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Administratively Closed	Administrative decision of the IRB based on investigator non-responsiveness to IRB requests. This can occur prior to initial IRB approval or any time following IRB approval.
Adverse Event	Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice). Adverse events encompass both physical and psychological harm. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research. (OHRP Guidance).
Approved	The IRB has reviewed the study and made the determination that the study has met all requirements.
Assent	A positive indication of willingness to participate in a study and/or a child's affirmative agreement to participate in research. Mere failure to object may not, absent affirmative agreement, be construed as assent. (45 CFR §46.402(b); 21 CFR §50.3(n)).
Audit	A systematic and independent examination of research-related activities and documents to determine whether the evaluated activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's procedures, good clinical practice, and the applicable regulatory requirements.
Authority to Determine that Research is Exempt	The authority to determine whether the research meets 45 CFR 46.101(b) (1-6) exemption criteria belongs to the IRB, typically the IRB Chair or delegate. Investigators are not permitted to determine whether research is exempt.
Authorized Official	An officer of an entity with the authority to speak for and legally commit the entity to comply with the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research.
Autonomy	Personal capacities to consider alternatives, make choices, and act without undue influence or interference of others.

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Belmont Report	A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.
Benefit	A valued or desired outcome; an advantage.
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 no harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.
Biologic	Any therapeutic serum, toxin, anti-toxin, or analogous microbial produce applicable to the prevention, treatment, or cure of diseases or injuries.
Business	Any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint-stock company, receivership, business or real estate trust, or any other legal entity organized for profit or charitable purposes.
Capacity to Consent	The ability to provide legally effective consent to enroll in a research study.
Certificate of Confidentiality	Certificates issued by the Secretary of Health and Human Services that limit the disclosure of identifiable, sensitive information, for the protection of subjects involved/engaged in biomedical, behavioral, clinical or other research in which identifiable, sensitive information is collected.
Certification	The official notification by the institution to the supporting federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance. (45 CFR 46.102(a)).
Children	Persons who have not attained the legal age for consent to treatments or procedures involved in the research or clinical investigations, under the applicable law of the jurisdiction in which the research or clinical investigations will be conducted. (45 CFR 46.402(a); 21 CFR 50.3(o)).
Clinical Investigation under Food and Drug Administration (FDA) Regulations	Any experiment with one or more human subjects that involves a test article such as a drug, device, food, or biologic and is: a. 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

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	b. not subject to requirements for prior submission to the FDA, 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. The term does not include experiments for nonclinical laboratory studies under 21 CFR 58. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. (21 CFR 50.3(c); 21 CFR 50.3(g); and 21 CFR 56.102(c)).
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 the interventions on biomedical or behavioral health-related outcomes. (45 CFR 46.102(b)).
Cognitively Impaired	Legally competent persons who may be compromised in any way in their ability to make decisions in their best interests.
Common Rule	The *Federal Policy for the Protection of Human Subjects* or the "Common Rule" was published in 1991, revised in 2009 and again in 2017 (known as the "2018 Revised Common Rule"); is codified in separate regulations by 15 federal departments and agencies. 45 CFR part 46, includes four subparts: Subpart A - *Basic HHS Policy for Protection of Human Research Subjects*; Subpart B - *Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research*; Subpart C - *Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects*; and Subpart D - *Additional Protections for Children Involved as Subjects in Research*. Except as listed in the "Exempt Categories," 45 CFR 46 applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research.
Competence	A legal term used to denote legal capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting in a certain way, and to make a choice. Everyone is presumed to be competent until a judge determines otherwise.
Compliance	Adherence to all applicable regulatory and institutional requirements.
Confidentiality	The treatment of information that an individual has disclosed in a relationship of trust, with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

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Conflict of Interest Management Committee (COIMC)	The HPHC committee with the authority to review disclosures of SFI, determine whether a SFI is a FCOI related to PHS-funded research, and develop and implement management plans.
Consent	See *Informed Consent*.
Continuing Review	Periodic review of a research study by an IRB to evaluate whether risks to subjects are reasonable in relation to potential benefits and to verify that the study continues to meet regulatory and institutional requirements. An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as follows; (1) Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances: (i) Research eligible for expedited review in accordance with 45 CFR 46.110; (ii) Research reviewed by the IRB in accordance with the limited IRB review described in 45 CFR 46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8); (iii) Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care. (45 CFR 46.109(e); 21 CFR 56.109(f)).
Contract	For purposes of human subjects research activity, an agreement that a specific research activity will be performed at the request, and under the direction, of an entity providing funds. Research performed under the contract is more closely controlled by the funding entity than research performed under a grant.
Cooperative (multi-site) Research	Research that involves more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects. An institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. Source: 45 CFR 46.114.
Data and Safety Monitoring Board	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.

