRC under a grant, contract or other sponsored agreement.

**Authorized Institutional Official.** An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research.

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

**B**

**BCRS.** Breast Cancer Reference Set.

**BOT.** FHCRC Board of Trustees.

**BPF.** FHCRC Biologics Production Facility.

**BS.** FHCRC Basic Sciences Division.

**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.

**BCRP. Breast Cancer Research Program.**

## **C**

**Cancer Consortium.** FHCRC/University of Washington Cancer Consortium.

**Center (The).** Fred Hutchinson Cancer Research Center.

**CDC.** Centers for Disease Control and Prevention; an agency within the Public Health Service, Department of Health and Human Services.

**CFR.** Code of Federal Regulations.

**Children.** Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46.401(a)].

**CIS.** UW Inpatient RN and Ancillary Svc Notes, some medications.

**CITI.** Collaborative IRB Training Initiative (<http://www.citiprogram.org/>)

**Clinical FYI.** CORE site; access to FHCRC protocols on-line, standard practice, Protocol office procedures, access to protocols and consents for PIs.

**Clinical Investigation.** The term used by the FDA to describe research subject to FDA regulations relating to informed consent and review by an IRB. Clinical Investigation means 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)].

**Clinical Trial.** A controlled study involving human subjects, designed to evaluate prospectively the safety and effectiveness of new drugs or devices or of behavioral interventions.

**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.

**COI.** Conflict of Interest.

**Compensation.** Payment or medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research. (Compare: Remuneration.)

**Confidentiality.** The treatment that must be afforded to individually identifiable information about human subjects or potential human subjects. Confidential treatment of information in the context of research is required for all non-public information that has been disclosed by or about human subjects to researchers with the expectation that it will not be disclosed to others without permission. The term “confidentiality” relates to information about human subjects whereas the term “privacy” concerns human subjects or potential human subjects as individuals.

**Confirmed noncompliance:** A report of non-compliance that can be determined to be true without further investigation or an allegation of non-compliance that is determined to be true after investigation under Policy 1.9. Unless circumstances clearly indicate otherwise, reports of noncompliance by or at the direction of principal investigators relating to studies for which they are responsible will be considered confirmed noncompliance for purposes of IRB Policy 1.9.

**Conflict of Interest.**

Non-Financial Interest:

- Personal Relationship: The IRB member or consultant has a personal relationship (e.g., spouse, domestic partner, immediate family member or close friend) with the principal investigator or key personnel (e.g. involved in the design, conduct or reporting) of a research protocol under review
- Relationship to the Research Study: The IRB member or consultant (or his/her spouse, domestic partner or immediate family member) is involved in the design, conduct or reporting of the research protocol under review
- Business Relationship or Affiliation: The IRB member or consultant to the IRB (or his/her spouse, domestic partner or immediate family member) serves as a trustee, director, officer, owner or partner of a for-profit entity that could be affected by the outcome of the research protocol under review by the IRB

Financial Interest: The IRB member or consultant (or his/her spouse, domestic partner or immediate family member) has a financial interest that could be affected by the outcome of the research protocol under review. Included in the definition of financial interests are equity interests (e.g. stock, stock options or other ownership interests)

other than interests held in a publicly traded, diversified mutual fund; payment or expectation of payment derived from intellectual property rights (e.g., patent royalties); and payments received from a for-profit entity for consulting or other services for the current and or preceding year (i.e., salary, honoraria, fees) or expectation of future payments or benefits. An example of a financial interest that could be affected by the outcome of the research protocol under review by the IRB is stock held in a company sponsoring the research study under review or whose product or service is being tested as part of the study

**Consent.** See: Informed Consent.

**Consent R.** A consent that is used at FHCRC when extra tissue samples will be collected during the clinical evaluation for research purposes.

**Continuing non-compliance:** Noncompliance that while not serious evidences a pattern of behavior that, if unaddressed, might jeopardize the rights and welfare of research participants the integrity of the study data or the integrity of the HRPP. 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.

**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.

**CORE:** Clinical Oncology Research Entrance (CORE) is a secure website through which eReview is accessed. CORE is maintained by the Clinical Research Division (CRD).

