HUMAN SUBJECTS RESEARCH
DEFINITIONS, TERMS, AND ACRONYMS

Tip: On your keyboard, press the CTRL and F buttons to search for specific terms.

Commonly Used Acronyms	Full Name
AIP	Approval-in-Principle
BBI	Benign Behavioral Intervention
CFR	Code of Federal Regulations
COC	Certificate of Confidentiality
COI	Conflict of Interest (see conflicting interest)
CPHS	Committee for the Protection of Human Subjects
CR	Continuing Review
DOD	Department of Defense
DSMB	Data Safety Monitoring Board
DSMP	Data Safety Monitoring Plan
EHS	Environmental Health and Safety
FDA	Food and Drug Administration
FWA	Federal Wide Assurance
HIPAA	Health Information Portability and Accountability Act
HHS	Health and Human Services
IAA	IRB Authorization Agreement
IIA	Individual Investigator Agreement
IRB	Institutional Review Board
IVD	In Vitro Diagnostic Product
JIT	Just-in-Time
LOA	Letter of Acknowledgment
OHRP	Office for Human Research Protections
MOD	Modification
MODCR	Modification/Continuing Review
NIH	National Institutes of Health
PHI	Protected Health Information
PI	Principal Investigator
pSite	Participating Site
RAP	Research Administration Portal
RCS	Research Compliance Services
RNI	Reportable New Information
sIRB	Single IRB
UO	University of Oregon

Definitions and Terms	Definition
Adults	Persons who have 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. In most cases, adults will be individuals over the age of 18. However, there may be contexts and jurisdictions where individuals under the age of 18 could be considered adults (e.g., emancipated minors, minors 15 years old or older giving consent for medical treatment).
Allegation of Non-Compliance	An unproved assertion of Non-Compliance.
Anonymous data/specimens	Data/specimens collected without any identifiable information and in no way can be linked to an individual.
Approval-in-Principle (AIP)	A type of submission for *funded* research lacking definite plans for the involvement of human subject research (also see 45 CFR 46.118). For example, projects in which human subjects' involvement is planned for a later phase of the research, but it is not possible to know the details for that phase because they will depend upon completion of instruments, prior animal studies, or purification of compounds. No human subjects may be involved in any project supported by these awards until the details and documents describing the human subjects research have been provided and the project has been reviewed and approved by the IRB. For more information, see the RCS AIP website.
Assent	Affirmative agreement to participate in research from a child or an adult who lacks capacity to consent for themselves (e.g., due to decisional impairment). Absent affirmative agreement, mere failure to object should not be construed as assent.
Authorization Agreement	Also called a Reliance Agreement, is the agreement that documents respective authorities, roles, responsibilities, and communication between an institution/organization providing the ethical review (IRB of record) and a participating institution (pSite) relying on the ethical review.
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.

Definitions and Terms	Definition
Benign Behavioral Intervention (BBI)	Benign behavioral interventions are harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects and are neither offensive nor embarrassing. Medical interventions (including medical tests, procedures and devices) may not be used. Behavioral interventions employ research procedures in the study of psychological states and processes, cognition, ideas and attitudes, or behavior. They do not include physical (bodily) tasks or physical manipulations unless these are minor activities that are incidental to the behavioral intervention and do not increase risk. Behavioral interventions typically rely only on communication or interpersonal contact with the participant, the performance of a cognitive, intellectual, educational or behavioral task, or manipulation of the subject's physical, sensory, social, or emotional environment. Exempt category 3 is limited to interventions that are not expected to cause physical or emotional harm, persistent discomfort, be experienced by the subject as embarrassing, or offensive. Ordinary, mild, transient forms of discomfort, such as the stress associated with completing a timed cognitive task, anxiety about performance, and boredom, are consistent with the intent of the exemption. Similarly, while research cannot meaningfully eliminate all risk of embarrassment or offense, the research should include only interventions that the researcher has no reason to think participants will find offensive or embarrassing considering the characteristics of the participant population, the research context, and how they might impact the participant's experience of the research intervention.
Biologics/Biological products	Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources - human, animal, or microorganism - and may be produced by biotechnology methods and other cutting-edge technologies. Although biological products are generally regulated as drugs by the FDA, they differ from most drugs that are chemically synthesized and their structure is known. Most biologics are complex mixtures that are not easily identified or characterized. Biological products, including those manufactured by biotechnology, tend to be heat sensitive and susceptible to microbial contamination.

Definitions and Terms	Definition
Biospecimens	Samples or specimens of material, such as urine, blood, saliva, tissue, cells, DNA, RNA, and protein.
Brief in Duration	In the context of benign behavioral interventions (BBI) for exempt category 3, brief in duration refers to the intervention itself. Data collection activities can proceed over a longer period of time separate from the intervention. However, if the intervention and the data collection are intertwined or difficult to separate, the entirety of the activity should be brief in duration. To qualify as "brief in duration" for exempt category 3, the benign behavioral intervention should last a few minutes to a few hours. While it does not have to occur in a single session, the entire time for the intervention should only add up to no more than a few hours. The more irritating or unpleasant the intervention will be, the less time a participant can be involved before it stops being 'brief'. For example, looking at images that are not upsetting may be brief for a few hours, while sitting in a particularly uncomfortable chair may stop being brief within a few minutes.
Certificate of Confidentiality (CoC)	A Certificate of Confidentiality (CoC) is a document issued by a component of HHS such as the National Institutes of Health (NIH), to protect the privacy of research participants enrolled in research that collects or uses identifiable, sensitive information. With limited exceptions, researchers may not disclose names or any information, documents or biospecimens containing identifiable, sensitive information. The Certificate prohibits disclosure in response to legal demands, such as a subpoena. For more information, see the NIH Frequently Asked Questions for CoCs.
Certification	The official notification by the institution to the supporting Federal department or agency component that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.
Children/Child	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. Also see Adults above.
Clinical Investigation (FDA)	Any experiment that involves a test article and one or more Human Subjects, and that meets any one of the following: • Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice; • Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR • Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

