UNIVERSITY OF OREGON

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

RESEARCH COMPLIANCE SERVICES

HUMAN SUBJECTS RESEARCH
DEFINITIONS, TERMS, AND ACRONYMS

Commonly Used Acronyms	Definition
CFR	Code of Federal Regulations
CPHS	Committee for the Protection of Human Subjects
DSMB	Data Safety Monitoring Board
DSMP	Data Safety Monitoring Plan
EHS	Environmental Health and Safety
HIPAA	Health Information Portability and Accountability Act
HHS	Health and Human Services
IRB	Institutional Review Board
OHRP	Office for Human Research Protections
PHI	Protected Health Information
PI	Principal Investigator
RCS	Research Compliance Services

Definitions and Terms	Definition
Anonymous	Refers to data collected without any identifiable information and in no way can be linked to an individual.
Assent	A child's affirmative agreement to participate in research. Absent affirmative agreement, mere failure to object should not be construed as assent.
Autonomous Person	An individual capable of deliberation about personal goals and of acting under the direction of such deliberation.
Belmont Report	The Belmont Report outlines the basic ethical principles in research involving human subjects: (1) respect for persons, (2) beneficence, and (3) justice. Named after the Belmont Conference Center where the Commission met when drafting the report.
Beneficence	A principle from the Belmont Report that persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.
Biospecimens	Samples or specimens of material, such as urine, blood, tissue, cells, DNA, RNA, and protein.
Children	Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.
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.
Code of Federal Regulations	The codification of the general and permanent rules published in the Federal Register by the departments and agencies of the Federal Government.
Coercion	An action considered coercive if it entails an overt or implicit threat of harm/negative consequence which could compel involuntary participation and/or compliance. For example, telling a prospective subject she will lose access to needed services if she does not participate in the research is coercive and would not be permitted. See also undue influence.

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Committee for the Protection of Human Subjects (CPHS)	The name of the University of Oregon's Institutional Review Board (IRB).
Common Rule	The Federal Policy for the Protection of Human Subjects promulgated by Department of Health and Human Services and adopted by at least 15 other federal departments and agencies. **Pre-2018 Common Rule/old rule/Common Rule** – Refers to the regulations promulgated between 1991-January 18, 2018 **2018 Common Rule/revised 2018 Common Rule/revised regulations/final rule** – Refers to the regulations effective January 19, 2018 and on.
Confidentiality	Refers to the researcher's agreement with the participant about how the participant's identifiable private information will be handled, managed, and disseminated.
Data Safety Monitoring Board (DSMB)	An independent group of experts that advise investigators.
Data Safety Monitoring Plan (DSMP)	A plan to ensure appropriate oversight and monitoring of the conduct of an investigation.
Dead fetus	A fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.
Debriefing	The process through which participants are given previously undisclosed information about the research project following completion of their participation.
Deceptive research	A study in which participants know they are participating in research, but not informed of its true purpose.
De-identified	Refers to data that has been stripped of personally identifiable information.
Delivery	Complete separation of the fetus from the woman by expulsion or extraction or any other means.
Encrypt	To change information from one form to another in order to hide its meaning. With encryption, words or data are scrambled in a methodical way so that only those with the ability to unscramble it can access the true meaning of the words or data. There are a range of encryption software packages and service available for individuals and organizations that want to better protect their communications and data.
Exempt Review	Research involving human subjects for which all activities determined to meet at least one of the eight categories established by the US Department of Health & Human Services and adopted by at least 15 other federal department or agencies qualifies for an exempt review process. The determination of "exempt" must be made by RCS.
Expedited Review	Research involving human subjects for which all activities determined to meet at least one of the nine categories established by the US Department of Health & Human Services qualifies for an exempt review process. In order to qualify for the exempt process, the research must present no more than minimal risk to the participants.
Fetus	The product of conception from implantation until delivery.

