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Section 2: Definitions

2.1 Definitions Applicable to All Sections of this Manual

Adverse events are any unfavorable medical occurrence in a human subject participating in research, regardless of whether it's believed to be related to the research itself. This can include any abnormal sign, symptom, or disease that happens during or after the research participation.

Agent of the Organization is a faculty member or non-faculty employee, who may also be a principal investigator of a research protocol or an Institutional Review Board member, or non-employees who perform institutionally designated activities or who exercise institutionally delegated authority or responsibility such as research or teaching activities. Examples would include community IRB members, University faculty who are conducting research at another institution, a faculty member performing research while on sabbatical or a University student conducting research at another institution as part of a course requirement.

Allegation of Noncompliance means an unproven assertion of noncompliance.

Anonymity means that the identity of a research subject cannot be readily ascertained by anyone, including the Principal Investigator, either directly or through the use of coded data.

Anonymous Data pertains to information that is collected or that an individual has disclosed in a study with the expectation that the information has no identifiers linked to the participant and therefore cannot in any way be traced to the participant. An example would be survey research that does not ask for the participants' names or any other form of personal identification. The words "anonymous" and "confidential" do not have the same meaning and are not interchangeable.

Applicable Clinical Trial means any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause and effect relationship between the intervention and a health or behavioral outcome.

Approved means a protocol is approved as written with no explicit conditions.

Approved Assurance means a document that fulfills the requirements of 45 CFR Part 46 and is approved by the Secretary of Department of Health and Human Services (HHS). The University of Denver has an approved Federal Wide Assurance on file with HHS.

Approved with Conditions means the protocol is approved with stipulations for minor changes or simple concurrence of the Principal Investigator that will be identified to the Principal Investigator and must be completed and documented prior to beginning the research. In most instances, the Institutional Review Board (IRB) Compliance Analyst will review and approve but if the modifications are deemed as significant or are directly relevant to regulatory criteria, the protocol must go back to the convened IRB for review and approval.



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Assent means an affirmative agreement to participate in research or clinical investigation. Mere failure to object or an absence of affirmative agreement may not be construed as assent. This most often is applicable to children and decisionally impaired adults.

Authorized deception means that a Principal Investigator has intentionally not described certain aspects of a research study but subjects are informed that certain information will be withheld until the subject completes the study tasks.

Basic community partnership research is a project that involves a relationship with a community partner in which the researcher makes the key decisions in the project but considers the needs and interests of the community in how the research is conducted and how the outcomes are disseminated.

Children are persons who have not attained the legal age for consent to treatments or procedures involved in research or clinical investigations. In Colorado, where federal regulations and state law both apply, individuals under the age of 18 are considered to meet the definition of children. For research conducted outside Colorado, children are defined under the applicable law of the jurisdiction in which the research or clinical investigations will occur. Some funding agencies may define children differently.

Children's Online Privacy Protection Act (COPPA) is a law to protect the privacy of children under 13. The Act specifies that sites must require parental consent for the collection or use of any personal information of young Website users.

Coded Information/Data means that identifying information that would enable the Investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Coercion is an overt or implicit threat of harm that is intentionally presented by one person to another in order to obtain compliance. For example, an investigator might tell a prospective subject that his or her grades might suffer if they do not participate in the research.

Collaborator is anyone who plays a part in the protocol and has access to study records.

Common rule refers to Department of Health & Human Services 45 CFR Part 46, Subpart A.

Community is a group that self-identifies by geography, age, ethnicity, gender, sexual orientation, disability, illness or health condition, common interest or cause, a sense of identification or shared emotional connection, shared values or norms, mutual influence, or commitment to meeting a shared need. Community need not be defined solely by geography. Defining "community" in a community-university partnership is more about the process of asking questions than about a strict definition of who "is" community or "represents" community: "Are those most affected by the problem at the table? Are community members at the table? Are those who have a stake in the issue being addressed at the table? Do they play decision making roles?" The purpose of the research partnership drives the definition - each project must define the community of interest.

