Tarrant County College District
Institutional Review Board
Definitions

Adverse Event: An unintended, but not necessarily unexpected, result of a research intervention that is unpleasant or dangerous.

Anonymity: In the context of the IRB, anonymity means that no one, including the researcher, knows the identity of the participant. No identification of subjects should be possible by the procedures employed or by the information solicited. For example, an online survey where no names or signatures are obtained and where the surveyed group is large enough to avoid inadvertent subject identification.

Anonymized: Refers to information or data where identifiers (and codes that are linked to identifiers) have been removed, as well as other values that would enable individuals to be identified through inference. In other words, anonymized data cannot be linked to the individual.

Anonymous Data: Refers to research information that is collected without any personal identifiers. An example would be survey research that does not ask for the participants' names or any other form of personal identification.

Assent: Affirmative agreement by an individual not competent to give legally valid informed consent (e.g., a child or person who is cognitively impaired) to participate in research.

Assurance: An agreement or contract between an institution and the Office of Human Research Protections (OHRP), on behalf of the Secretary of Health and Human Services. Assurance stipulates the methods by which the institution will protect the rights and welfare of research subjects in accordance with the federal regulations.

***Belmont Report*:** A statement of basic ethical principles governing research involving human subjects. The *Belmont Repor*t was issued by the National Commission for the Protection of Human Subjects in 1978.

Benefit: A research outcome that may be valuable or desired by participants. For example, learning about ways to increase academic success. Please note that payment for research participation *is not* considered a benefit.

Certification: Official District notification to a supporting department or agency that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Child/Minor: A person who has not attained the legal age for consent to treatments or procedures involved in the research. In the state of Texas, children/minors are identified as individuals under 18 years of age.

Clinical Investigation: Any experiment that involves a test article and one or more human subjects.

Coded: Data that is identified to enable a researcher to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced by a letter, number, symbol or combination of the aforementioned. A key to deciphering the code is created, thereby enabling the linkage of the individual's identity to the private information/specimens.

Coercion: Use of a credible threat of harm or force to control another. Pertaining to unacceptable subject recruitment methods which involve undue influence or indirect pressure for participation from a subject. For example, a student may feel pressured to participate in a research project where the incentive given by the instructor is unusually large.

Common Rule: A federal policy adopted by 17 federal agencies that conduct research involving human subjects. The acceptance of the Common Rule created a common set of elements regarding: (a) institutional assurance, (b) informed consent, (c) IRB composition and operations and (d) vulnerable populations.

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

Confidentiality: The manner of treating private information, which has been disclosed by the individual subject of the information to a particular person or persons for a specific purpose, such that further disclosure of the information will not be allowed to occur without authorization.

Continual Review: Research that has been approved will undergo review until the completion or termination of the research, including scheduled continual reviews of research that will occur at least annually.

Data: Refers to information that is collected for analysis or used to reason or make a decision.

Data Privacy: Informational privacy especially when the information in question is stored in a database.

Deception: In research, this means that the subject is not fully informed of the nature and purpose of the research at the time of the data collection in order to prevent biased behaviors or responses from the subject/respondent.

De-Identified: Refers to information or data where direct identifiers such as names and addresses were 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.

Device (medical): Therapeutic, diagnostic or prosthetic articles, which do not interact chemically with the body, e.g., pacemakers, diagnostic test kits, crutches and artificial joints.

Educational Setting: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on: (a) regular and special education instructional strategies or (b) the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

Emancipated Minor: An individual who is considered to have reached maturity: (a) by the appointment by a court of a guardian or (b) upon marriage.

Engaged Institution: An institution is considered engaged in human research when its employees or agents, for the purposes of non-exempt research projects obtain: (a) data about the subjects of the research through intervention or interaction with them, (b) identifiable private information about the subjects of the research, (c) the informed consent of human subjects for the research or (d) when the institution receives a direct federal award to conduct human subject research, even when all activities involving human subjects are carried out by a subcontractor, i.e., employees or agents of another institution.

Exempt: The Department of Health and Human Services' 45 CFR 46.101(b) specifies that *research activities may be exempt from IRB oversight if human subjects involvement is limited to one of the listed scenarios, including studies involving the collection or study of existing data when those data either are publicly available or are not personally identifiable.* Please note that TCCD's IRB requires individuals to submit their research proposals regardless if the researcher feels the study is exempt. TCCD's IRB has the final determination regarding IRB research categories.

