Glossary of Commonly Used Terms in Research Ethics (and Compliance*)

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A

Accountability: taking personal responsibility for one's conduct.

Accreditation: a process in which an accrediting body determines whether an institution or organization meets certain standards developed by the body. For example, the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) accredits animal research programs, and the Association for the Accreditation of Human Research Protection Programs (AAHRPP) accredits human subjects research programs.

Adverse event (AE): a medically undesirable event occurring in a research subject, such as an abnormal sign, symptom, worsening of a disease, injury, etc. A serious adverse event (SAE) results in death, hospitalization (or increased hospital stay), persistent disability, birth defect, or any other outcome that seriously jeopardizes the subject's health. AEs which are also unanticipated problems should be reported promptly to institutional review boards and other appropriate officials.

Animal care committee: see Institutional Animal Care and Use Committee (IACUC).

Animal rights: the view that (non-human) animals have moral or legal rights. Proponents of animal rights tend to regard animal experimentation as unethical because animals cannot consent to research.

Animal welfare: 1. The health and well-being of animals. 2. The ethical obligation to protect and promote animal welfare in research. Factors affecting animal welfare include: food, water, housing, climate, mental stimulation, and freedom from pain, suffering, disease, and disability. See also Three Rs.

Asilomar Conference: a meeting of scientists, held in Asilomar, CA in 1975, who were involved in development recombinant DNA techniques concerning the oversight of responsible use of this technology. The scientists recommended the development of safety protocols as a means of protecting laboratory workers and the public from harm.

Assent: a subject's affirmative agreement to participate in research. Assent may take place when the subject does not have the capacity to provide informed consent (e.g. the subject is a child or mentally disabled) but has the capacity to meaningfully assent. See Informed Consent.

Audit: a formal review of research records, policies, activities, personnel, or facilities to ensure compliance with ethical or legal standards or institutional policies. Audits may be conducted regularly, at random, or for-cause (i.e., in response to a problem).

Author: a person who makes a significant contribution to a creative work. Many journal guidelines define an author as someone who makes a significant contribution to 1) research conception and design, 2) data acquisition, or 3) data analysis or interpretation; and who drafts or critically reads the paper and approves the final manuscript.

Authorship, ghost: failing to list someone as an author on a work even though they have made a significant contribution to it.

Authorship, honorary: receiving authorship credit when one has not made a significant contribution to the work.

Autonomy: 1. the capacity for self-governance, i.e., the ability to make reasonable decisions. 2. A moral principle barring interference with autonomous decision-making. See Decision-making capacity.

B

Bad apples theory: the idea that most research misconduct is committed by individuals who are morally corrupt or psychologically ill. This idea can be contrasted with the view that social, financial, institutional, and cultural factors play a major role in causing research misconduct. See Culture of integrity.

Belmont Report: A report issued by the U.S. National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research in 1979, which has had a significant influence over human subjects research ethics, regulation, and policy. The report provided a conceptual foundation for the Common Rule and articulated three principles of ethics: respect for persons, beneficence, and justice.

Beneficence: the ethical obligation to do good and avoid causing harm. See also Belmont Report.

Benefit: a desirable outcome or state of affairs, such as medical treatment, clinically useful information, or self-esteem. In the oversight of human subjects research, money is usually not treated as a benefit.

Bias: the tendency for research results to reflect the scientist's subjective opinions, unproven assumptions, political views, or personal or financial interests, rather than the truth or facts. See also Conflict of Interest.

Biobank: a repository for biological specimens used in research. Biobanks may share specimens with other researchers if they

agree to certain conditions for using those specimens.

Bioethics: the study of ethical, social, or legal issues arising in biomedicine and biomedical research.

C

Censorship: taking steps to prevent or deter the public communication of information or ideas. In science, censorship may involve prohibiting the publication of research or allowing publication only in redacted form (with some information removed).

Citation amnesia: failing to cite important work in the field in a paper, book, or presentation.

Classified research: research that the government keeps secret to protect national security. Access to classified research is granted to individuals with the appropriate security clearance on a need-to-know basis.

Clinical investigator: a research involved in conducting a clinical trial.