Community-based research is research that takes place in or involves a community. The more precise definitions below reflect the degree of engagement of the community in the research, which can take place along a spectrum of engagement and shared governance.

Community-placed research is a researcher-initiated project involving a one-time or short-term relationship between the PI and the community, with limited community involvement beyond



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being a venue for recruiting research subjects or for implementing research procedures.

Community-based participatory research (CBPR) is a project defined by co-creation of project ideas and procedures by Principal Investigator and a community, active and substantive participation by the community in all or nearly all stages of the research, and shared power and decision-making responsibilities. There is an expectation that findings will be used to change systems or solve community problems. CBPR sees research subjects as both individuals and as a community comprised of individuals. Issues of confidentiality in CBPR should be viewed differently than with individual subjects and decisions made as to what may or may not be appropriate.

Confidential pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission or in ways that are inconsistent with the understanding of the original disclosure. For example, there may be a legal responsibility to divulge information and that should be stated in the consent form. The words "anonymous" and "confidential" do not have the same meaning and are not interchangeable.

Conflict of Interest is defined as any situation in which financial or personal obligations may compromise or present the appearance of compromising an individual or group's professional judgment in conducting, reviewing, or reporting research. Members of the Institutional Review Board may not review, deliberate on or approve research if they have a conflict of interest related to the research.

Data and Safety Monitoring Plan (DSMP) is an individualized plan, written by the Principal Investigator (PI) responsible for the study. The DSMP sets forth mechanisms for reviewing and evaluating unanticipated problems and other study-relevant data. The rationale for requiring a DSMP is the need to enhance research subject safety by clearly defining safety related issues prior to subjects being enrolled in a study. These issues include:

1. Monitoring the safety of the environment including the safe handling of drugs, solutions, specimens, physical space, and equipment;
2. Monitoring and protecting the validity and integrity of the data collected for the study; and
3. Documenting, grading, attributing, and reporting unanticipated problems involving risks to subjects or others.

De-Identified refers to information or data where direct identifiers such as name and address have been removed. In common use, the term refers to data where it may still be possible to identify individuals by inference or through codes held by the investigator or a third party.

Therefore data that is de-identified may not be anonymous because it may still permit at least probabilistic re-identification when analyzed in conjunction with other datasets.

Deception (as applies to research) means intentionally giving research subjects false information in order to establish false beliefs during the course of a research study.

Designated Reviewers are experienced IRB members, defined in this policy as being an IRB member and having been trained on the expedited process.

Disapproved means the protocol describes a research activity that is deemed to have risks which outweigh potential benefits or the protocol is significantly deficient in several major areas. The protocol and/or other documents will need to be completely re-written and re-submitted as a new submission. Principal Investigators may request reconsideration of a determination for disapproval in writing and possibly be invited to attend an Institutional Review Board meeting and presenting reasons for reconsideration.



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Engaged in human subjects research as defined by the Department of Health and Human Services guidance document states that in general an institution is considered engaged in a particular human subjects research project when its employees or agents, for the purposes of the research project, obtain:

1. Data about the subjects of the research through intervention or interaction with them.
2. Identifiable private information about the subjects of the research.
3. Informed consent of human subjects for the research.

Enrollment includes all subjects intended to be included in a study, including screen failures and dropouts. (Example: The investigator has a target enrollment of 100 and expects 75 to be screen failures so the study will accrue 25).

Family Educational Rights and Privacy Act (FERPA) is a Federal law administered by the U.S. Department of Education; 34 CFR Part 99. FERPA applies to all educational agencies and institutions that receive federal funding and protects the privacy of student education records.

Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services. FDA is responsible for protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, our nation's food supply, cosmetics, dietary supplements, and products that give off radiation.

