IRB GLOSSARY

Note: The following glossary is not intended to be a complete social science research glossary, but seeks to cover concepts that are important in the completion of IRB applications. This glossary does not include terms specific to medical research.

Adverse Effect: An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention.

Anonymity: A research condition in which no one, including the researcher, knows the identities of research subjects.

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

Atomistic Fallacy: The fallacy one commits when making inferences about groups or aggregates from individuals (see **Ecological Fallacy**).

Autonomy: The personal capacity subjects should possess in research conditions to consider alternatives, make choices, and act without undue influence or interference of others.

Biased Sample: A **sample** that is not representative of the **population** from which it was drawn (see **Representative Sample**).

Beneficence: An ethical principle that requires an obligation to protect research subjects 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.

Benefit: A valued or desired outcome; an advantage.

Case Study: A research strategy that focuses on one case (an individual, a group, an organization, etc.) within its social context during one time period.

Causal Hypothesis: A statement hypothesizing that the **independent variable** affects the **dependent variable** in some way.

Causal Relationship: A relationship where an **independent variable** affects a **dependent variable** in some way.

Children: Persons who have not yet attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted.

Claim: A statement, similar to a **hypothesis**, which is made in response to the research question at hand, and that is backed up with evidence based on research.

(Classic) Controlled Experiment: An **experimental design** with two or more randomly selected groups (an **experimental group** and **control group**) in which the researcher controls or introduces

the **independent variable** and measures the **dependent variable** at least two times (pre- and post-test measurements).

Closed-ended Questions: Survey questions that can only be answered in predetermined ways (for example, a scale of one to five measuring satisfaction with something).

Cluster Sample: A **probability sample** that is determined by randomly selecting clusters of people from a **population** and subsequently selecting every person in each cluster for inclusion in the **sample**.

Cognitively Impaired: 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. Capacity for **autonomy** and **voluntary participation** is thus impaired. Others, including people 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.

Cohort: A group of people born within a given time frame or experiencing a life event at approximately the same time.

Cohort Study: A specific kind of **trend study** involving the study of a **cohort** over time.

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

Competence: Used as a legal term to indicate a person's capacity to act on one's own behalf; a person's ability to understand information presented, to realize the consequences of acting (or not acting) on that information, and to make a choice (see **Incompetence** and **Incapacity**).

Confidentiality: A research condition in which no one except the researcher(s) knows the identities of the research **subjects**. The treatment of information that a subject has disclosed to the researcher in a relationship of trust and with the expectation that it will not be revealed to others in ways that violate the original agreement, unless permission is granted by the subject.

Content Analysis: The systematic and **quantitative study** of some form of communication (e.g. speeches, TV programs, newspaper articles, advertisements, etc.).

Confounding Factor: Any factor that might serve as an alternative explanation for a study's result; confounding factors include **non-randomized samples**, **selection bias**, and any arbitrary differences between people that are being compared.

Contraindicated: Disadvantageous, perhaps dangerous; a treatment that should not be used in certain individuals or conditions due to risks. For instance, a drug may be contraindicated for pregnant women and people with high blood pressure. Such individuals should not be involved in the study.

Control Group: The group in an **experimental design** that receives either no treatment or a different treatment from the **experimental group**. This group can thus be compared to the experimental group.

Convenience Sample: A **non-probability sample** that is determined by selecting subjects that are readily accessible (convenient) to the researcher, (examples in studies of Colorado College students might include going to an organizational meeting or hanging out outside of Rastall and asking students exiting the lunchroom to take a survey).

Correlational Relationship: A relationship where two **variables** are associated (this can be measured in terms of strength and direction using **statistical tests**) but not **causally related**. They vary together in some way, but the variation of one does not itself cause the variation of the other (see **Correlation Coefficient**).