**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.

**CPA.** Cooperative Project Assurance.

**CRAB.** Cancer Research and Biostatistics.

**CRD.** FHCRC Clinical Research Division.

**CRR.** Continuation Review Report Form.

**CSS.** Cancer Surveillance System.

## 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 Plan (DSMP).**

**Dear PI Responsibility Memo.** A memo attached to all approved new applications stating that the PI is responsible for reporting any emergent problems, serious adverse effects or reactions, or proposed procedural modifications and that no modifications will be put into effect without prior IRB approval except where necessary to eliminate apparent immediate hazards; that unless otherwise directed by the IRB Chair, will renew the application with the IRB annually; that the research project will be conducted in compliance with the IRBs understanding and recommendations; that the IRB will be provided with all the information on the research project necessary for its complete review; and that the research project will not be put into effect until final IRB approval is received.

**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.

**DHEW.** A federal agency: U.S. Department of Health, Education and Welfare; reorganized in 1980 as the Department of Health and Human Services (DHHS) and the Department of Education.

**DHHS.** A federal agency: U.S. Department of Health and Human Services; formerly the Department of Health, Education and Welfare (DHEW).

**DOD.** Department of Defense.

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

**DSMB.** Data and Safety Monitoring Board.

**DSMP.** Data and Safety Monitoring Plan.

## E

**EDRN.** Early Detection Research Network.

**EH&S (also EHS).** FHCRC Environmental Health & Safety Department.

**EIN.** Federal Entity Identification (tax number).

**Elements of Consent.** By regulation, the information to be provided to each prospective research participant. Basic elements are listed at 45 CFR 46.116(a), additional elements (included when appropriate) at 45 CFR 46.116(b). Consent documents used for FDA-regulated studies should refer to the elements of consent found in 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.

**Engaged in Research.** An institution becomes “engaged” in human subjects research when its employees or agents (all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility) (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45 CFR 46.102(d),(f)]. Solicitation of consent by performance site staff would be considered engagement.

**EPIC Cadence.** Outpatient scheduling.

**Epidemiology.** A scientific discipline that studies the factors determining the causes, frequency, and distribution of diseases in a community or given population.

**Equitable.** Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed [Federal Policy §\_\_\_\_.111(a)(3)].

**ERC.** FHCRC External Relations and Communications.

**eReview.** A secure, web-based, electronic archive for IRB document review and comments.

**Expedited Reporting.** Expedited reporting to the Institutional Review Office (IRO) is required on all adverse events that are: Unexpected, Serious, and Possibly Related to study treatment or intervention. Adverse events meeting all of the criteria MUST be reported to the IRO FHCRC as soon as possible or within 7 calendar days of the investigator learning of the event. All deaths that occur within 30 days of the study intervention must also be reported to the IRB within 7 calendar days of the investigator learning of the death. All AE's that do not meet the expedited reporting criteria are reported at the time of Continuing Review.

**Expedited Review.** Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules

permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research [Federal Policy §\_\_\_\_.110].

**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.

## **F**

**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.

**Federal Policy (The).** The federal policy that provides regulations for the involvement of human subjects in research. The 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. Currently, sixteen federal agencies have adopted the Federal Policy. (Also known as the “Common Rule.”)

**FWA. Federalwide Assurance .** 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 [Federal Policy §\_\_\_\_.103]. Since December 31, 2005, OHRP only recognizes Federalwide Assurances.

**Fetus.** The product of conception from implantation until delivery.

**FHCRC.** Fred Hutchinson Cancer Research Center.

**FSD.** Funding Source Document. The grant, contract or other sponsored agreement that supports the research study.

**Full Committee Review.** Review of proposed research at a convened 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. For the research to be approved, it must receive the approval of a majority of those members present at the meeting [Federal Policy §\_\_\_\_.108].

## **G**

**Gateway.** FHCRC Research database; also used for clinical purposes by SCCA.

**GCP.** Good Clinical Practices.

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

**Genotype.** The genetic constitution of an individual.

**GOG.** Gynecological Oncology Group.

**GVHD.** Graft-Versus-Host Disease.

**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.

**Greater Than Minimal Risk.** The probability 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.

**Grant and Contract Administration (GCA).** See **OSR**.

**Guardian.** An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care [45 CFR 46.402(3)].

## **H**

**HB.** FHCRC Human Biology Division.

**HHS.** Health and Human Services.

**HIPAA.** Health Insurance Portability and Accountability Act Public Law 104-191 (1996). regulates, among other things, the disclosure of protected health information (“PHI”) about patients treated by most health care providers and organizations in the United States (“Covered Entities”). In the context of research involving human subjects, HIPAA establishes a federal standard for the manner in which the confidentiality 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 human subjects or potential human subjects.