Definitions and Terms	Definition
Clinical Trial (FDA – 42 CFR 11.10)	A clinical investigation or a clinical study in which human subject(s) are prospectively assigned, according to a protocol, to one or more interventions (or no intervention) to evaluate the effect(s) of the intervention(s) on biomedical or health-related outcomes. **Note**: not all studies that meet the above clinical trial definition are required to meet the clinical trial registration and reporting requirements. Unless the study is NIH funded or otherwise federally funded, an FDA regulated study must meet one of the applicable clinical trial definitions below (i.e., Applicable Device Clinical Trial or Applicable Drug Clinical Trial) to be required to comply with the clinical trial registration and reporting requirements. However, researchers can choose to adhere to those requirements voluntarily.
Clinical Trial (FDA - Applicable Device Clinical Trial)	A prospective clinical study of health outcomes comparing an intervention with a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(k), 21 U.S.C. 360e, 21 U.S.C. 360j(m)) against a control in human subjects (other than a small clinical trial to determine the feasibility of a device product, or a clinical trial to test prototype device products where the primary outcome measure relates to feasibility and not to health outcomes); (2) a pediatric postmarket surveillance of a device product as required under section 522 of the FD&C Act (21 U.S.C. 360l); or (3) a clinical trial of a combination product with a device primary mode of action under 21 CFR Part 3, provided that it meets all other criteria of the definition under this part. [Source: 42 CFR 11.10(a)].
Clinical Trial (FDA - Applicable Drug Clinical Trial)	A controlled clinical investigation, other than a phase 1 clinical investigation, of a drug product subject to section 505 of the FD&C Act (21 U.S.C. 355) or a biological product subject to section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), where "clinical investigation" has the meaning given in 21 CFR 312.3 and "phase 1" has the meaning given in 21 CFR 312.21. A clinical trial of a combination product with a drug primary mode of action under 21 CFR Part 3 is also an applicable drug clinical trial, provided that it meets all other criteria of the definition under this part. [Source: 42 CFR 11.10(a)].
Clinical Trial (HHS)	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. • This definition applies to federally funded or supported studies. The NIH definition for NIH funded research is equivalent to this definition and you can find additional resources for NIH clinical trials on NIH's Definition of a Clinical Trial website.

Definitions and Terms	Definition
Closure/Closed	When researchers are done with their study, they will need to close their IRB submission. A study can be closed when the following criteria are met: • Study is permanently closed to enrollment (i.e., no new participants will be recruited, consented or enrolled and no new identifiable data/specimens will be added to the study) • All participants have completed all study related interventions and interactions • Collection of identifiable private information and identifiable biospecimens is complete • Analysis of identifiable private information and identifiable biospecimens is complete In some cases, an ongoing study can be closed at the UO if IRB oversight has been transferred to another IRB of record. A closure is submitted in the RAP through a Continuing Review (CR) submission type.
Coded information/ specimens	Information and/or specimens that are associated with identifiers indirectly. The data/specimens have been stripped of direct identifiers and replaced with a code (e.g., 001, 002) and a key is maintained separately that links that code back to identifiers. Coding is one method for limiting access to identifiable information (also see confidential information/specimens). Because identifiers are maintained and can still be associated with the information/specimens, coded information/specimens are not entirely de-identified or anonymous to those who have access to the linking key or other means to re-identify participants.
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 is 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 they will lose access to needed services if they do not participate in the research is coercive and would not be permitted. See also undue influence.
Collaborative Study	A study in which two or more institutions coordinate, with each institution completing a portion of the human research activities outlined in a specific protocol (e.g., one institution does consenting, interactions/intervention and data collection while other institution does data analysis only).
Committee for the Protection of Human Subjects (CPHS)	The name of the University of Oregon's Institutional Review Boards (IRBs).

Definitions and Terms	Definition
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:** regulations promulgated between 1991-January 18, 2018. Pre-2018 studies can be transitioned to the 2018 Common Rule. **2018 Common Rule/revised 2018 Common Rule/revised regulations/final rule:** Refers to the regulations effective January 19, 2018 and on.
Confidential information/specimens	Information and/or specimens that may be identifiable but will remain protected from unauthorized access and disclosure. The research team is obligated to keep confidential information/specimens private. For example, responses may be combined and reported in aggregate form. To ensure confidentiality, there should also be other mechanisms limiting access to identifiers (e.g., securely storing the data, removing identifiers from the data and replacing it with a code and maintaining a separate key to the code that is securely stored separately from the data, using passwords and encryption to make data available only to authorized users).
Confidentiality	Refers to the researcher's agreement with the participant about how the participant's identifiable private information will be handled, managed, and disseminated.
Conflicting Interest/Conflict of Interest (COI)	An individual involved in research review is automatically considered to have a conflicting interest when the individual or their Relative have any of the following interests in the sponsor, product or service being tested, or competitor of the sponsor held by the individual or the individual's immediate family: • Involvement in the design, conduct, or reporting of the research. • Ownership interest, stock options, or other ownership interest of any value exclusive of interests in publicly-traded, diversified mutual funds. • Compensation of any amount in the past year or of any amount expected in the next year, excluding compensation for costs directly related to conducting research. • Proprietary interest including, but not limited to, a patent, trademark, copyright or licensing agreement. • Board or executive relationship, regardless of compensation. • Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center. Any other reason for which the individual believes that they cannot be independent. Not all conflicting interests are financial in nature. Even if you do not have a financial conflict, you should address in your IRB submission any circumstances that may impact your ability to be impartial. For more information about types of conflicting interest and how to manage them, see the UO Conflict of Interest Website or contact COI (COI@uoregon.edu).