Correlation Coefficient: A statistical measurement of the degree of **correlational relationship** between two variables. Values of correlation coefficients range from –1.00 to +1.00. A correlation coefficient of 0.00 indicates no relationship between the variables. Correlations approaching –1.00 or +1.00 indicate strong relationships between the variables.

Cross-Over Design: Same as **Within-Subjects Design**.

Debriefing: After running a study, explaining to a participant what happened and what the study is for, explaining any **deception** used in the study, asking for any remaining comments or concerns, and ensuring that the participant is left with no adverse consequences from the experience. This sometimes involves providing contact information for groups that can provide support regarding a difficult issue.

Deception: The intentional withholding of information from participants, or deception about the study's purpose and exact nature, that is deemed necessary by the researcher in order to meet the study's goals. Deception should only be used when the researcher feels that participant knowledge about the study would alter participants' behavior or responses in the study. Deception should not cause any adverse consequences to the participants, and participants should be **debriefed** after running the study. **IRB** guidelines on the use of deception should be reviewed. A study that cannot justify the use of deception may not receive IRB approval.

Demand Characteristics: A bias that results when participants display characteristics because they are aware that they are being observed.

Dependent Variable: A **variable** that varies due (at least in part) to the impact of the **independent variable** – that is, its value "depends" on the value of the independent variable. In the variables "sex" and "academic major," academic major is the dependent variable, meaning that your major can't determine whether you are male or female, but your sex might indirectly lead you to favor one major over another (nationally, men tend to major in engineering, women in education).

Descriptive Study: Any study that is not truly experimental (*e.g.*, quasi-experimental studies, correlational studies, record reviews, case histories, and observational studies).

Double-Blind Design: An experiment in which neither the participants nor the research staff who interact with them knows the memberships of the **experimental** or **control** groups. Also known as **Double-Masked Design** (see **Single-Blind Design** and **Open Design**).

Double-Masked Design: Same as **Double-Blind Design**.

Ecological Fallacy: The fallacy one commits when making inferences about individuals from information about groups or aggregates (See **Atomistic Fallacy**).

Emancipated Minor: A legal status given to those individuals who have not yet attained the age of legal **competency** as defined by state law, but who are entitled to adult treatment because of assuming adult responsibilities such as being self-supporting and not living at home, marriage, or procreation (see **Mature Minor**).

Equitable: Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed (see **Justice**).

Ethical Research: Research that follows widely held guidelines about what is ethical, moral and responsible in research settings (e.g. not plagiarizing others' work, not misreporting sources, not submitting questionable data, not destroying or concealing sources, etc.) and that considers its role in the broader community and the effect of its findings on the community.

Ethnographic Research: Ethnography is the study of people and their cultures. Ethnographic research involves observation of and interactions with the people or group being studied in the group's own environment, often for long periods of time (see **Field Research**).

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.

Experimental: Term used to denote a therapy (drug, device, procedure) that is unproven or not yet scientifically validated in terms of safety and efficacy. A procedure may be considered "experimental" without necessarily being part of a formal study to evaluate its usefulness.

Experimental Design: A study design that calls for the control or manipulation of the **independent variable** in some way. A study design in which subjects are randomly assigned to **experimental groups** and receive treatment in the form of the independent variable.

Experimental Group: The group in an **experimental design** study that receives treatment in the form, or in various forms, of the **independent variable**. This group can thus be compared to the **control** group.

False Negative: Same as **Type II Error**.

False Positive: Same as **Type I Error**.

Federal Policy (The): The federal policy that provides regulations for the involvement of human subjects in research. The Policy applies to all research involving human subjects that is conducted, supported, or otherwise subject to regulation by any federal department or agency.

Field Research: Behavioral, social, or anthropological research involving the study of people or groups in their own environment and without manipulation for research purposes. Research conducted in natural, real-life settings, outside the laboratory. This involves observation and, in many cases, interactions with the people being studied (see **Ethnographic Research**).

Full Board Review: Review of proposed research at a convened meeting at which the majority of the **IRB** members are present, including 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.