**HPA.** Human Protections Administrator.

**HRPP.** FHCRC Human Research Protection Program.

**HST.** Human Subject Training.

**Human Research Protection 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.

**Human Subjects or Human Research Participants.** Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project or activity.

Under DHHS regulations, a human subject is a living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information [45 CFR 46.102] Under FDA regulations, a human subject is an individual who is or becomes a participant in research either as a recipient of the test article or as a control. Under FDA regulations, a subject can be either a healthy individual or a patient. Research using health care information about a patient (whether alive or deceased) is subject to review by an institutional review board according to the Washington Uniform Health Care Information Act.

**Human Subjects Research.** Any activity that either:

- Meets the FDA definition of “clinical investigation” and involves “human subjects” as defined by FDA; OR
- Meets the DHHS definition of “research” and involves “human subjects” as defined by DHHS; OR
- Involves the research use of “health care information” of a “patient” as defined by Washington’s Uniform Health Care Information Act.

Research:

The DHHS regulations define research as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research even if they are a component of a larger non-research activity (e.g., instruction, demonstration).

The regulations of the FDA use the term “clinical investigation” rather than the term “research.” A “clinical investigation” as defined by the FDA means 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 under section 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; or, is not subject to requirements for prior submission to the FDA under these sections of the Act, but the results of which 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)]. 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. For study-specific assistance with FDA regulations in the protocol development phase, contact the FHCRC Research Trials Office. 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.

Human Subjects also known as Human Research Participants.

See definition above

**HVTN.** HIV Vaccine Trials Network.

## I

**IAA.** IRB Authorization Agreement.

**IACUC.** Institutional Animal Care and Use Committee.

**IBC.** Institutional Biosafety Committee.

**IDE.** Investigational Device Exemption.

**Identifiable Private Information.** Information about a living individual that is used for research purposes and 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 which the individual can reasonably expect will not be made public (e.g., a medical record). Under the OHRP regulations, private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

**IEC.** Independent Ethics Committee (similar to IRB, but outside the USA).

**IND.** Investigational New Drug.

**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.

**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 [Federal Policy §116; 21 CFR 50.20 and 50.25].

**Institutional Official(s).** The person authorized to act for the institution and assumes overall responsibility for compliance with the federal regulations for the protection of human participants. This individual is the person who signs the Office for Human Research Protections assurance of compliance.

**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.

**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.

**Investigational Device Exemption (IDE).** Exemptions from certain regulations found in the Medical Device Amendments that allow shipment of unapproved devices for use in clinical investigations [21 CFR 812.20].

**Investigational New Drug Or Device (IND).** A drug or device permitted by FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing.

**Investigator.** In research, an individual who actually conducts an investigation [21 CFR 312.3]. Any interventions (e.g., drugs) involved in the study are administered to subjects under the immediate direction of the investigator. (See also: Principal Investigator.)

**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).

**IO.** Institutional Official.

**IR.** Institutional Review.

**IRB.** See **Institutional Review Board**.

**IRB Authorization Agreement.** An agreement used when FHCRC engages in research with a participating site who may or may not rely on FHCRCs IRB review in order to avoid dual review.

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

**IRB of Record.** The IRB responsible for review of research involving a performance site.

**IRO.** FHCRC Institutional Review Office.

**IRO Staff.** Staff employed within the IRO that are responsible for the IRB operations and HRPP which includes support to three IRB committees. Includes a Director, Assistant Director, IRB Analysts, Consent Editor, IRB Administrative Assistant II, SOP Administrator, IRO Specialist, Attachment A and AE Administrative Assistant II, IRO Director's Administrative Assistant I. Copies of these job descriptions are appended as supporting documents.

## 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.** All individuals responsible for the design, conduct, or reporting of the study. This includes staff that interacts with subjects or handles identifiable data.

## L

**Legally Authorized Representative.** A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human subjects research, 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 [Federal Policy §\_\_\_\_.102(c)].

**Life-threatening Adverse Event.** Any adverse event that places the subject, in the view of the investigator, at risk of death.

**Longitudinal Study.** A study designed to follow subjects forward through time.

## M

**Medical Device.** A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Such devices include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment.

**Medical Device Amendments (MDA).** Amendments to the Federal Food, Drug and Cosmetic Act passed in 1976 to regulate the distribution of medical devices and diagnostic products.