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Deferred	The IRB has reviewed the study and determined that additional information and/or extensive changes are necessary to secure approval. The study with revisions will be reviewed by the IRB at a convened meeting.
De-Identified	Information or data where direct identifiers such as name and address have been removed. However, it may still be possible to identify individuals by inference or through codes held by the investigator or a third party. Therefore, data that is de-identified may not be anonymized because it may still permit at least probabilistic re-identification when analyzed in conjunction with other datasets.
Design, Conduct or Reporting of Research	Oversight, decision-making or participation in research that includes creating the structure, roles, and/or protocol of a research project; participating in the execution of the research roles and protocol; participating in the publishing, presentation, or discussion of the research results.
Disapproved	Where the IRB has reviewed the study protocol or plan and determined that it is not approved and may not receive further review.
Disclosure for IRB Members	The requirement for an IRB Chair, IRB member or consultant to disclose to IRB staff any financial, personal or professional COI related to their responsibilities to the IRB process. Disclosure reporting is required: (1) upon initial retention of IRB members and consultants to IRB review on the *Conflict of Interest Statement for IRB Members and Consultants*; (2) annually in January of each subsequent year by IRB members and consultants on the *Conflict of Interest Statement for IRB Members and Consultants;* and (3) at each IRB meeting.
Disclosure for Key Leaders in the Organization	Disclosure: the requirement for a Key Leader to disclose any organizational FCOI related to their responsibilities as a Key Leader. Disclosure reporting is required: • upon initial appointment as a Key Leader; • annually in January of each subsequent year; and • as any new potential organization FCOI arises by submitting the *Conflict of Interest Statement* for Key Leaders.
Disclosure for Researcher and Research Staff	Disclosure: the requirement for an individual to notify the Institute of financial interests related to their institutional responsibilities. Disclosure reporting is required: (1) annually by Institute employees; (2) at the time of initial application for federally funded research; and (3) prior to any expenditure under a federal award.

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	Researchers and research staff are also required to update their disclosure within 30 days of discovering or acquiring a new financial interest. Exclusions: •salary, royalties, or other remuneration paid by the Institute, including intellectual property rights assigned to the Institute and agreements to share in royalties related to such rights; •equity and related income from investment vehicles such as mutual funds and retirement accounts over which the individual exercises no control; •income from seminars, lectures, or teaching engagements sponsored by government agencies, institutions of higher education and research institutes affiliated with them, academic medical centers, and teaching hospitals; •income from a private organization acting as a contractor to a state, local, or federal government agency; •travel reimbursed by a government agency, an institution of higher education, an academic teaching hospital, medical center, or research institute affiliated with an institution of higher education.
Drug	Any chemical compound that may be used on or administered to humans as an aid in the diagnosis, treatment, cure, mitigation, or prevention of disease or other abnormal conditions.
Engaged	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: • data about the subjects of the research through intervention or interaction with them; • identifiable private information about the subjects of the research; or • the informed consent of human subjects for the research.
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 Research	Unless otherwise required by law or governmental agencies, research activities in which the only involvement of human subjects will be in one or more of the categories listed below in section (d), are exempt from the requirements of the 2018 Revised Common Rule except that these research activities must still comply with the requirements of this section and as specified in each category. Use of the exemption categories for research subject to the requirements of subparts B, C, and D is as follows:

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	(a) Subpart B (Additional Protections for **Pregnant Women, Human Fetuses and Neonates**) – Each of the exemptions at this section may be applied to research subject to Subpart B **if the conditions of the exemptions are met.** (b) Subpart C (Additional Protections Pertaining to Biomedical and Behavioral Research Involving **Prisoners** as subjects) – The exemptions at this section do not apply to research subject to Subpart C, **except for research aimed at involving a broader subject population that only incidentally includes prisoners**. (c) Subpart D (Additional Protections for **Children** Involved as Subjects in Research) – The exemptions at (d)(1), (4), (5), (6), (7), and (8) may be applied to research subject to subpart D if the conditions of the exemptions are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to Subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to Subpart D. (d) Except as described in the above paragraph, the following categories of human subjects research are exempt from this policy: (1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

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	(ii) Any disclosure of the human subject's responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained I recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7) to determine if there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data. (3) (i) Research involves benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by45 CFR 46.111(a)(7) to determine if there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data. (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects 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.