Generalizability: The ability to apply the results of a specific study to groups or situations beyond those actually studied.

Guardian: An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care.

Historical Controls: Control subjects (followed at some time in the past or whose data are available through records) who are used for comparison with subjects being treated concurrently. The study is considered historically controlled when the present condition of subjects is compared with their own condition on a prior regimen or treatment.

Human Subjects: Individuals whose physiological or behavioral characteristics and responses are the object of study in a research project. Under federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

Hypothesis: A testable statement of how two or more **variables** are expected to be related to one another.

Incapacity: Refers to a person's mental status and means the inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice (see **Incompetence**).

Incompetence: Used as a legal term to indicate the inability to manage one's own affairs.

Independent Variable: The conditions of an experiment that are systematically manipulated by the investigator. A **variable** that is not impacted by the **dependent variable**, and that itself impacts the dependent variable. In the earlier example of "sex" and "academic major," (see **Dependent Variable**) sex is the independent variable.

In-Depth Interview: A method of data collection in which a participant is interviewed in detail about a certain research subject. In this format, the interviewer leads the discussion flexibly along some pre-structured topics, but also allows the participant to expand upon topics in-depth and to explore new avenues of discussion.

Informant: In field research, a person who is "native" to the social situation being studied, who assists the researcher by providing insider information and serving as a go-between.

Informed Consent: The principle that potential **subjects** are given adequate and accurate information about a study before they are asked to agree to participate, and that they do in fact agree (consent) to participate. In giving informed consent, subjects many 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.

Institutional Review Board (IRB): A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

Institutionalized: Confined, either voluntarily or involuntarily (*e.g.*, a hospital, prison, or nursing home).

Institutionalized Cognitively Impaired: Persons who are confined, either voluntarily or involuntarily, in a facility for the care of the mentally or otherwise disabled (*e.g.* a psychiatric hospital, home, or school for the mentally disabled).

Investigator: In clinical trials, the individual who actually conducts the investigation (see **Principal Investigator**).

Justice: An ethical principle that requires fairness in the distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly (see **Equitable**).

Legally Authorized Representative: A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human subjects research this refers to an individual (or judicial) authorized under applicable law to consent on behalf of a subject to the subject's participation in the research.

Longitudinal Study: A study in which data are collected from the same **sample** at least two different times. A study designed to follow subjects through time.

Mature Minor: Someone who has not reached adulthood (as defined by state law) but who may be treated as an adult for certain purposes (*e.g.* consenting to medical care). A mature minor is not necessarily an **emancipated minor** (see **Emancipated Minor**).

Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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. The definition of minimal risk for research involving prisoners differs somewhat from that given for non-**institutionalized** adults (see **Risk**).

Monitoring: The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design and subject protections.

Multistage Sample: A **probability sample** that involves several stages (and frequently a **cluster sampling** stage), such as randomly selecting clusters from a **population**, then randomly selecting people from each of the clusters.

Non-affiliated Member: Member of an **Institutional Review Board** who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community (*e.g.*, minister, business person, attorney, teacher).

Non-probability Sample: A subset of the **population** chosen in a way that does not give every member of the population a known (nonzero) chance of being selected.

Non-therapeutic Research: Research that has no likelihood or intent of producing a diagnostic, preventive, or therapeutic benefit to the current subjects, although it may benefit subjects with a similar condition in the future.

Non-response Bias: The bias that results from differences between those who agree to participate in a **survey** and those who don't.

Null Hypothesis: The proposition, to be tested statistically, that the experimental intervention has "no effect," meaning that the **treatment** and **control groups** will not differ as a result of the intervention. Investigators usually hope that the data will demonstrate some effect from the intervention, thus allowing the investigator to reject the null hypothesis.

Observational Techniques:

> **Participant Observation:** Observation performed by an observer who takes part in the activities he or she observes.
>
> **Non-participant Observation:** Observation performed by an observer who remains as distant as possible from those being observed.