Definitions and Terms	Definition
Continuing Non-Compliance	A pattern of Non-Compliance that, in the judgment of a convened IRB: • Indicates a lack of understanding or disregard for the regulations or institutional requirements that protect the rights, safety and/or welfare of participants; • Compromises the integrity of a study such that important conclusions can no longer be reached; • Suggests a likelihood that noncompliance will continue without intervention; and/or • Involves frequent instances of minor noncompliance, for example, repetitive protocol non-compliance or unreviewed deviations that were not needed to address an immediate safety risk. Examples: • Generally, persistent failure to adhere to the laws, regulations, or policies governing human research would be regarded as continuing non-compliance. This typically would include (but is not limited to) the following: • Repeated failure to respond to requests, directives, or requirements of the IRB • Repeated lapses in approval of non-exempt research • Noncompliance that continues to occur after IRB discovery of noncompliance and/or implementation of a corrective action plan
Continuing Review (CR)	A process where the IRB periodically re-evaluates an approved research study to ensure it is still being conducted ethically and in compliance with regulations, including monitoring for any new risks or changes in the study design, and to extend the study's approval period if necessary. The regulations require continuing review annually for greater than minimal risk research, FDA regulated research, and non-exempt research under the pre-2018 common rule. The UO IRB also requires non-regulatory continuing reviews at minimum every five years to ensure an ongoing study remains appropriate and safe for participants. A CR submission type in the RAP can be used to extend or close a study and does not allow for any document changes. See the RCS continuing review website for more information.
Data Safety Monitoring Board (DSMB)	An independent group of experts that monitors research to ensure the safety of participants and the integrity of the study. They are responsible for evaluating adverse events and conducting interim reviews. When a study is funded by the National Institutes of Health (NIH), a DSMB is required for all phase III clinical trials. The NIH and other funders may also require a DMSB for phase I or phase II studies that are greater than minimal risk. The Food and Drug Administration (FDA) also recommends the use of a DSMB if participants are at risk of serious morbidity or mortality (e.g., hospitalization, heart attack, stroke, death) or study products could cause serious unexpected adverse events.

Definitions and Terms	Definition
Data Safety Monitoring Plan (DSMP)	A plan to ensure appropriate oversight and monitoring of the conduct of an investigation. All greater than minimal risk studies must have a DSMP either within the research plan or in a separate document.
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.
Deception	Deception involves intentionally providing inaccurate or false information to subjects. For example, telling participants that they will be interacting with another participant online by playing a game together when they are actually playing against a computer. Incomplete disclosure is another form of deception that involves withholding information about the study purpose and/or details about the study procedures. Incomplete disclosure is often used to minimize the chance of biasing results or priming participants. For example, telling participants that they will be asked to provide information about their perceptions about people based on their photographs but not informing them that researchers are interested in seeing how the race or gender of the person pictured impacts their perceptions. For exemption under category 3, no deception may be used or if deception is used, the participants must be told that they will be kept unaware of or misled regarding the nature or purpose of the research. For example, participants may be informed that they will not be told the purpose of the research until after the study session is completed as long as they are informed of what will occur during the session.
De-identified	Refers to data or specimens that was initially associated with identifiers but have been stripped of personally identifiable information.
Delivery	Complete separation of the fetus from a pregnant person by expulsion or extraction or any other means.
Designated Reviewer	The IRB chair or an Experienced IRB Member designated by the IRB chair to conduct Non-Committee Reviews.

Definitions and Terms	Definition
Device (FDA)	An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: • (A) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, • (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals, or • (C) intended to affect the structure or any function of the body of humans or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. **Note**: software, applications and Artificial Intelligence (AI) can also sometimes be considered an FDA regulated device when FDA criteria are met.
Discard (RAP)	A button in the RAP that allows researchers or RCS to remove a study from review. A discarded project can still be viewed and copied to create a new submission but cannot be edited and/or resubmitted. If a researcher would like to pursue a discarded study, they will need to create a separate new study. A project or a follow-on may be discarded by RCS if requested by the researcher (e.g., they no longer want to do the study), if the wrong type of submission was created by mistake (e.g., researcher created a study team member only modification when they actually needed to change other parts of the study), a researcher leaves the UO without completing a submission, and/or if a study has been waiting with a researcher for more than 45 days after clarifications have been requested and RCS received no response to check-in communications. When a researcher does not respond to a request for changes and check in communications, the next step is usually to withdraw the submission rather than discard it. However, if the study continues to remain in the same state unchanged for an extended period of time and no communication is received from the researchers, a submission will eventually be discarded. If researchers find that they cannot make the requested changes within 45 days, they should email the person named in the RAP as your IRB Coordinator or use Add Comment on the submission in the RAP (and check IRB Coordinator in the comment box) to let them know you need more time. RCS will generally send check-in communications via the RAP and/or via email before discarding a study for lack of response.