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	(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in a research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. (4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of , a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on t information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S. C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S. C. 552a, and if, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq. (5) Research or demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of

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	the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act as amended. (i) each Federal department or agency conducting or supporting the research and demonstration projects must establish on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects. (ii) [Intentionally blank]. (6) Taste and food quality evaluation and consumer acceptance studies: (i) if wholesome foods without additives are consumed, or (ii) if a food is consumed that contains a food ingredient oat or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. (7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determination required by 45 CFR 46.111(a)(8). (8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (i) Broad consent for the storage, maintenance, and secondary

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	research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116(a)(1) through (4), (a)(6), and (d); (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117; (iii) An IRB conducts a limited IRB review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph(d)(8)(1) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results
Expedited Review	Review of proposed research by the IRB Chair or designated voting IRB member(s) rather than by the entire IRB. Federal regulations permit expedited review for certain kinds of research involving no more than minimal risk, for minor changes in approved research, or for which limited IRB review is a condition of exemption. (45 CFR 46.110).
External Adverse Event	From the perspective of one institution engaged in a multicenter clinical trial, *external adverse events* are those adverse events experienced by subjects enrolled by investigators at other institutions engaged in the clinical trial.
Family Member	The individual's spouse, domestic partner and/or dependent children.
Federalwide Assurance (FWA)	An agreement between a federally funded entity and the Office of Human Research Protections (OHRP) that stipulates methods by which the entity will protect research subjects.
Fetus	The product of conception from implantation to delivery. (45 CFR 46.202(c)).
Financial Interest	Anything of monetary value whether or not the value is readily ascertainable.
Financial Conflict of Interest (FCOI)	A significant financial interest that the Institute reasonably determines could directly and significantly affect the design, conduct, or reporting of research.

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Financial Conflict of Interest Management Committee (FCOIMC)	A committee that consists of the HPHC Ethics Advisory Officer, the HPHC VP of Corporate Compliance, and an attorney from the HPHC Legal Department, that meets on an ad hoc basis upon request by the Research Integrity & Compliance Officer to review FCOI and develop FCOI management plans, as applicable.
Financial Conflict of Interest Management Plan	A detailed plan describing the actions taken to address a financial conflict of interest. This plan outlines the actions necessary to manage, reduce, or eliminate a FCOI to ensure, to the extent possible, that the design, conduct and reporting of research will be free of bias.
Full IRB Review	Review of proposed research at a convened meeting at which a majority of the voting membership of the IRB is 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 voting members present at the meeting.
Generalizable Knowledge	Knowledge that is widely applicable beyond the circumstances of its collection (i.e., knowledge gained from a study may be applied to populations beyond the specific study population or used to develop policy).
Grant	For purposes of human subjects research, 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 the approved research supported by a grant.
Greater-than-Minor Changes or Amendments	Any change which materially affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study. Examples of greater-than-minor amendments include, but are not limited to: omitted or changed items (e.g., funding) that may affect the level of risk; an increase in the number of study subjects; a change in procedure that requires a change in the consent; changes in the inclusion/exclusion criteria that result from changes in side effects; changes that may affect the level of risk.
Guardian	An individual who is authorized under applicable state or local law to consent on behalf of a person to general medical care (45 CFR 46.402(e) and 21 CFR 50.3(s)).
Health Care Agent	An adult to whom authority to make health care decisions is delegated under a health care proxy (MGL Ch. 201D).
HIPAA	Health Insurance Portability and Accountability Act of 1996 is the federal law with provisions for portability of health insurance coverage, privacy and security of PHI.