Open Design: An experimental design in which both the investigator(s) and the subjects know the treatment group(s) to which subjects are assigned (see **Double-Blind Design** and **Single-Blind Design**).

Open-ended Questions: Survey questions that allow respondents to answer in their own words. (All **in-depth interviews** use open-ended questions.)

Operational Definition: Statements of the specific ways in which the absence, presence, and/or the degree of presence of a phenomenon will be determined in a specific research process.

Paternalism: Making decisions for others against or apart from their wishes with the intent of doing them good.

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

Placebo: A chemically inert substance (*e.g.*, sugar pills) given to **control groups** as if it were the medicine or **treatment** for its psychologically suggestive effect; it is used in controlled clinical

trials to determine whether improvement and side effects may reflect imagination or anticipation rather than actual power of a drug.

Principal Investigator: The scientist or scholar with primary responsibility for the design and conduct of a research project (see **Investigator**).

Population: The entire group (or set or type) of people from which a researcher samples, and to which she or he would ideally like to generalize.

Prisoner: An individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statue; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities.

Privacy: A person's capacity to control the extent, timing, and circumstances of shared oneself (physically, behaviorally, or intellectually) with others.

Probability Sample: A subset of the **population** chosen in such a way that every member of the population has a known (nonzero) chance of being selected into the sample.

Prospective Studies: Studies designed to observe outcomes or events that occur after the group of subjects has been identified. Prospective studies do not have to involve manipulation or intervention but may be purely observational or involve only the collection of data instead.

Protocol: The formal design or plan of an experiment or research activity; specifically, the plan submitted to an **IRB** for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Qualitative Research: The collection of non-numerical data. Often multi-method in focus, qualitative research involves an interpretive, meaning-driven approach to its subject matter.

Quantitative Research: The collection of numerical data in order to describe, explain, predict and/or control phenomena of interest.

Quasi-experiment: An **experimental design** that is missing one or more aspects of the **(classic) controlled experiment**.

Questionnaire: A data collection method in which participants read and answer questions in a written format.

Random Sample: A specific type of **probability sample** in which subjects are selected from a population list using a table of random numbers or a random number generator. (A random sample requires a list of **population** members in which each member can be assigned a discrete number.) The assignment of subjects to different treatments, interventions, or conditions according to chance, rather than systematically. Random assignment of subjects increases the probability that differences observed between subject groups are the result of the experimental intervention.

Repeated Measures Design: Same as **Within-Subjects Design**.

Reliability: The degree to which a measure yields consistent results.

Remuneration: Payment for participation in research; this is different from **compensation**, which typically refers to payment for research-related injuries (see **Compensation**).

Representative Sample: A **sample** in which the participants closely match the characteristics of the **population**, and thus, all segments of the population are represented in the sample. A representative sample allows results to be generalized from the sample to the population.

Research: A systematic investigation (*i.e.*, the gathering and analysis of information) designed to develop or contribute to generalizable knowledge.

Respect for Persons: An ethical principle requiring that individual **autonomy** be respected and that persons with diminished autonomy be protected (see **Cognitively Impaired, Incompetence**, and **Incapacity**).

Retrospective Studies: Research conducted by reviewing records from the past (*e.g.*, birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. **Case studies** are an example of this type of research.

Review (of Research): The concurrent oversight of research on a periodic basis by an IRB. In addition to the at least annual reviews mandated by the federal regulations, reviews may, if deemed appropriate, also be conducted on a continuous or periodic basis.

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 (see **Minimal Risk**).

Sample: A subset of a given **population** used for research purposes.

Selection Bias: A bias in the way the **experimental** and **control** or comparison groups are selected, resulting in pre-existing differences between the groups that may serve as **confounding factors**.