Definitions and Terms	Definition
Drug (FDA)	A substance that meets one or more of the following criteria: • recognized by an official pharmacopoeia or formulary. • intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. • intended to affect the structure or any function of the body (and is not food or a dietary supplement) • intended for use as a component of a medicine but not a device or a component, part or accessory of a device. Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)
Educational Tests	Tests of cognitive, diagnostic, aptitude, or achievement. Examples include the SATs, ACTs, and placement tests to determine if a student should be placed in an advanced or intermediate class.
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 services available for individuals and organizations that want to better protect their communications and data. Refer to UO minimum information security controls standard website for more details about UO specific requirements for encryption. Also see the Data Security Resources on the UO Safety Monitoring, Participant Privacy and Confidentiality of Data website.
Engaged	When an activity or role requires an institution to provide IRB oversight or enter into an authorization agreement with another institution for oversight, that institution is considered "engaged" in the research. In general, an institution is considered to be engaged in human subjects research when its employees or agents: 1. obtain data about living individuals for research purposes through intervention or interaction with them, 2. obtain individually identifiable private information or specimens for research purposes (45 CFR 46.102(d),(f)); or 3. obtain the informed consent of human subjects. **Note**: Other activities can also engage the institution, such as receiving direct federal award to support such research (i.e., UO is primary awardee of federal grant), even if all of the human subjects activities will be performed by agents or employees of another institution.

Definitions and Terms	Definition
Enrolled	A participant counts towards enrollment if they meet the definition of human subject at any point in their involvement. • This includes someone who signs the consent document but does not complete the study. • It also includes situations when researchers obtain identifiable private information or identifiable biospecimens about or from an individual, even if the researchers do not interact directly with the individual. • Example: A potential participant who completes pre-screening prior to consent is not considered enrolled in the research unless the pre-screening data will also be used for research analyses or future research. However, if the pre-screening data will be used for research purposes or if an individual signs a consent form and there is further screening and they screen fail at that point, that participant was enrolled and considered a withdrawal. For flexibility, we recommend that researchers describe how many participants they plan to consent/enroll and how many participants they need to complete all study activities to achieve study aims.
Established or commonly accepted educational settings	Settings where specific educational offerings normally take place or a setting where one would go in order to have an educational experience. Examples include K-12 schools and college classrooms, after-school programs, preschools, vocational schools, alternative education programs, professional development seminars, and religious education settings.
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 expedited review process. In order to qualify for the expedited review process, the research must also present no more than minimal risk to the participants.
Experienced IRB Member	An IRB member is considered experienced if the IRB chair considers the IRB member to have sufficient experience in and knowledge of conducting IRB reviews.
Experimental Subject (per DOD)	For Department of Defense (DOD) research, research involving an "experimental subject" is an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving "experimental subjects" is a subset of research involving human participants.

Definitions and Terms	Definition
Expiration Date	The first date that the protocol is no longer approved. The date after the end date of the approval period. All research activities involving human subjects must stop after IRB approval expires, unless it is determined to be in the best interest of already enrolled subjects to continue participating in the research. Enrollment of new subjects cannot occur after the expiration of IRB approval.
Family Educational Rights and Privacy Act (FERPA)	A federal law that was enacted to protect the privacy of parents and students and provides guidelines for maintaining the confidentiality of education records for students. It gives parents/caregivers and adult students control over the students' education records and prevents schools from sharing information without written consent unless certain exceptions are met. FERPA applies to educational agencies/institutions such as elementary schools, middle schools, high schools, and universities that receive federal funds. **Note:** If research involves access to and/or release/transfer of FERPA protected education records, signed and dated written consent must be obtained before an educational agency or institution discloses *personally identifiable information* from the student's education records (see 34 CFR 99.3 for FERPA specific definitions). Opt-out or "passive consent" will not fulfill this requirement. It also requires additional details to be included in the consent materials (e.g., specify the records that may be disclosed, purpose of disclosure, parties or class of parties who will have access to the records). See 34 CFR 99.31 for details about FERPA exceptions to consent.
Federal Wide Assurance (FWA) or Assurance	Documentation of an institution's commitment to comply with Federal regulations and maintain policies and procedures for the protection of human participants. See OHRP's FWA website for more information.
Fetus	The product of conception from implantation until delivery.
Finding of Non-Compliance	Non-Compliance in fact.
Focus group	A group of participants convened to discuss a specific topic, conduct an evaluation, or test new ideas.
Follow-on Submissions	After a study is approved, there can be several follow-on submissions which change a study, provide additional details or allow a study to continue. Follow-on submissions include MODs, CRs, MODCRs, and RNIs. Each follow-on submission in the Research Administration Portal (RAP) gets its own identification number. When that follow-on is approved, the applicable details from that follow-on submission are transferred to the parent study. For example, if a new consent form is added to an approved study via a modification, that new consent form will appear in the parent study once that modification is approved. You can see all follow-on submissions for a project in the RAP by clicking on the Follow-on Submissions tab for the parent study.

Definitions and Terms	Definition
Food and Drug Administration (FDA)	The Food and Drug Administration (FDA) regulates products such as drugs, devices and biologics. When those products are used in human research, FDA regulations will apply that are different from and in addition to the HHS regulations (e.g., 21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812).
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 that does not qualify under the nine categories established by the US Department of Health & Human Services for expedited review, research involving ionizing radiation and research involving invasive procedures will always require a full board review.
Generalizable knowledge	Information that expands the knowledge base of a scientific discipline or other scholarly field of study and yields one or both of the following: • Results that are applicable to a larger population beyond the site of data collection or the specific participants studied and/or • Results that are intended to be used to develop, test, or support theories, principles and statements of relationships and/or to inform policy beyond the study. Although publications/presentations alone are not always indicative of generalizable knowledge, they are often a means of making research findings available for the development of knowledge beyond the scope of the study.
Genetic Characteristic	*State of Oregon Definition:* Includes a gene, chromosome or alteration thereof that may be tested to determine the existence or risk of a disease, disorder, trait, propensity or syndrome, or to identify an individual or a blood relative. "Genetic characteristic" does not include family history or a genetically transmitted characteristic whose existence or identity is determined other than through a genetic test.
Genetic Information	*State of Oregon Definition:* Information about an individual or the individual's blood relatives obtained from a genetic test.
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.