Financial Interest in or related to the research means financial interest of any amount in the sponsor, product or service being provided, or a competitor of the sponsor. This can also be referred to as Financial Conflict of Interest (FCOI).

GDPR (European Union General Data Protection Regulation) is a standardized data protection law across all 28 European Union (EU) countries and imposes strict new rules on controlling and processing of personal information. This law came into effect as of May 25, 2018. The GDPR applies to any organization outside of the EU that processes the personal information of an individual who is physically located in the EU which either (i) offers goods or services to such individual, or (ii) monitors the behavior of such individual.

Generalizable Knowledge means information from which one may infer a general conclusion; knowledge brought into general use or that can be applied to a wider or different range of circumstances. For example, publication and presentation are typical methods used to disseminate research findings, thereby contributing to "generalizable knowledge." However, not all information that is published or presented represents generalizable knowledge. Generalizable knowledge is also interpreted to include data intended for general use, regardless of its eventual distribution or acceptance.

Guardian means a person appointed by a court to have full authority to make decisions for and act on behalf of a child or decisionally impaired adult, except as otherwise provided for by law. For research conducted outside Colorado, children are defined under the applicable law of the jurisdiction in which the research or clinical investigations will occur.

HIPAA is the acronym for the Health Insurance Portability and Accountability Act of 1996 and intended to provide standards for protecting the privacy of personally identifiable health information (PHI).

Human Subjects has two definitions depending on the federal agency overseeing the research.

1. Department of Health and Human Services regulations define human subjects as living individuals* about whom the Principal investigator conducting research obtains:
 - a. Data through intervention or interaction with the individual; or



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- b. Identifiable private information or identifiable biospecimens.
 - i. Intervention means both physical procedures by which data are gathered and manipulation of the subject or the subject's environment for research purposes.
 - ii. Interaction includes communications or interpersonal contact between the investigator and the subject, i.e., obtaining informed consent.
 - iii. Private information includes information about behavior when the subject can reasonably expect that no observation is taking place and information that has been provided for specific purposes and which the subject can reasonably expect will not be made public (e.g., medical record). Private information is individually identifiable, i.e., the identity of the subject may be readily ascertained by the investigator.
- 2. The definition provided in the **Common Rule** is expanded to include investigators, technicians, and others assisting investigators, when they serve in a "subject" role by being observed, manipulated, or sampled. For the purposes of this manual, research involving human biological specimens (e.g., urine, blood, tissue, and other bodily fluids) will be considered human subjects research.

*Note: Research on autopsy materials or specimens from deceased individuals is not considered to be human subjects research. However, some research, such as genetic studies providing private medical information about living relatives may need IRB review.
- 3. Food and Drug Administration definition is an individual who is or becomes a participant in research, either as a recipient of a test article (investigational drug, biologic, or device) or as a control and may be either a healthy human or a patient. The definition also includes an individual on whose specimen a device is used.

Human Subjects Research has reference to two definitions defined by federal agencies.

- 1. Department of Health and Human Services defines human subjects research as systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)) and includes a living individual about whom the investigator conducting research obtains:
 - a. through intervention or interaction with the individual.
 - b. Identifiable private information and identifiable biospecimens.
 - c. Data about the subjects of the research through intervention or interaction with them.
 - d. Identifiable private information about the subjects of the research.
 - e. Informed consent of human subjects for the research.
- 2. Food and Drug Administration (FDA) defines human subjects research as (21 CFR 56.102):
 - a. A clinical investigation on one or more individuals who are or become
 - b. participants in the investigation, either as recipients of a test article (drug, biologic, or device) or as controls and may be either patients or healthy non-patients.
 - c. The data obtained from participants (and controls) will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product, or data obtained from the use of a device (in vitro diagnostic device) on tissue specimens will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product.

If the research does not meet either HHS or FDA definitions, it is not human subjects research.

Incidents of Noncompliance/ Protocol Violations means that principal investigators did not



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adhere to Federal Regulations and/or The University of Denver policies, procedures, requirements, or Institutional Review Board determinations for conducting research involving human subjects.