Clinical trial: an experiment designed to test the safety or efficacy of a type of therapy (such as a drug).

Clinical trial, active controlled: a clinical trial in which the control group receives a treatment known to be effective. The goal of the trial is to compare different treatments.

Clinical trial, placebo controlled: a clinical trial in which the control group receives a placebo. The goal of the trial is to compare a treatment to a placebo.

Clinical trial, phases: sequential stages of clinical testing, required by regulatory agencies, used in the development of medical treatments. Pre-clinical testing involves experiments on animals or cells to estimate safety and potential efficacy. Phase I trials are small studies (50-100 subjects) conducted in human beings for the first time to assess safety, pharmacology, or dosing. Phase I studies are usually conducted on healthy volunteers though some are conducted on patients with terminal diseases, such as cancer patients. Phase II trials are larger studies (500 or more subjects) conducted on patients with a disease to assess safety and efficacy and establish a therapeutic dose. Phase III trials are large studies (up to several thousand subjects) conducted on patients to obtain more information on safety and efficacy. Phase IV (or post-marketing) studies are conducted after a treatment has been approved for marketing to gather more information on safety and efficacy and to expand the range of the population being treated.

Clinical trial, registration: providing information about a clinical trial in a public registry. Most journals and funding agencies require that clinical trials be registered. Registration information includes the name of the trial, the sponsor, study design and methods, population, inclusion/exclusion criteria, and outcome measures.

Clinical utility: the clinical usefulness of information, e.g., for making decisions concerning diagnosis, prevention, or treatment.

***Code of Ethics**: Institutional policy for all employees outlining expectations and standards of workplace behavior.

Coercion: using force, threats, or intimidation achieve compliance.

Collaboration agreement: an agreement between two or more collaborating research groups concerning the conduct of research. The agreement may address the roles and responsibilities of the scientists, access to data, authorship, and intellectual property.

Commercialization: the process of developing and marketing commercial products (e.g., drugs, medical devices, or other technologies) from research. See also Copyrights, Intellectual Property, Patents.

Common law: a body of law based on judicial decisions and rulings.

Common Rule: The U.S. Department of Health and Human Services regulations (45 CFR 46) for protecting human subjects, which has been adopted by 17 federal agencies. The Common Rule includes subparts with additional protections for children, neonates, pregnant women and fetuses, and prisoners.

Community review: a process for involving a community in the review of research conducted on members of the community. Some research studies include community advisory boards as a way of involving the community.

Competence: the legal right to make decisions for one's self. Adults are considered to be legally competent until they are adjudicated incompetent by a court. See Decision-making capacity.

***Compliance**: in research, complying with laws, institutional policies and ethical guidelines related to research.

***Complainant:** the person who raises charges of research misconduct against another person(s). See Respondent.

Confidentiality: the obligation to keep some types of information confidential or secret. In science, confidential information typically includes: private data pertaining to human subjects, papers or research proposals submitted for peer review, personnel records, proceedings from misconduct inquiries or investigations, and proprietary data. See also Privacy.

Conflict of interest (COI): a situation in which a person has a financial, personal, political or other interest which is likely to bias his or her judgment or decision-making concerning the performance of his or her ethical or legal obligation or duties.

Conflict of interest, apparent or perceived: a situation in which a person has a financial, personal, political or other interest that is not likely to bias his or her judgment or decision-making concerning the performance of his or her ethical or legal obligation or duties but which may appear to an outside observer to bias his or her judgment or decision-making.

Conflict of interest, institutional: a situation in which an institution (such as a university) has financial, political, or other interests which are likely to bias institutional decision-making concerning the performance of institutional ethical or legal duties.

Conflict of interest, management: strategies for minimizing the adverse impacts of a conflict of interest, such as disclosure, oversight, or recusal/prohibition.

Consent: See Informed consent.

Consequentialism: an approach to ethics, such as utilitarianism, which emphasizes maximizing good over bad consequences resulting from actions or policies.

Continuing review: in human subjects research, subsequent review of a study after it has been approved by an IRB. Continuing review usually happens on an annual basis.

