Columbia
COLLEGE CHICAGO

Institutional Review Board

DEFINITIONS OF COMMONLY USED TERMS

anonymity: The condition achieved when the identities of subjects are confidential, or when the researcher does not know their names or any characteristics that might reasonably lead the researcher or anyone to discover their identities. The researcher cannot link the data to the participant.

autonomy: The personal capacity to consider alternatives, make choices, and act without undue influence or interference of others. Potential subjects have the right to decide whether to participate in the study, to decline to answer specific questions or engage in certain activities, and to withdraw from the study at any time.

Belmont Report (The): A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1979. The report was developed in response to concerns about research studies in which subjects had been placed at serious risk and sometimes seriously harmed. It describes three ethical principles: (1) respect for persons, (2) beneficence, and (3) justice.

beneficence: An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm. Researchers may not harm subjects. The risks and benefits of participating in a study must be clearly identified and explained to potential subjects. Researchers may not intentionally injure any person during the conduct of research, regardless of any possible benefits that may result.

benefit: A valued or desired outcome; an advantage. Something of positive value to the health or well-being of subjects. Benefits can be known, probable, or possible outcomes.

children: Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. Generally the law considers any person under 18 years old to be a child.

- Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- Guardian means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.
- Parent means a child's biological or adoptive parent.
- Permission means the agreement of parent(s) or guardian to the participation of their child or ward in research.

clandestine research: A study in which subjects do not know they are participating in a research study. Example: Tearoom Trade project.

classified research: See federal classified research.

cognitively impaired: A condition of having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

confidentiality: A condition that results when research participants' identities or characteristics are not revealed as a result of a study. The researcher may be able to identify a participant's data but will not reveal the participant's identity to anyone else.

Common Rule: The Federal Policy for the Protection of Human Subjects is referred to as the "Common Rule." The HHS regulations incorporate the Common Rule as Subpart A of 45 CFR 46.

co-researcher: A co-researcher may be a collaborator at UI&U or at another institution. In action research studies, participants are sometimes referred to as "co-researchers."

debriefing: A process through which subjects are given previously undisclosed information about the research project following completion of their participation in the research. (Note that this usage, which occurs within the behavioral sciences, departs from the standard meaning in which debriefing is obtaining rather than imparting information.)

deceptive research: A study in which subjects know they are participating in a research project, but they are not told its true purpose. Example: Milgrim's Shock Psychology study.

exempt/exemption (review for exemption): Research projects determined to meet exemption criteria are designated as "exempt" from the federal regulations for the protection of human subjects, as allowed by the regulations. Even though federal approval criteria and consent elements may not apply, ethical codes still apply. A class-related project may receive an exemption from IRB review if the project meets certain requirements.

expedited review: Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research [45 CFR §46.110].

federal classified research: Research, knowledge of the procedures, and results of which, is restricted to individuals with United States government security clearances.

focus group: A group (usually of six to ten people) convened to discuss a specific topic, conduct an evaluation, or test new ideas, etc. It usually involves group interviews.

full board review: Review of proposed research at a convened meeting at which a majority of the IRB members are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting [45 CFR §46.108].

HIPAA Privacy Rule: The Health Information Portability and Accountability Act (HIPAA), Privacy Act, establishes the conditions under which protected health information (PHI) may be used or disclosed by covered entities for research purposes. PHI includes information such as physician / psychologist notes, test results, genetic information, medical conditions, diagnoses, treatments, and medications.

human subject: A living individual about whom an investigator (whether professional or student) conducting research obtains: (1) Data through intervention or interaction with the individual, or (2) Identifiable private information. See intervention and private information.

informed consent: A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence [45 CFR §46.116; 21 CFR 50.20 and 50.25].

interaction: Communication or interpersonal contact between investigator and subject.

intervention: (1) Physical procedures by which data are gathered (for example, venipuncture) and (2) manipulations of the subject or the subject's environment performed for research purposes.

justice: An ethical principle discussed in The Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly. Injustice occurs when benefits of research are denied to participating subjects or when burdens of research are imposed unduly.

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.

pilot study (test): A mini version of a full-scale study and the pre-testing of a particular research instrument such as a questionnaire or interview questions. Also known as a feasibility study.

practice: An intervention or action designed to enhance the well-being of an individual, having a reasonable expectation of achieving that goal. Practice may include testing, diagnosis, teaching, preventive treatment, therapy, etc.

principal investigator (PI): The scientist or scholar with primary responsibility for the design and conduct of a research project.

prisoner: Any individual (minors or adults) involuntarily confined or detained in a penal institution. Individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing are included. Individuals in hospitals, alcohol / drug treatment facilities, work-release, or at-home detention programs are also included.

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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

protected health information (PHI): Individually identifiable health information such as physician / psychologist notes, test results, genetic information, medical conditions, diagnoses, treatments, and medications.

purpose: The purpose of a study is to find an answer to the research question. For learners, fulfillment of degree requirements is also a purpose.

research: "A systematic investigation (i.e., the gathering and analysis of information), including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." (please see 45 CFR §46.102 Definitions (d) Research.)

respect for persons: An ethical principle discussed in The Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected. Each potential participant has the right to decide whether to participate, to refuse to participate in some activities or respond to some questions, and to withdraw at any time for any reason.

risk: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." Risk can be a known, probable, or possible outcome. (See also minimal risk.)

surveys: Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.

third parties: Persons, such as relatives, friends, social acquaintances, or spouses, who are not participants in a research study but who may be discussed by a study participant. The third party becomes a human subject if and when the researcher obtains information about her/him that is both private and individually identifiable. The Common Rule then applies and requires informed consent of the subject. If certain criteria are met, the subject's informed consent may be waived.

Title 45 CFR Part 46: The section (Part 46) of Title 45 (Public Welfare) of the Code of Federal Regulations that addresses protection of human subjects.

variable (noun): An element or factor the research is designed to study, either as an experimental intervention or a possible outcome (or factor affecting the outcome) of that intervention.

voluntary: Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.