Incomplete disclosure means that the principal investigator withholds some information about the real purpose of the study or the nature of the research procedures.

Individually Identifiable Information means any information about a living individual that is linked, associated with, or contains the name or any details of the individual that would allow someone to be able to directly or indirectly identify a subject from the information collected.

Informed Consent means the knowing consent of an individual or his/her legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. Information conveyed in the informed consent procedure must include all essential elements listed later in this manual.

Institution means any public or private institution or agency (including federal, state, and local government agencies).

Institutional Official (IO) is the University official responsible for ensuring that the Institutional Review Board (IRB) has the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects research. The IO is legally authorized to represent the institution, is the signatory official for all Assurances, and assumes the obligations of the institution's Assurance. At the University of Denver, the Senior Vice Provost for Research and Graduate Education is the IO.

Interaction means communication or interpersonal contact between an investigator and a participant.

Intervention is a physical procedure by which data are gathered or manipulation of the participant or the participant's environment for research purposes.

Investigator is considered to be an individual performing various tasks related to the conduct of human subjects research activities such as:

1. Obtaining information about living individuals by intervening or interacting with them for research purposes.
2. Obtaining identifiable private information about living individuals for research purposes.
3. Obtaining voluntary informed consent of individuals to be subjects in research.
4. Studying, interpreting or analyzing identifiable private information or data for research purposes.

IRBNet (IRB electronic submission system) is an online program used by investigators to submit protocol applications and used by the DU IRB Office to process and manage submissions for review and approval.

Lapse of approval means that, for whatever reason, the Institutional Review Board (IRB) has not received or reviewed required documentation for protocol continuation prior to the protocol's expiration date and all research activities must cease. Continuing review of research activities by the IRB must occur at least annually and a request for continuation must be accompanied by a report and other pertinent documentation. By regulation, no grace period is allowed. The IRB notifies Principal Investigators of lapses in approval and the requirement to cease all research activities until approval for continuation is obtained.



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Legally authorized representative (LAR) means an individual, judicial or other entity authorized under applicable law to consent on behalf of a prospective subject to such subject's participation in the particular research activity or procedure. For research conducted in Colorado where federal regulation and Colorado law both apply, for healthcare related treatments and procedures and for non-healthcare procedures, individuals in the following order may serve as an LAR: a legal guardian, persons appointed as health care agents under Durable Power of Attorney for Health Care, a spouse, adult child, parent, or an adult sibling. For research conducted outside of Colorado, individuals who meet the definition of a LAR are those who are described under the applicable law of the jurisdiction in which the research will be conducted.

Legally effective informed consent means that the Principal Investigator obtained consent to participate from a subject or the subject's legally authorized representative (LAR) and documented it in a manner consistent with the human subjects protection regulations and applicable laws of the jurisdiction in which the research is conducted. It is expected that the Principal Investigator will seek consent only under circumstances that provide the prospective subject or LAR sufficient opportunity to consider whether or not to participate and to minimize the possibility of coercion or undue influence. The information provided in the consent process should be understandable to the subject or subject's LAR and may not include any exculpatory language.

Member includes an Institutional Review Board member or consultant and their immediate family members defined as spouse and dependent children and step-children.

Minimal Risk means that the risks of harm anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. These are risks that reflect background risks that are familiar and part of the routine experience of life for an average person in the general population. For children, the definition means research in which 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 (of a healthy child) or during the performance of routine physical or psychological examinations or tests. For 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 who are not prisoners.

Next Report Due is a term used within the IRBNet electronic submission system to assign dates to research protocols that do not require a continuing review. The dates assigned to protocols are not a regulatory requirement but are used by the IRB to track and manage approved projects.

Noncompliance means that researchers or individuals other than researchers, such as research staff, Institutional Review Board (IRB) staff, or IRB members, did not adhere to Federal Regulations and/or The University of Denver policies, procedures, requirements, or IRB determinations for conducting research involving human subjects.