Definitions and Terms	Definition
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. HIPAA applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. See the RCS HIPAA website for more information.
Human Research	Any activity that either: • Is Research as Defined by DHHS and involves Human Subjects as Defined by DHHS; or • Is a Clinical Investigation as Defined by FDA and involves Human Subjects as Defined by FDA.
Human Subject/Human Participant	*DHHS Definition*: 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. *FDA Definition*: an individual who is or becomes a participant in research/clinical investigation, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. For devices, a subject is also a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control.
Identifiable Biospecimen	Biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Definitions and Terms	Definition
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 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. The dataset needs to be considered in its entirety and considered within the context of the study population to determine if it is identifiable. Different regulations may have different standards for what may be considered identifiable information. For example, both HIPAA and FERPA regulations provide a list of specific variables that make data/specimens identifiable. When those regulations are not applicable, UO applies the readily ascertainable standard (i.e., data/specimens are identifiable when the identity of the subject is or may readily be ascertained by the investigator or associated with the information).
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. Also see identifiable data/information above and Protected Health Information.
Individual Investigator	Researchers who are not working on a project as an employee or agent of the UO or another institution that has a federal wide assurance (FWA) but is engaged in the human subjects research. Individual investigators may be affiliated with an institution that has an FWA but are doing the research independent from that affiliation or are researchers who are not affiliated with any institution that has an FWA. For more information, see our Collaborations in Research website.
Individual Investigator Agreement (IIA)	A mechanism that allows an institution holding an OHRP-approved Federalwide Assurance (FWA) to extend the applicability of its FWA to cover individual investigators who are not affiliated with the UO or another institution with an FWA. For more information, see our Collaborations in Research website.

Definitions and Terms	Definition
Informed Consent	An active process of sharing information between the investigator and prospective participants that informs them about their rights and what they will experience during the research. The informed consent process involves three key features: (1) disclosing to potential research participants information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate in the research. Informed consent must be free from coercion and undue influence, legally effective, and prospectively obtained. The procedures used in seeking and obtaining informed consent should be designed to communicate with the participant population in terms that they can understand. Information about a research project must be presented in such a way that enables each person to voluntarily decide whether or not to participate in research. Thus, the information must be conveyed in language understandable to those being asked to participate in the research. For more information, see the RCS informed consent website.
Institution	Any public or private entity, or department or agency (including federal, state, and other agencies).
Institutional Official/ Organizational Official (IO/OO):	Institutional Official (IO): Term utilized by DHHS. • The Institutional Official (IO) is the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance. The IO is responsible for ensuring that the Human Research Protection Program (HRPP) functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents the institution named in the Federalwide Assurance (FWA). The IO is designated by the University President. The IO may then delegate scoped authority to the Research Compliance Services Director Organizational Official (OO): Term utilized by AAHRPP. • An identified, knowledgeable leader of the HRPP who is responsible for the program and has the authority to implement the program. This individual may rely on others for the interpretation of laws, regulations, codes, and guidance and the day-to-day operations of the HRPP, and should have a basic understanding of the relevant laws, codes, regulations and guidance that govern research involving human participants, the responsibilities of an organizational official, and the responsibilities of the IRB or EC and researchers and research staff in protecting research participants. This individual should be directly involved in the allocation of resources to the HRPP. In some circumstances, more than one individual serves in this capacity.

Definitions and Terms	Definition
Institutional Profile	A record of information an institution keeps about another collaborating institution/organization for one or more Collaborative or Multi-Site Studies. Creating an institutional profile is the first step in adding another institution into the RAP that could be an IRB of record or a pSite for a collaborative or multi-site study. An institutional profile only needs to be set up once for each institution.
Institutional Review Board (IRB)	An independent committee that has been formally designated to approve, monitor, and review research involving humans.
Interaction	Communication or interpersonal contact between investigator and subject.
Interim Findings	Preliminary results or observations from a research study that are reported to the IRB, sponsor, Data and Safety Monitoring Board or regulatory body before the study is fully completed. Interim findings usually provide an update on the progress of the research and identify possible safety concerns or ethical issues that may need to be addressed mid-study.
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.
Interviews	Information collected about individuals through conversations or discussions. Interviews can be in person, over the phone, or online using platforms such as zoom. They may be audio or video recorded. Interviews can be individual or can include activities such as focus groups.
Investigation	A searching inquiry for facts; detailed or careful examination.
In Vitro Diagnostic (IVD) products	In vitro diagnostic products are those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. The FDA classifies IVDs are medical devices and may also be biological products in some cases.
Ionizing Radiation	Radiation consisting of particles, X-rays, or gamma rays with sufficient energy to liberate electrons from atoms or molecules. Examples of devices/materials that involve ionizing radiation include but are not limited to Computed Tomography (CT) scans, X-rays, Dual-energy C-ray Absorptiometry (DEXA) scans, Positron Emission Tomography (PET) scans, Radio-labeled materials.