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Focus group	A group of participants convened to discuss a specific topic, conduct an evaluation, or test new ideas.
Full Board Review	Research involving human subjects which potentially pose a greater than minimal risk to the participants or involve certain participant populations require review by a fully convened IRB/CPHS. Research on prisoners, research involving ionizing radiation and research involving invasive procedures will always require a full board review.
Generalizable knowledge	A study contributes to generalizable knowledge if the findings of a study are intended to be applicable to a larger population, and/or if the intent is to present or publish anything about the study or otherwise make the findings of it available for the development of knowledge beyond the scope of the study
Genetic Information	State of Oregon Definition: A test of determining the presence or absence of genetic characteristics in an individual or the individual's blood relatives, including tests of nucleic acids, such as DNA, RNA, and mitochondrial DNA, chromosomes or proteins in order to diagnose or determine a genetic characteristic.
Genetic Services	Federal Definition: A genetic test, genetic counseling (including obtaining, interpreting, or assessing genetic information), or genetic education.
Genetic Test	Federal Definition: An analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes. State of Oregon Definition: A test of determining the presence or absence of genetic characteristics in an individual or the individual's blood relatives, including tests of nucleic acids, such as DNA, RNA, and mitochondrial DNA, chromosomes or proteins in order to diagnose or determine a genetic characteristic.
Guardian	An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.
Health and Human Services (HHS)	The US government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. The Office for Human Research Protections (OHRP) is housed with HHS and is the office that promulgates and enforces the Common Rule.
HIPAA Privacy Rule	The HIPAA Privacy Rule establishes national standards to protect individuals' medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically.
Human Subject	Living individual **about whom** an investigator (whether professional or student) conducting research obtains: (1) 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.
Identifiable Biospecimen	Biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
Identifiable Data/ Information	Information that by itself, or in combination with other information, could be used by the researchers or another party to identify a participant in the research and/or the participant's contributions during the research process. For example, legal names, email addresses, and even screen or Avatar names can be used to identify individuals. Similarly, personal information that is disclosed during research about a person's identity and/or experiences (e.g. their narrative of a particular event) could also be considered identifiable information.

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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
Identifiers	Any information that permits the data to be linked to individually identifiable participants. Identifiers can be names, numbers or codes.
Informed Consent	A process to ensure that a research participant is aware of all the reasonably foreseeable risks and costs involved in participation in research and enable persons to voluntarily decide whether or not to participate as a research subject.
Institution	Any public or private entity, or department or agency (including federal, state, and other agencies).
Institutional Review Board (IRB)	An independent committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans.
Interaction	Communication or interpersonal contact between investigator and subject.
Intervention	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.
Ionizing Radiation	Radiation consisting of particles, X-rays, or gamma rays with sufficient energy to liberate electrons from atoms or molecules.
Justice	The principle in the Belmont Report refers to the distribution of benefits and burdens to participants in research.
Legally Authorized Representative (LAR)	An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.
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.
Neonate	A newborn.
Nonviable Neonate	A neonate after delivery that, although living, is not viable.
Office for Human Research Protections (OHRP)	OHRP provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the US Department of Health and Human Services (HHS).
Parent	A child's biological or adoptive parent.
Permission	The agreement of parent(s) or guardian to the participation of their child or ward in research.
Pilot Study	An initial research study created to assess and modify procedure in readying for a subsequent and more complex research project intended to test the viability of proposed research.
Pregnancy	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.

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Principal Investigator	The primary person responsible for the design, conduct, execution, and/or reporting of research.
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
Privacy	Refers to a person's desire to control the access of others to themselves.
Private information	Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information 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).
Protected Heath Information (PHI)	Individually identifiable health information transmitted or maintained in any form or medium by a HIPAA covered entity.
Protocol	The official procedure or system in place, including standard materials, by which research is conducted.
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.
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, 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. 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.

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Research Compliance Services (RCS)	The office at the University of Oregon which supports and protects the interests of the University, faculty, staff, students and human research subjects in research compliance matters through guidance, education, and technical assistance.
Respect for Persons	The principle from the Belmont Report incorporating at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection.
Risk	The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in research.
Systematic	Having or involving a system, method, or plan.
Undue influence	An act that includes an excessive or inappropriate reward or other overture may constitute undue influence. For example, offering college students $100 each to complete a 20 minute survey on illegal drug and alcohol use could be viewed as unduly influential because the amount could entice students to disclose information that they would not otherwise willfully disclose to strangers. See also coercion.
Viable	As it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.
Vulnerable populations	People who are more likely to be susceptible to coercion or undue influence, such as children, prisoners, pregnant woman, mentally disabled persons, or economically or educationally disadvantaged persons.
Voluntary	Free of coercion, duress, or undue inducement.
Written, or In Writing	Written, or in writing, refers to writing on a tangible medium (e.g., paper) or in an electronic format.