Office for Human Research Protections is an office in the Office of the Secretary of Health and Human Services that is responsible for regulatory oversight of human subjects research.

Parent means a child's biological or adoptive parent.

Permission means the agreement of parent(s) or guardian to the participation of the child in the research or clinical investigation.

PHI is the acronym for personal health information which is protected under the HIPAA regulations.

Pregnancy encompasses the period of time from implantation until delivery. A woman shall be



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assumed pregnant if she exhibits any of the presumptive signs of pregnancy, particularly missed menses, until the results of pregnancy testing are negative or until delivery.

Principal Investigator (PI) means an individual under whose research is conducted or in the event of research conducted by a team of individuals, is the responsible leader of that team.

When the University of Denver (University) accepts a grant or contract from an outside sponsoring agency, certain legal and ethical obligations are stated or implied in the document of agreement. The University becomes responsible for the proper performance of the stated work and for fiscal management of the funds received from the sponsor. Sponsors usually require an individual be named to oversee the project with the reasonable assurance that the agreed responsibilities will be discharged faithfully and prudently in the mutual interest of the sponsor and the University and over the full period of the award.

In order to implement these obligations, only individuals in the categories shown below are authorized to be PIs for sponsored projects. Only in rare instances will others be authorized, and then only with the approval of the Institutional Official.

1. Members of the faculty in the professorial ranks (assistant professor, associate professor and professor)
2. Directors
3. Research scientists/engineers and senior research scientists/engineers
4. Students who list a full-time faculty member as a faculty sponsor.

Prisoner means 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. Some common examples of the definition are:

1. Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration.
2. Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to criminal prosecution or incarceration.
3. Individuals who have been voluntarily admitted for treatment or who have been civilly committed to non-penal institutions for treatment because their illness makes them a danger to themselves or others are not prisoners.
4. Parolees who are detained in a treatment center as a condition of parole. Parolees living in the community, even with community-supervised monitoring, are not prisoners.
5. Probationers and individuals wearing monitoring devices are generally not considered to be prisoners. However, some situations of this kind may require analysis of circumstances and Office for Human Research Protections should be consulted when questions arise about research involving this population.

Prisoner Advocate is an individual representing the interests of incarcerated persons who may be approached and enrolled as research subjects.

Privacy means having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally or intellectually) with others.

Privacy Board is a review body that may be established to act upon requests for waiver or alteration of the requirement for a signed "Authorization for Use or Disclosure of Protected Health Information (PHI)" under the HIPAA Privacy Rule for uses and disclosures of PHI for a particular research study. A Privacy Board may waive or alter all or part of the Authorization requirements



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for a specified research project or protocol. The IRB may act as a privacy board.

Private Information consists of the following:

1. Information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical record).
2. Information that can be readily identified with individuals, even if the information was not specifically collected for the study in question.
3. Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.

Protection of Pupil Rights Amendment (PPRA) is a Federal law that provides certain rights to parents of minor students with regard to surveys that ask questions of a personal nature. The law requires that schools obtain written consent from parents before minor students are required to participate in any U.S. Department of Education funded survey, analysis, or evaluation concerning certain topics.

Protocol Deviation means a deviation from Institutional Review Board-approved activities related to a research study. This means that the principal investigator(s) has performed activities that are different than those described in the protocol, that procedures not previously described in the protocol were performed, or that procedures described in the protocol were not performed.

Quality Improvement (QI) projects are defined as those activities that are designed purely to evaluate and improve practice to conform to established or accepted standards. These types of activities are generally not subject to Institutional Review Board (IRB) review and approval. However, if data from the QI activity are used to draw general or widely applicable conclusions beyond evaluating a particular program or activity, the activity probably is research. The distinction is not always clear. The intent to publish, in and of itself, does not require that an activity be reviewed by the IRB. If the activities and data being reported are a result of QI assessment, then no IRB review is required for the activity or for its publication.