Definitions and Terms	Definition
IRB Authorization Agreement (IAA)	A type of agreement between two institutions that are engaged in human subjects research when both institutions have Federal Wide Assurances (FWAs). This agreement allows one institution to extend its FWA to cover another institution. These agreements are intended to minimize the regulatory burden on IRB review as only one IRB will be the IRB of record and the other IRB will rely on the other IRB for a regulatory review.
IRB of Record	The IRB conducting the regulatory review and serving as the IRB for a study. This term is most often used in the context of collaborative or multi-site studies where there is more than one site engaged in the research and the IRB of record is serving as the IRB for all of the sites.
Justice	The principle in the Belmont Report which refers to the distribution of benefits and burdens to participants in research.
Just-in-Time (JIT)	A procedure for certain award programs such as the NIH that allow some elements of the application, such as IRB approval, to be submitted later in the application process after the application is in serious consideration for funding. If your grant application receives a just-in-time notice, you still need to submit a complete IRB submission for review to the IRB if you have not already done so. As soon as you receive the first auto-generated JIT email request and determine that your score is likely to be competitive for an award, you should begin the initial new protocol submission or modification process with the IRB. If your IRB submission's approval is pending as the JIT submission date approaches, the pending status does not jeopardize your funding opportunity and there is no cause for alarm. Often, informing the funder of the anticipated IRB review date or letting them know that the application is under review is sufficient. If your IRB submission is still under review, inform your Grant Officer, who will then inform the funding agency.
Lapse in Approval/Lapsed	A lapse in approval occurs when a research study's IRB approval has expired. This often happens because the investigator did not submit a timely continuing review submission or forgot to close their study when they were done, resulting in the study no longer having active ethical clearance to conduct research activities with human subjects. To minimize the chance of a lapse occurring, researchers should plan to submit a continuing review (CR) submission to either request continuation of their project or to request study closure at least 45 days prior to the study's expiration date. Researchers will receive reminders in the RAP when their study is coming up for continuing review. The regulations make no provision for any grace period extending conduct of research beyond the expiration date of IRB approval. All research activities involving human subjects must stop after IRB approval expires, unless it is determined to be in the best interests of already enrolled subjects to continue participating in the research. Enrollment of new subjects cannot occur after the expiration of IRB approval.

Definitions and Terms	Definition
Legally Authorized Representative (LAR)	An individual, judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures(s) involved in the research. • **Note**: The UO relies on the State of Oregon's medical definition of LAR for the purposes of research. In the State of Oregon, the following individuals meet this definition (in descending order): competent adults who are appointed to make health care decisions, spouse, adult designated by an authorized parents/guardian (when there is no objection by the parent/guardian), majority of their adult children who can be located, either parent, majority of adult siblings, any adult relative or adult friend.
Letter of Acknowledgment (LOA)	Similar to IAAs, a letter of acknowledgment (LOA) is also an authorization agreement between two institutions that are engaged in human subjects research when both institutions have Federal Wide Assurances (FWAs). However, this type if agreement is unique to institutions who use SMART IRB.
Long-Term Follow-up	The continued monitoring and data collection from research participants even after they have completed the primary intervention phase of a study, allowing researchers to track the long-term effects of the research intervention. Long-term follow-up may include: • Research interactions that involve no more than minimal risk to subjects (e.g., quality of life surveys); and • Collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol. **Note**: long-term follow-up excludes research interventions that would not have been performed for clinical purposes, even if the research interventions involve no more than minimal risk.
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. *In research involving prisoners*: Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. • **Note**: The above definitions refers to the daily life of the average person. If participants experience significant risks in their everyday life, they should not be exposed to greater risks for research and still have the research be considered "minimal risk" (e.g., life or death situations experienced by military service members, law enforcement, and people who engage in high-risk behaviors, severe pain and discomfort caused by pre-existing medical conditions).

Definitions and Terms	Definition
Modification (MOD) / Amendment	A modification is a submission type in the RAP that allows researchers to make changes to their previously approved materials, procedures, personnel and other details. For non-exempt studies, the IRB is required to review and approve *all* changes to the research prior to the implementation of those changes with the only exception being changes performed to eliminate apparent immediate hazards to the participants. This includes minor changes that do not impact risk. Changes to previously approved *exempt* research will also generally require review and approval by RCS before implementing changes with the exception of certain minor changes (e.g., editorial changes, wordsmithing, addition of clarifying questions, deletion of questions, minor changes to recruitment materials). When in doubt about whether a modification is required, researchers should Contact RCS. For more information about modifications, see the RCS Modifying an Existing Protocol website.
Modification/Continuing Review (MODCR)	A submission type in the RAP that combines a modification and a continuing review. Changes submitted at time of continuing review via a MODCR should be limited to minor changes. Making substantial changes at time of continuing review (e.g., adding a greater than minimal risk procedure/test article, adding new sub-study) may result in a lapse in approval and should be avoided whenever possible.
Multi-Site Study	A study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol.
Neonate	A newborn (28 days old or younger).
Non-Committee Review	Reviews that are not conducted by the fully convened IRB at a board meeting. Non-committee review may include any of the following: • Determination of whether an activity is Human Research. • Determination of whether Human Research is exempt from regulation. • Reviews of non-exempt research using the expedited procedure. • Determinations of which subjects can continue in expired research. • Concurrence of IRB Chair or designee for non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use) or non-emergency individual patient expanded access IND with request for authorization to use alternative IRB review procedures.
Non-Compliance	Failure to follow the regulations, the requirements and/or determinations of the IRB. In the case of research funded or conducted by the Department of Defense (DOD), Non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (DOD) instruction 3216.02, its references, or applicable requirements.

Definitions and Terms	Definition
Nonviable Neonate	A neonate after delivery that, although living, is not viable.
Normal Educational Practices	The term "normal educational practices" refers to proven instructional techniques or classroom management already in use. Examples of research that would fall under exempt category 1 would be a study to evaluate the use of accepted or revised standardized tests or evaluation of a continuing education program. However, a randomized controlled trial with the control group receiving the "normal educational practice" and the experimental group receiving a new or innovative practice would generally not fall under this exemption. Exempt category 1 includes 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.
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.
Parent Study	When a new study is created in the RAP, that new study will become the parent study for the project once approved. Unless it is a study that has migrated into the RAP from the legacy system, the parent study will have a number assigned to it that begins with "STUDY" (e.g., STUDY00000000). This parent study can be modified over time. Once a modification is approved, the parent study information and materials are updated to reflect the most up to date versions approved. Parent studies that are set up to be multi-site/collaborative studies allow researchers and RCS staff to add pSites as well. The parent study describes activities and personnel at the UO and houses documents applicable to the study as a whole (i.e., materials for all sites) or documents that are only used at the UO while the pSite contains materials and information specific to each pSite.
Participating Site (pSite):	An institution that participates in a Single IRB (sIRB) Study and will rely on the IRB of record. pSites are also a submission type in the RAP that houses authorization agreements and other reliance materials for researchers external to the University of Oregon (UO) that document UO's willingness to serve as the IRB of record for their site. A pSite only needs to be created when researchers at another site are engaged in the human subjects research.
Permission	The agreement of parent(s) or guardian to the participation of their child or ward in research.