**MINDscape.** On-line Medical Record for UWMC, HMC, SCCA adult patients and any outpatients.

**Minimal Risk.** A risk is minimal 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. [45 CFR 26.102 (i)] For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

The definition of minimal risk for research involving prisoners differs somewhat from that given for noninstitutionalized adults. [See 45 CFR 46.303(d) and Guidebook Chapter 6, Section E, "Prisoners."]

**Minor noncompliance:** Noncompliance that is neither serious nor continuing. Unless required by the applicable protocol, instances of noncompliance that clearly constitute minor noncompliance do not need to be reported. Minor noncompliance includes, but is not limited to, individual instances of the omission or modification of research activities that are in the best interests of human research participants; provided, that the omission or modification does not materially increase the risks to or otherwise seriously jeopardize the rights and welfare of human research participants or materially impair the integrity of the study data. It is recommended that principal investigators initially prepare and, as necessary, amend protocols to minimize instances of minor noncompliance.

**MMF.** Mycophenolate Mofetil.

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

**MPA.** Multiple Project Assurance.

**MTA.** Materials Transfer Agreement.

**Multi-Center Study.** A study involving more than one performance site engaged in research.

## **N**

**NIH.** National Institutes of Health: a federal agency within the Public Health Service, DHHS, comprising 21 institutes and centers. It is responsible for carrying out and supporting biomedical and behavioral research.

**Neonate.** A newborn.

**NCI.** National Cancer Institute, an institute of NIH.

**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 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 and DHHS regulations. For purposes of this policy, noncompliance may be serious, continuing or minor. “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 or by 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 reportable under *IRB Policy 2.6, Unanticipated Problems Involving Risks to Subjects or Others*.

**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 HS.** Not Human Subject.

**NPAAS.** Nutrition and Physical Activity Assessment Study.

**NSABP.** National Surgical Adjuvant Breast & Bowel Project.

**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

**ORCA PowerChart.** On-line Medical Record for UWMC, HMC, SCCA adult patients and any outpatients.

**OD.** FHCRC Office of the Director.

**OHRP.** Office Of Human Research Protections The office within the National Institutes of Health, an agency of the Public Health Service, Department of Health and Human Services, responsible for implementing DHHS regulations (45 CFR Part 46) governing research involving human subjects.

**Operations Center or Coordinating Center Involving No Interaction or Intervention with Research Participants.** FHCRC investigators and their employees or agents may maintain “operations centers” or “coordinating centers” for multi-site collaborative research. Where institutional activities involve no interaction or intervention with research participants, the FHCRC IRB need not review each

collaborative protocol. However, the FHCRC IRB will determine and document that the operations or coordinating center has sufficient mechanisms in place to ensure that (i) management, data analysis, and Data Safety and Monitoring (DSM) systems are adequate, given the nature of the research involved; (ii) sample protocols and informed consent documents are developed and distributed to each collaborating institution; (iii) each collaborating institution holds an applicable OHRP-approved Assurance; (iv) each protocol is reviewed and approved by the IRB at the collaborating institution prior to the enrollment of research participants; (v) any substantive modification by the collaborating institution of sample consent information related to risks or alternative procedures is appropriately justified; and (vi) informed consent is obtained from each subject in compliance with HHS regulations.

**OSR.** FHCRC Office of Sponsored Research (formerly Grant and Contract Administration).

**OWL.** Research charts on-line (FHCRC, SCCA). Scanned documents.

## **P**

**PATS.** Patient Accrual Tracking System. Supports NCI Core grant reporting.

**PDMC.** Cancer Consortium Protocol and Data Monitoring Committee.

**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 [45 CFR 46.402(c)].

PeopleSoft. Personnel management; Ordering supplies; reports

**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 [21 CFR §312.85].

**Phenotype.** The physical manifestation of a gene function.

**PDF.** Protocol Disposition Form

**PMF.** Protocol Modification Form.

**PHS (Public Health Service).** A Federal Agency that is part of the U.S. Department of Health and Human Services, it includes FDA, NIH, CDC, SAMHSA, and HRSA.

**PHS. FHCR Public Health Sciences Division.** A research division at FHCR that is involved in statistical, epidemiological and prevention research projects.

**PI. Principal Investigator**

**PMRS.** Protocol Monitoring and Review System.

**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.

**Principal Investigator.** 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.

**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 human subjects or potential human subjects as individuals whereas the term "confidentiality" is used to refer to the treatment of information about those individuals.

**Proband.** The person whose case serves as the stimulus for the study of other members of the family to identify the possible genetic factors involved in a given disease, condition, or characteristic.