Quorum is defined as a majority of the voting members. In the case of the Institutional Review Board (IRB), a quorum will consist of at least 51% of the voting IRB members and must include at least one non-scientific and one unaffiliated member. All members present have equal voting power. At meetings of the IRB, a quorum must be established and maintained throughout the entire meeting. A member with a conflict of interest cannot contribute to a quorum. For Food and Drug Administration-regulated research, a licensed physician must be present during the review, deliberation and voting to satisfy the quorum requirement under Code of Federal Regulations Title 21 CFR 56.108(c).

Research by definition of Department of Health and Human Services means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)) or, under Food and Drug Administration (FDA) regulations, an activity that involves a drug or drug, other than use of a market drug in the course of medical practice, or the use of a device to evaluate safety and effectiveness of that device, and data from the activity will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product. If the activity is designed to improve internal practices it is not research.

Research Records are records consisting of both Institutional Review Board-related records and any data gathered for research purposes.

Secretary means the Secretary of Department of Health and Human Services (HHS) and/or any other officer or employee of the HHS to whom authority has been delegated.



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Sponsor means any person or entity that takes responsibility for, initiates or funds a study. The sponsor may be an individual, pharmaceutical company, device manufacturer, governmental agency, academic institution, private organization, or other organization.

Student means any individual who is enrolled as a student at The University of Denver.

Staff means all employees of the University of Denver.

Suspension means a temporary cessation of research activities, to include enrollment of new subjects, collection of data from enrolled subjects, and performance of any research activities described in the approved protocol. Suspensions can be administered by the Institutional Review Board (IRB), the IRB Chair, or the principal investigator in order to eliminate an immediate hazard to subjects. A suspended protocol requires continuing review.

Systematic Investigation is a planned activity involving qualitative or quantitative data collection and data analysis that sets forth an objective(s) and a set of procedures intended to reach the objective(s), i.e., to acquire knowledge, develop a theory, or answer a question.

Tabled means generally, the protocol or consent form has deficiencies that prevent accurate determination of risks and benefits or requires significant clarifications, modifications or conditions that, when met or addressed, require full Institutional Review Board (IRB) review and approval of the Principal Investigator's (PI) responses and revisions. The deficiencies will be specified to the PI, and on occasion the PI is asked to attend the full board meeting in order to clarify the points in question. The PI must revise the protocol, consent forms, or other documents as specified by the IRB and re-submit.

Termination means a permanent discontinuance of research activities described in a research protocol due to withdrawal of Institutional Review Board (IRB) or regulatory agency approval. If subjects are currently enrolled, the IRB and Principal Investigator must implement actions for immediate care of and safe withdrawal of subjects from the research study. A terminated protocol does not require submission for continuing review.

Unaffiliated investigator is an individual who has no affiliation with the University, except as a collaborator on a research project that has a DU Principal Investigator on the project. Persons who are alumni are considered unaffiliated.

Unaffiliated member means an IRB member who has no affiliation with the University except as a member of the IRB. Persons retired from the University or those who have family members (spouse, parent, children) employed by the University are not considered unaffiliated.

Unanticipated problem involving risks to subjects and others means any problem, event, occurrence or new information related to the research project that is unanticipated and indicates that subjects or others are at increased risk of harm.

Undue influence is an offer or implication, real or perceived, of an excessive or inappropriate reward or other overture in order to obtain compliance. For example, professors recruiting their students may lead to the perception of undue influence to participate.

Vulnerable population refers to certain human subjects that require special treatment with respect to safeguards of their well-being. Examples include pregnant women, human fetuses and neonates, children, cognitively impaired persons, prisoners, students and employees, and economically or educationally disadvantaged individuals.

Ward is defined as a child who is placed in the legal custody of the state or other agency, institution or entity consistent with applicable federal, state or local law.



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