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HPHC	Harvard Pilgrim Health Care, Inc.
HPHCI	Harvard Pilgrim Health Care Institute, LLC.
HPHC/I	Collectively, HPHC and HPHCI.
HPHC/I Personnel	HPHC/I employees including the Institutional Official (IO), faculty, staff, fellows, contingent workers, students, and volunteers (including IRB members).
Human Research Protection Program (HRPP)	The research integrity & compliance program in the Office of Sponsored Programs that is responsible for the oversight and direction of the human research protection program at HPHC and HPHCI, including administrative oversight of the IRB, export controls, conflicts of interest, research integrity, quality assurance/quality improvement, accreditation, and intellectual property.
Human Subject	Under the "2018 Revised Common Rule," "human subject" means 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)(1)). Under the FDA regulations, *human subject* means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject might 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. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.
Human Subjects Research	An activity that involves the following three elements: (1) Research = a systematic investigation designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)); (2) Involving human subjects = the research involves obtaining individually identifiable information about living individuals (45 CFR 102(f); and (3) Involving intervention or interaction with the individuals (45 CFR 46.102).

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Identifiable Biospecimen	Biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen. (45 CFR 46.102(e)(6)).
Identifiable Private Information	Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. (45 CFR 46.102(e)(5)).
Identifiable, Sensitive Information	Information about an individual that is gathered or used during the course of biomedical, behavioral, clinical, or other research, where: (1) an individual is identified; or (2) 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.
Immediate Family Member	Spouse, domestic partner, or dependent children of the individual.
Incapacity	A person's mental status whereby he/she lacks the ability to understand and appreciate the nature and consequences of information presented and actions taken or not taken, and thus lacks the ability to make an informed decision. Often incorrectly used as a synonym for "incompetence."
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 entity, or agents thereof from liability for negligence.
Institution	Any public or private entity, or department or agency (including federal, state or other agencies). (45 CFR 46.102(f)).
Institutional Official (IO)	For human subject research purposes only, the 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 FWA. The IO is responsible for ensuring that the 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 FWA. The IO should be an individual of sufficient rank who has the authority to ensure that all obligations of the HRPP are carried out effectively and efficiently. This person is usually the President, Chancellor, Director General, Chief Executive Officer, or Chief Operating Officer for the legal entity that constitutes the institution conducting research. The IO should be at a level of responsibility sufficient to allow

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	authorization of necessary administrative or legal action, should that be required. Thus, department chairs, division directors or other officials who only have authority over one portion of the institution would generally not be an appropriate IO. Similarly, OHRP recommends that the IO not be the chair or member of any IRB designated under the FWA. At HPHC/HPHCI, the IO is the individual that holds the position of Vice President, Corporate Compliance.
Institutional Review Board (IRB)	The board established in accordance with 45 CFR 46 that performs ethical review of proposed research in order to protect the welfare of human subjects recruited to participate in biomedical or behavioral research. (45 CFR 46.102(g)).
Interaction	Includes communication or interpersonal contact between investigator and subject. (45 CFR 46.102(e)(3))).
Internal Adverse Event	In the context of a single-center clinical trial, all adverse events would be considered *internal adverse events.* From the perspective of one particular institution engaged in a multicenter clinical trial, *internal adverse events* are those adverse events experienced by subjects enrolled by the investigator(s) at that institution, whereas *external adverse events* are those adverse events experienced by subjects enrolled by investigators at other institutions engaged in the clinical trial.
Intervention	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)).
Investigator	Any individual who is responsible for the design, conduct, or reporting of research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator, co-investigator or sub-investigator on a particular protocol, and may include other faculty, fellows, postdoctoral associates, senior scientists, graduate students, project managers and data analysts and any other individual who has a substantive role in the research. Substantive roles include those in which individuals have decision making authority or provide advice to those who have decision making authority with respect to: the design of the research; the conduct of the work or the reporting of results. The definition may also include collaborators or consultants as appropriate.
IRB	See *Institutional Review Board.*

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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. (45 CFR 46.102(h)).
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.
Key Leaders	Those senior administrative leaders who have direct authority over, but not limited to, faculty appointments, salaries, promotions, and/or allocation of institutional resources, such as assignment of graduate students or other trainees, funding or space, for faculty/investigators who are conducting human subjects research. Key Leaders include, but are not limited to those in the positions of: • Board of Managers; • Executive Director HPHCI/Chair, Department of Population Medicine; • Vice Chair, Department of Population Medicine; • Director, Institute Administration; • Director of Research; • Director of Office of Sponsored Programs; • HPHC VP Controller; and • HPHC VP Corporate Compliance/Institutional Official.
Laws	Any rule or set of rules, enforceable by the courts, prescribed under the authority of a local, state, federal or international government, including, but not limited to, statutes, regulations, codes.
Legally Authorized Representative (LAR)	An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, LAR means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research. (45 CFR §46.102(i)); 21 CFR §50.3(l)). Depending on the circumstances, this may include, but is not limited to, a parent, guardian, or health care agent.
Minimal Risk	The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 CFR 46.102(j)).