Expedite: The Department of Health and Human Services' 45 CFR 46.110 specifies that research activities may be eligible for expedited review if the protocol involves only minimal risk or a previously reviewed protocol is receiving minor modifications. Expedited review is carried out by the IRB Chair or by a

designee. Expedited reviews have the force of full reviews, except that if the protocol is found not acceptable, it must be reviewed by the full committee, as the chair or designee alone cannot reject a proposal.

Family Educational Rights and Privacy Act (FERPA): FERPA is a federal law that protects the privacy of student education records.

Generalizable Knowledge: Knowledge that is expressed in theories, principles and statements of relationships that can be widely applied to other experiences. Typically statements about a population are made based on a sample. The term is often used when disseminating research results beyond an individual or internal group.

Guardian: An individual who is authorized under applicable state or local laws to consent on behalf of another person (e.g., children) to general medical care.

Health Information Privacy: Informational privacy especially when the information pertains to the health or medical condition an individual.

HIPPA: The Health Insurance Portability and Accountability Act (HIPPA) of 1996 protects certain health information. The Act was issued to protect the privacy of health information that identifies individuals who are living or deceased.

Human Subjects: A human subject is a living person. A researcher typically obtains the following information regarding human subjects: (a) data through an intervention or interaction with the participant and/or (b) identifiable participant information. Examples of participant data collection includes, but is not limited to: (a) questionnaires/surveys, (b) interviews and (c) behavioral and/or classroom observations 45 CFR 46102(d). If your research involves human subjects or identifiable data on human participants, you ***must*** gain IRB approval to conduct your research.

Human Subject at Risk: Any individual who may be exposed to the possibility of: (a) economic, (b) legal, (c) physical, (d) psychological or (e) social injury as a consequence of participating as a subject in a research project.

Hypothesis: A proposed explanation for the occurrence of phenomena to be tested by research. In other words, a hypothesis is an idea that can be supported or refuted through an experiment or observation.

Incentive: A benefit designed to motivate qualified subjects to participate in a research study. Incentives can be money, goods or services.

Individually Identifiable Information: Some information gathered by researchers contains data that allows the researcher to determine who has provided the information. Identifiers include, but are not limited to: (a) names, (b) social security numbers, (c) student ID numbers, (d) date of birth, (e) addresses, (f) videos and (g) photos. Even with small sample sizes, particularly in qualitative research, it is possible to piece together a subject's identify from anecdotal information. HIPAA has defined 18 personal identifiers of human subjects that are considered protected health information. These include:

- Names;
- All geographical subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and equivalent geocodes, except for the initial three digits of a ZIP code (with some exemptions);
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- Phone and fax numbers;
- Electronic mail addresses;
- Social Security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints;
- Full face photographic images and any comparable images and
- Any other unique identifying number, characteristic or code.

Incompetent: In the context of the human subjects review process, an individual who is unqualified to give or incapable of giving informed consent.

Informational Privacy: The right of individuals to control access to, and the use of, information about themselves.

Informed Informed consent is the disclosure of a survey's purpose, process,

Consent: benefits/risks and confidentiality of the information provided by survey respondents. Informed consent should be written at the *6th to 8th grade levels*.

Intermediary: An impartial individual or organization that in another capacity has contact with a prospective subject population and that cooperates with a researcher by obtaining consent from prospective subjects for the release of their names, addresses or telephone numbers to the investigator.

Institution: Any public or private entity or agency (including federal, state and other agencies).

Institutional Review Board (IRB): An IRB is an Institutional Review Board for human subjects. Institutions that receive federal funding to conduct research are required to have their research approved by an IRB. The TCCD IRB can: (a) review, (b) approve, (c) disapprove or (d) require modifications to submitted research proposals that involve human subjects. The District's IRB does not evaluate the merits of research design or review proposals for contribution to scholarly literature. The sole role of the TCCD IRB is to review research proposals for standards of compliance in regards to participant risk, informed consent and confidentiality.