Definitions and Terms	Definition
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.
Definitions and Terms	**Definition**
Pregnancy	The period of time from implantation until delivery. An individual of child-bearing potential shall be assumed to be pregnant if they exhibit any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.
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. Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial.
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 such as a hospital or medical clinic. In order to be PHI, the information must contain one or more of the 18 HIPAA identifiers and health information (e.g., medications, diagnoses, surgeries). See the RCS HIPAA website for more information.
Protocol	The official procedure or system in place, including standard materials, by which research is conducted.
Public Behavior	Behavior that occurs in a public place where there is no expectation of privacy and where no special permission is required to observe others. Public behavior is behavior that can be observed by anyone and observations should not be considered inappropriately intrusive. Behavior in classrooms or other venues that require special permission to access or behavior in restrooms or other venues where there is an expectation of privacy are not considered public behavior.

Definitions and Terms	Definition
Publicly Available	Data and/or biospecimens that are accessible to anyone in the general public, without the need for special qualifications, permissions, or privileges. Access may be free or provided at a nominal cost. The source may be from a commercial entity if the information can be obtained by members of the general public. Examples include data/biospecimens available for public purchase, searchable online, or available at a library. Data and/or biospecimens that are restricted and require special qualifications to access may not be able to be considered publicly available. Contact RCS to discuss the specifics.
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.
Related to the Research	A financial interest is Related to the Research when the interest is in: • A sponsor of the research; • A competitor of the sponsor of the research; • A product or service being tested; or • A competitor of the product or service being tested.
Relative	Any of the following: • The spouse, parent, stepparent, child, sibling, stepsibling, son-in-law or daughter-in- law of the public official or candidate; • The parent, stepparent, child, sibling, stepsibling, son-in-law or daughter-in-law of the spouse of the public official or candidate; • Any individual for whom the public official or candidate has a legal support obligation; • Any individual for whom the public official provides benefits arising from the public official's public employment or from whom the public official receives benefits arising from that individual's employment; or • Any individual from whom the candidate receives benefits arising from that individual's employment.
Reportable New Information (RNI)	Submission type in the RAP that allows researchers to report events such as unanticipated problems involving risk, non-compliance and other reportable events related to the research. Events must be reported promptly. See the RCS Report new Information website for more information.
Research Administration Portal (RAP)	The online submission system for research administration used by the UO for units such as the IRB, IACUC, and COI. See the OVPRI RAP website and IRB specific RAP guidance for more information.

Definitions and Terms	Definition
Research as Defined by DHHS	A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. For examples of exceptions, see 45 CFR 46.102(l)(1-4).
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.
Restricted	Applies to investigators who are delinquent in meeting IRB requirements
Risk	The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in research.
Secondary Research	Research with biospecimens and/or data that was initially collected for purposes other than the planned research. The biospecimens/data might have initially been collected for non-research purposes (for example, as part of routine clinical care) or as part a different research protocol.
Serious Non-Compliance	Non-Compliance, including behavior, action or omission in the conduct or oversight of human research may be considered serious non-compliance in the judgment of the convened IRB based on the following principles if there was: • An effect on rights, safety and/or welfare of participants; • Harm or potentially increased risk of harm to a research participant(s) or others • Compromise in the integrity or validity of the research and/or • Intentional, reckless or knowing misconduct on the part of the researcher(s) Examples: Generally, failure to adhere to the laws, regulations, or policies governing human research would be regarded as serious non-compliance. This typically would include (but is not limited to) the following: • Conducting research without appropriate IRB approval, • Conducting research without appropriate informed consent, • Implementing changes to IRB approved research without IRB approval (except those necessary to address an immediate safety risk to one or more human subjects) and/or • Enrolling participants who fall outside inclusion/exclusion criteria without appropriate notification/approval by the IRB For Department of Defense (DOD) research Serious Non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (DOD) Instruction 3216.02 and its references such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.

Definitions and Terms	Definition
Single IRB (sIRB) Study	A study in which two or more institutions (participating sites, or pSites) coordinate to complete the research activities, but all institutions rely on a single institution's/organization's IRB for ethical review. The reviewing IRB (also called the IRB of record) may or may not be affiliated with any of the pSites. sIRB is mandated for federally funded studies.
Smartform	Within the Research Administration Portal (RAP), the smartform is the series of questions built into the RAP that you complete when creating a new study or when creating a follow-on submission. The smartform will branch based on your answers and may present additional questions if needed. Additional documents may also need to be uploaded into the smartform to provide the IRB with a complete submission. The smartform is what you see when you click View Study or Edit study or View Modification/CR or Edit Modification/CR etc. in the RAP.
SMART IRB	A platform designed to ease common challenges associated with initiating multisite research and to provide a roadmap for institutions to implement the sIRB mandate for federally funded research. Participating institutions using SMART IRB have agreed to certain terms for collaborative/multi-site research. Institutions using SMART IRB can either use the SMART IRB Online Reliance System or they can choose to draft and sign a SMART IRB Letter of Acknowledgment (LOA). Institutions using the SMART IRB Online Reliance System or SMART IRB LOA do not also need an IAA.
Surveys	Information collected about individuals through questionnaires or similar procedures
Suspension of IRB	An action of the IRB, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval. Suspended studies remain open and are subject to continuing review. However, researchers cannot conduct any research activities involving human subjects until the suspension is lifted.
Systematic	Having or involving a system, method, or plan.
Termination of IRB Approval	An action of the IRB, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review. Unless otherwise documented, an administrative closure issued by the UO RCS/IRB office is not the same as a termination of IRB approval.