**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.

**Protocol and Data Monitoring Committee.** A committee of scientists, physicians, statisticians, and others that performs ongoing reviews throughout the accrual life of a protocol to provide continued review and monitoring.

**PSOC.** Puget Sound Oncology Consortium.

## **Q**

**Quorum.** One more than half of the voting members identified on the OHRP approved IRB Committee Roster.

## **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. See Guidebook Chapter 5, Section H, “Human Genetic Research.”

**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.

**Reportable non-compliance.** Non-compliance that is serious or continuing non-compliance or minor non-compliance reportable under *Procedures*, Section 1.a. of IRB Policy 1.9.

**Research.** A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge. See also **Engaged in Research**.

**REPOC.** FHCRC Research Ethics and Patient Protection Oversight Committee. The PPOC was created by the Board of Trustees and recommended by the Committee for Patient Protection in Research Trials (CPPRT) to assure oversight of the Center’s activities in conducting clinical trials. This is a standing committee of the Center’s Board.

**Research Staff.** Persons responsible for the design, conduct or reporting of this research

**RSC.** FHCRC Radiation Safety Committee.

**RTO.** Cancer Consortium Research Trials Office.

**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 [Federal Policy §\_\_\_\_.108(e)].

**Risk.** The probability 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. Federal regulations define only “minimal risk.” (See also: Minimal Risk.)

## **S**

**SACHRP.** Secretary’s Advisory Committee on Human Research Protection.

**SCCA.** Seattle Cancer Care Alliance.

**Screeners.** IRO departmental forms.

**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.

**Serious Adverse Event.** 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.

**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. Serious noncompliance may include, but is not limited to, (i) the failure to obtain IRB approval of human subjects research when required under the HRPP or applicable laws and regulations, (ii) enrolling a research participant who does not fit the inclusion and exclusion criteria in the protocol, (iii) Failing to obtain or document informed consent, (iv) administering a drug required by the protocol at a dose or schedule that has not been approved by the IRB except when necessary to eliminate apparent immediate hazards to the research participant (see IRB Policy 2.5).

**SOP.** Standard Operating Procedure.

**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. Corporations, agencies, or other institutions do not qualify as sponsor-investigators.

**SRC.** Cancer Consortium Scientific Review Committee. A FHCRC Committee that provides the formal internal peer-review process required for the Consortium as a comprehensive cancer center. The committee has a defined membership representing all of the major clinical research areas of the Consortium.

**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).

**Subcommittee for IRB Activity Review:** A subcommittee typically involves two or more IRB Members and includes the original primary and secondary reviewers of an activity.

**Suspension.** Study accrual is temporarily closed and the treatment of or intervention with previously enrolled research participants must temporarily cease subject to the health requirements of research participants.

## **I**

**Termination of IRB approval.** Accrual is permanently closed and treatment and intervention with previously enrolled research participants must cease, as determined by the IRB.

**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.

**Translation.** Conversion of a written document from one language to another.

## U

### **Unanticipated Problems that Involve Risk to Research Participants or Others.**

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

- Unexpected (in terms of nature [specificity], 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;
- Indicates 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.

**Unanticipated Adverse Device Effect:** An unanticipated adverse device effect means any serious adverse event caused by, or associated with, a device, if that event was not previously identified in nature, severity, or degree of incidence in the investigational plan or investigational device exemption (“IDE”) application, or any unanticipated serious problem associated with a device and related to the rights, safety, or welfare of research participants. If there is no IDE for the device, an unanticipated adverse device effect means any serious adverse event caused by, or associated with, a device, if that event was not previously identified in nature, severity, or degree of incidence in the study protocol or consent, or any unanticipated serious problem associated with a device and related to the rights, safety, or welfare of research participants.

**Unexpected Adverse Event:** An adverse event is “unexpected” when its nature (specificity), severity, or frequency are not consistent with (a) the known or foreseeable risk of adverse events associated with the research procedures described in the protocol-related documents, such as the IRB-approved research protocol, informed consent document and other relevant sources of information such as product labeling and package inserts; and are also not consistent with (b) the characteristics of the subject population being studied including the expected natural progression of any underlying disease, disorder or condition or any predisposing risk factor profile for the adverse event.

**UW.** University of Washington.

## 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.

**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 Populations.** Prospective research participants likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.  
45 CFR 46.111.

## **W**

**WSIRB.** Washington State Institutional Review Board.