Single-Blind Design: Typically, a study design in which the investigator, but not the subject, knows the identity of the treatment assignment. Occasionally the subject, but not the investigator, knows the assignment. Also known as **Single-Masked Design** (see **Double-Blind Design** and **Open Design**).

Single-Masked Design: See **Single-Blind Design**.

Site Visit: A visit by agency officials, representatives, or consultants to the location of a research activity to assess the adequacy of **IRB** protection of human subjects or the capability of personnel to conduct the research.

Snowball Sample: A **non-probability sample** that is created by using members of the group of interest to identify other members of the group (for example, asking a subject at the end of an interview for suggestions about who else to interview).

Social Experimentation: Systematic manipulation of, or experimentation in, social or economic systems; used in planning public policy.

Statistical Tests: Researchers use statistical tests to make **quantitative** decisions about whether a study's data indicate a significant effect from the intervention and allow the researcher to reject the **null hypothesis**. That is, statistical tests show whether the differences between the outcomes of the **control** and **experimental** groups are great enough to be **statistically significant**. If differences are found to be statistically significant, it means that the probability (or likelihood) that these differences occurred solely due to chance is relatively low. Most researchers agree that a significance value of .05 or less (there is a 95% probability that the differences are real) sufficiently determines significance.

Statistical Significance: The probability that difference between the outcomes of the **control** and **experimental** group are great enough that it is unlikely it is due solely to chance. The probability that the **null hypothesis** can be rejected at a predetermined significance level (0.05 or 0.01).

Stratified Sample: A **probability sample** that is determined by dividing the **population** into groups or strata defined by the presence of certain characteristics and then **random sampling** from each of the strata. This is a good way to make sure that a student sample is racially diverse (for instance).

Structured Interview: A data collection method in which an interviewer reads a standardized interview schedule to the respondent and records the answers. (Not to be confused with an **in-depth interview**.)

Subjects/Respondents: Research participants, who fill out a **survey**, are interviewed, participate in an experiment, are observed in a naturalistic setting, or who are otherwise studied.

Survey: A study in which the same data are collected from all members of the **sample** using a highly structured **questionnaire** and analyzed using **statistical tests**.

Systematic Sample: A probability sample that is determined by selecting every 'nth' (5^{th}, 10^{th}, 50^{th}, etc.) person from a list of the entire **population**, after the first person has been randomly selected.

Theory: A general explanation about a specific behavior or set of events that is based on known principles and serves to organize related events in a meaningful way. A theory is not as specific as a **hypothesis**.

Treatment Group: Same as **Experimental Group**.

Type I Error: When a test wrongly shows an effect or condition to be present (*e.g.* that a woman is pregnant when, in fact, she is not). When a researcher falsely rejects the **null hypothesis** (see **False Positive**).

Type II Error: When a test wrongly shows an effect or condition to be absent (*e.g.* that a woman is not pregnant when, in fact, she is). When a researcher fails to reject the **null hypothesis** (see **False Negative**).

Validity: The degree to which a measure assesses what we think it is assessing. There are different types of validity, including:
Internal validity (does a study's conclusions about **causal relationships** agree with what is actually true?)
Face validity (at face value, does the measure seem valid?)
Construct validity (does the measure of a given concept relate to a measure of another theoretically associated concept?)
Content validity (does the measure cover diverse meanings of the concept?)
Criterion validity (is the measure associated with expected behaviors?)

Variable: Any characteristic or trait that can vary from one person to another (race, sex, academic major) or for one person over time (age, political beliefs).

Voluntary Participation: The principle that study participants choose to participate of their own free will, rather than being coerced or forced to participate. For **IRB** purposes, this is a key part of your study proposal; you must demonstrate that subjects will be participating voluntarily for a study to be approved by the IRB.

Within-Subjects Design: A research design in which each subject experiences, at different times, all levels of the **independent variable** (or both the **experimental** and **control treatment**). Thus, each subject is tested once in each condition (see **Cross-Over Design** and **Repeated Measures Design**).