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Minor Amendment	Minor amendment: a change that would <u>not</u> materially affect an assessment of the risks and benefits of the study or does not substantially change the specific aims or design of the study. Examples of minor amendments include, but are not limited to: changes in a mailing address; editorial corrections; changes in non-treatment equipment that will not affect the study outcome.
Monitoring	The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design, and subject protections.
Multi-site Research	See definition for *Cooperative Research.*
Neonate	Newborn. (45 CFR 46.202(d)).
Nonaffiliated Member	Member of the IRB who has no ties to the parent entity, its staff, or faculty. This individual is usually from the local community (e.g., minister, business person, attorney, teacher, or homemaker).
Office for Human Research Protections (OHRP)	The office within the U.S. Department of Health and Human Services (DHHS), responsible for implementing DHHS regulations (45 CFR 46) governing research involving human subjects.
Organizational Financial Conflict of Interest (OFCOI) in Research	Any situation in which the financial investments or holdings of HPHC/I or the personal financial interests or holdings of Key Leaders might affect or reasonably appear to affect processes for the design, conduct, reporting, review, or oversight of human subjects research. An OFCOI in research may arise when: • a Key Leader with any direct or indirect business or significant financial interest in an entity is able to act on behalf of HPHC/I regarding research activities in a way that may benefit or be perceived to benefit the entity; • HPHC/I licenses an invention to an entity and holds royalty or equity interests in the entity that may be affected by ongoing HPHC/I research or other HPHC/I activities; • a HPHC/I vendor donates a gift to HPHC/I or to HPHC Foundation on behalf of or for use with/for HPHC/I research activities; • HPHC/I or HPHC Foundation holds investments in a business entity that has a research relationship with HPHC/I;

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	• HPHC/I enters into a commercial transaction that compromises or appears to compromise HPHC/I's research, teaching, or outreach mission activities, or its institutional reputation; or • HPHC/I has a business or significant financial interest in a business entity whose commercial interests may be affected by human subjects research conducted at HPHCI.
Parent	A child's biological or adoptive parent. (45 CFR 402(d)).
Permission	Written agreement by parent(s) or guardian(s) to the participation of their child or ward in research.
Pregnancy	The period of time from implantation until delivery. A person shall be assumed to be pregnant if they exhibit any of the pertinent presumptive signs of pregnancy, such as a missed menses, until the results of a pregnancy test are negative or until delivery.
Preparatory-to-Research	Reviewing the minimum amount necessary of PHI of a covered entity to determine the feasibility of using the data for a funding application or to prepare a research protocol.
Principal Investigator (PI)	The scientist or scholar with the ultimate responsibility for the design and conduct of a research product.
Prisoner	Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial or sentencing. (45 CFR 46.303(c)).
Privacy Board	An IRB or another review body which reviews requests to use or disclose protected health information (PHI) for research purposes without authorization under HIPAA.
Private Information	Includes information about: 1) behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place; and 2) 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). (45 CFR 46.102(e)(4)).

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Prospective Studies	Studies designed to observe outcomes or events that occur subsequent to the identification of the group of subjects to be studied. Prospective studies need not involve manipulation or intervention but may be purely observational or involve only the collection of data.
Prospectively Assigned	Refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.
Protected Health Information (PHI)	Individually identifiable health information transmitted and/or maintained by electronic media, oral, paper or in any other form or medium.
Protocol	The formal design or plan of research activity submitted to the IRB for review and to an agency for funding. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the research activity, and the proposed methods of analysis that will be performed on the collected data.
Protocol Deviation	Any departure from the IRB-approved protocol, made with or without prior IRB approval. Examples of Protocol Deviations include: • targeted physical exam documented instead of complete physical exam; • urine dipstick is completed but not sent for laboratory analysis; • vital signs obtained prior to informed consent; • weighing a subject with shoes on.
Protocol Violation	Any protocol deviation that also reduces the quality or completeness of the data, impacts a subject's safety, rights or welfare, or affects the scientific integrity. Examples of protocol violations include: • enrollment of subjects not meeting inclusion/exclusion criteria; • falsifications; • inadequate informed consent; • inadequate record keeping; • mishandled samples; • unreported serious adverse events.