Intentionally Identified: Subjects' names are identified in connection with the data when the research results are presented to the public. This procedure is common for journalistic-type interview studies, where subjects are public figures or in oral histories. Researchers must obtain explicit consent from the subjects for the use of their names in connection with their data.

Interaction: Includes communication or interpersonal contact between researchers and subjects.

Intervention: Collecting data through physical procedures (e.g., taking blood) and/or manipulation of the subject or the subject's environment for research purposes.

IRB Approval: The IRB has reviewed a research proposal and the research is approved to be conducted at a specified institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Legally Authorized Repre-sentative (LAR): An individual or other body authorized under Texas law to consent on behalf of a prospective subject to the subject's participation in the research procedures.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Neonate: Newborn (viable or non-viable).

Oral History: Tape-recorded historical information obtained in interviews involving personal experiences and recollections.

Parent: A child's biological or adoptive parent.

Permission: The agreement of parent(s) or guardian(s) to the participation of their child or ward in research.

Personally Identifiable Health Information: Health or medical data or information that can be linked to an individual, either directly or inferentially.

Personal and Potentially Sensitive: Examples include, but are not limited to: (a) information about sexual attitudes, preferences or practices; (b) the use of alcohol, drugs, or other addictive products; (c) information that could damage an individual's financial standing, employability or reputation; (d) information in a subject's medical record that could lead to social stigmatization or discrimination; (e) information about a subject's psychological well-being or mental healthcare; and/or other (f) records, such as medical, academic, photographic, audio and videotapes.

Population (*N*): A population is a collection of data whose properties are analyzed. The population is the complete collection to be studied, it contains all subjects of interest. It is the entire group one is interested in drawing conclusions about.

Principal Investigator: A Principal Investigator (PI) is the primary individual responsible for the preparation, conduct and administration of a: (a) research grant, (b) cooperative agreement, (c) training or public service project, (d) contract or (e) other sponsored project. PIs are responsible for ensuring that their research project is in compliance with applicable laws and regulations, including institutional policy.

Private Information: Any data that reveals a subject's identity or describes their behaviors or answers given during an experiment. Private information also includes information that is provided for a specific purpose (e.g., medical care or social services).

Protocol: The formal design or plan of an experiment or research activity.

Regulations: Regulations are rules that institutions issue that provide specific guidance regarding how they will implement pertinent laws. In regard to the IRB, regulations typically refer to Department of Health and Human Services' regulations on human subjects protection.

Remuneration: Payment for participation in research.

Research: Research is *the systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge* (45 CFR 46102(f)).

Right to Privacy: The right of individuals to decide for themselves how much they will share with others regarding their thoughts, feelings and facts of their personal lives.

Risk: The probability of harm or injury (physical, psychological, social or economic) occurring as a result of participation in a study. Both the probability and magnitude of possible harm may vary from minimal to significant.

Sample (*n*): A sample is a part of the population of interest, a sub-collection selected from a population.

Significant Risk: A study's design that presents a potential for serious risk to the health, safety or welfare of the subjects.

Scientific Research: Studies undertaken to contribute to the body of generalizable knowledge.

Subject Advocate: An individual who participates in the consent process on behalf of an adult subject who has not been declared legally incompetent, but whose ability to give informed consent is in question. The subject advocate should be a family member, close friend or someone who knows the subject well enough to attest to the subject's probable agreement to participate.

Survey Methodology: Includes, but is not limited to: (a) mail and online questionnaires, (b) telephone interviews, (c) personal interviews and (d) group questionnaires that seek to collect data from any population or sample of individuals.

Test Article: Any: (a) drug, biological product or medical device for human use, (b) human food or color additives, (c) electronic products or (d) any other article subject to FDA regulations.

Voluntary: Free from coercion duress or undue inducement. Voluntary is used in the research context to refer to a subject's decision to participate (and/or to continue participation) in a research activity.

Vulnerable Populations: Vulnerable populations include, but are not limited to: (a) pregnant women, human fetuses and neonates, (b) prisoners, (c) children and/or adolescents, (d) cognitively impaired persons, (e) economically and/or educationally disadvantaged, (f) AIDS/HIV+ individuals or (g) terminally ill individuals. The IRB follows the guidelines set forth by the Department of Health and Human Services, Criteria for IRB Approval of Research per 45 CFR 46.111.