Definitions and Terms	Definition
Test Article	Any drug (including a biological product), and/or medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulations under the act or under sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n).
Therapeutic Misconception	The tendency to view experimental research procedures and test articles as effective methods/treatments that will directly benefit research subjects/participants. Therapeutic misconception can make it difficult to get meaningful consent from subjects/participants as they may have unreasonable expectations of the research. This could include expecting benefits of the research that are unrealistic, falsely assuming they are receiving safe and/or effective treatment or other effects from the experimental research that are not known, and the possibility of unreasonably discounting the research risks of harm.
Unanticipated Problem Involving Risks to Subjects or Others	Any information that is (1) unanticipated, (2) related to the research, and (3) indicates that subjects or others are at increased risk of harm. • For Department of Defense (DOD) research the term Unanticipated Problem Involving Risks to Subjects or Others includes any incident, experience, or outcome that meets ALL three of the following conditions: ○ Is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g., the IRB- approved research protocol and informed consent document) and the characteristics of the human subject population being studied. ○ Is related or possibly related to participation in the research (in this Instruction, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research). ○ Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.
Undue influence	An act that includes an excessive or inappropriate persuasion, authority, reward or other overture to pressure an individual to participate in research. Undue influence may be unintentional and result from a power differential between the investigator and the potential participants (e.g., Employers targeting own employees as participants and employees feel like they cannot say no to the research without repercussions, Offering college students $100 each to complete a 20-minute survey on illegal drug and alcohol use could also be viewed as unduly influential because the amount could entice students to disclose information that they would not otherwise willfully disclose). See also coercion.

Definitions and Terms	Definition
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 persons, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. Vulnerable populations may also be susceptible to increased harm due to pregnancy or medical conditions.
Voluntary	Free of coercion, duress, or undue inducement.
Waiver of Consent	When certain criteria are met, the IRB may approve research involving human subjects without any informed consent process or documentation. The criteria that must be met for a waiver of informed consent include: (i) The research involves no more than minimal risk to the subjects; (ii) The research could not practicably be carried out without the waiver (i.e., research could not be done with informed consent); (iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; (iv) The waiver will not adversely affect the rights and welfare of the subjects; and (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation. All criteria must be met and the waiver approved by the IRB before non-exempt research can be conducted without informed consent. Passive consent procedures must also meet all waiver of consent criteria to be approved. See the RCS informed consent website for more information.
Waiver of Documentation of Consent	When certain criteria are met, the IRB may approve research involving human subjects with an informed consent process that does not involve documenting consent with a signed informed consent document. This is a waiver of the signature requirement only. A non-exempt study with a waiver of documentation of consent still has a consent process where participants are provided with consent details that contain all elements of consent, but participant consent is provided verbally or by other means other than a signed consent form. There are several different ways of getting a waiver of consent documentation. The waiver must be approved by the IRB before non-exempt research can be conducted without signed informed consent. See the RCS informed consent website for more information.

Definitions and Terms	Definition
Withdraw/withdrawal (participant)	Participants must be free to leave a study at any time without penalty or negative consequences. When a participant decides to withdraw from all components of a research study, researchers must discontinue research activities involving the participant's participation including • Interacting or intervening with the participant in order to obtain additional data and/or biospecimens for the research study • Obtaining additional identifiable private information about or identifiable biospecimens related to the participant from any source. • Obtaining additional identifiable private information about the participant by observing or recording their private behavior When a participant withdraws, researchers may ask the participant if they would like to withdraw from the intervention but still continue with other research activities (e.g., follow-up interviews, obtain data from medical records or other sources. Continued participation in secondary components of a research study may be particularly important in clinical trials designed to evaluate the safety and effectiveness of specific interventions in the management of diseases or disorders. For this reason, OHRP guidance on this topic recommends that the investigators conducting the clinical trial should ask the withdrawing participant to clarify whether they wish to withdraw from all components of the trial or only from the primary interventional component of the trial and their wishes should determine if follow-up is still okay. Investigators can retain and analyze data collected prior to withdrawal, provided such analysis falls within the scope of the analysis described in the IRB-approved protocol and consent form. For research not subject to FDA regulations, investigators can choose to honor a research participant's request that the investigator exclude the participant's data from any analysis. However, for FDA regulated research, the data collected on the participant to the point of withdrawal remains part of the study database and may not be removed.
Withdraw (RAP)	A button in the RAP that allows researchers or RCS to put a study back in the pre-submission phase of review. A withdrawn project can be edited by the researchers and resubmitted again. A submission may be withdrawn if it is incomplete upon submission (e.g., missing a key document needed before the review can begin), if there is no faculty advisor on a student led project, or if a study has been waiting with a researcher for 45 days after clarifications have been requested and RCS received no response to their communications. If researchers find that they cannot make the requested changes within 45 days, they should email the person named in the RAP as the IRB Coordinator or use Add Comment on your submission in the RAP (and check IRB Coordinator in the comment box) to let them know more time is needed. RCS will generally send check-in communications via the RAP and/or via email before withdrawing a study for lack of response.

Definitions and Terms	Definition
Written, or In Writing	Written, or in writing, refers to writing on a tangible medium (e.g., paper) or in an electronic format.