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Public Health Authority	An agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate. (45 CFR 46.102(k)).
Quorum	Fifty percent of the membership plus one. An IRB quorum must include at least one member whose primary concerns are in non-scientific areas. A quorum must be established, recorded, and maintained for the deliberation and vote on all matters requiring a vote.
Research	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 that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research; (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. (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). (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. (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions. (45 CFR 46.102(l)).

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	For definition of research under the FDA, see *Clinical Investigation under Food and Drug Administration (FDA) Regulations*
Researcher	See *Investigator.*
Research Participants	See *Human Subjects.*
Research Staff	See *Investigator.*
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 oversight of research on a periodic basis by the 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 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: *Minimal Risk*.)
Serious Adverse Event (SAE)	Any adverse event associated with the subject's participation in research that meets any of the following criteria that: (1) results in death; (2) is life-threatening (places the subject at immediate risk of death from the event as it occurred); (3) results in inpatient hospitalization (for a person not already hospitalized) or prolongation of existing hospitalization for a patient already hospitalized); (4) results in a persistent or significant disability or incapacity; (5) results in a congenital anomaly and/or birth defects; or (6) based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed

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	in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse). (Modified from the definition of serious adverse drug experience in FDA regulations at 21 CFR 312.32(a).) See https://www.hhs.gov/ohrp/sites/default/files/ohrp/policy/advevntguid.pdf
Significant Financial Interest (SFI) of a Researcher	A financial interest of the researcher and research staff and/or immediate family that reasonably appears to be related to the individual's institutional responsibilities that meets one or more of the following criteria established by the PHS: (a) Financial Income: payments or anything of monetary value from a single entity that when aggregated for the individual and family for the past 12 months or expected over the next 12 months exceeds $5,000. This includes salary and other payments by the entity (e.g. consulting fees, honoraria, paid authorship, etc.); (b) Equity Interest: for a publicly traded business, an equity interest (e.g., stock, stock options, or other ownership interest) that when aggregated for the individual and family exceeds $5,000. For a non-publicly traded business, any equity interest in such business, regardless of the amount, even if the value of the equity is unknown; (c) Intellectual Property Interest: any income (regardless of amount) related to intellectual property rights and interests (patents, copyrights, etc.). (d) Travel: any reimbursed or sponsored travel when the amount or value of the travel received from any entity, when aggregated, is $5,000 or more within the 12 months preceding the grant application or renewal, related to institutional responsibilities, which was paid on the individual's behalf.
Sponsor	The person or entity responsible for the award, administration, and monitoring of funded research activities. Usually this is an institute or center at a federal or state agency, but it may also be a private funder or a commercial funder (such as a pharmaceutical or device company).
Study	All components of a research project.
Study Closure	IRB-approved study that may be closed by the investigator, the sponsor, the IRB, HPHC, HPHCI or by an affiliated entity.
Study Completed	Study completed as approved by the IRB, including data analysis, and finalized.

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Survey	Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.
Suspension of Approval	A halt in all research activities, including the enrollment of new subjects, activities involving previously enrolled subjects and other research activities, until the IRB determines whether the research may continue or whether it shall be terminated. Studies which have been suspended require submission of a written correction plan by the PI and approval by the IRB before any research can resume. Suspended studies shall require ongoing continuing review by the IRB.
Systematic Approach	Involves a predetermined method or plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing a theory. A systematic approach incorporates collection of data, either quantitative or qualitative, or specimens; and analysis.
Termination of Approval	A permanent stop to the research and all related activities.
Unanticipated Event	Any incident, experience, or outcome that does not meet all three defined requirements of an Unanticipated Problem.
Unanticipated Problem	Unanticipated problems involving risks to subjects or others includes any incident, experience, or outcome that meets all three of the following criteria: (1) unexpected (in terms of nature, severity, or frequency) given (a) the nature of the research procedures described in the protocol-related documents and (b) the characteristics of the subject population being studied; (2) related or possibly related to a subject's participation in the research; and (3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
Unexpected Adverse Event	Any adverse event occurring in one or more subjects in a research protocol, the nature, frequency, or severity of which is not consistent with either:

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	(1) the informed consent, current investigator brochure or product labeling; nor consistent with the risk information described in the general investigational plan or proposal; 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. 21 CFR 312.32(a).
Voluntary	Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.
Written or In Writing	For purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format. (45 CFR 46.102(m)).

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