Copyright: a right, granted by a government, which prohibits unauthorized copying, performance, or alteration of creative works. Copyright laws include a fair use exemption which allows limited, unauthorized uses for non-commercial purposes.

Correction (or errata): fixing a minor problem with a published paper. A minor problem is one that does not impact the reliability or integrity of the data or results. Journals publish correction notices and identify corrected papers in electronic databases to alert the scientific community to problems with the paper. See also Retraction.

***Culture of integrity**: the idea that the institutional culture plays a key role in preventing research misconduct and promoting research integrity. Strategies to promote a culture of integrity include education and mentoring in the responsible conduct of research; research policy development; institutional support for research ethics oversight, consultation, and curriculum development; and ethical leadership.

D

Data: recorded information used to test scientific hypotheses or theories. Data may include laboratory notebooks (paper or digital), field notes, transcribed interviews, spreadsheets, digital images, x-ray photographs, audio or video recordings, and outputs from machines (such as gas chromatographs or DNA sequencers). Original (or primary data) is drawn directly from the data source; secondary (or derived) data is based on the primary data.

***DATA**: Digital Accountability and Transparency Act

Data auditing: See Audit.

Data and safety monitoring board (DSMB): a committee that monitors data from human subjects research to protect participants from harm and promote their welfare. DSMBs may recommend to an institutional review board that a study be stopped or altered.

Data imputation: use of statistical methods to fill in or replace missing or lost data. Imputation is not considered to be fabrication if it is done honestly and appropriately.

Data management: Practices and policies related to recording, storing, auditing, archiving, analyzing, interpreting, sharing, and publishing data.

Data outlier: a data point that is more than two standards deviations from the mean. Removal of outliers without articulating a legitimate reason may constitute data, falsification.

Data use agreement (DUA): an agreement between institutions for the sharing and use of research data.

Deception: in human subjects research, using methods to deceive subjects about the goals and nature of a study or the methods, tests, interventions, or procedures used in the study. See also Placebo, Observer effect.

***Deciding Official (DO)**: The DO is the institutional official who makes final determinations on allegations of research misconduct and on any institutional administrative action that may be taken as a result of the misconduct proceedings.

Decision-making capacity (DMC): the ability to make sound decisions. DMC is often situational and comes in degrees: for example, a person may be able to order food from a menu but not be able to make a decision concerning complex medical treatment. Factors that can compromise DMC include mental illness or disability, extreme emotional stress, drugs, age, or serious physical illness. DMC is not the same as legal competence: a demented adult may be legally competent but lack DMC.

De-identified data or samples: data or biological samples which have been stripped of information, such as name or medical record number, which personally identifies individuals.

Deontology: an approach to ethics, such as Kantianism, which emphasizes adherence to rules or principles of conduct.

Discrimination: treating people differently based on irrelevant characteristics, such as skin color, ethnicity, or gender.

Double-blinding: processes used to prevent human subjects research and researchers from discovering who is receiving an experimental treatment vs. a placebo. Double-blinding is used to control for the placebo effect.

Dual use research (of concern) [DURC]: research that can be readily used for beneficial or harmful purposes.

Duplicate publication: republishing the same paper or data without proper acknowledgment.

E

Emergency research: in human subjects research, research that is conducted when a subject who cannot provide informed consent faces a life-threatening illness that requires immediate treatment and has no available legally authorized representative to provide consent. The Food and Drug Administration has developed special rules for emergency research involving products that it regulates.

***Environmental Health and Safety (EHS)**: An office or department that oversees typical laboratory safety concerns (e.g., chemicals, select agents, fire, bloodborne pathogens, personal protective equipment – PPE).

Error: an unintended adverse outcome; a mistake.

Ethical dilemma: A situation in which two or more potential actions appear to be equally justifiable from an ethical point of view, i.e., one must choose between the lesser of two evils or the greater of two goods.

Ethical reasoning: Making a decision in response to a moral dilemma based a careful and thorough assessment of the different options in light of the facts and circumstances and ethical considerations.

Ethical relativism: The view that ethical standards are relative to a particular culture, society, historical period, etc. When in Rome, do as the Romans do. See Ethical universalism.

Ethical theory: A set of statements that attempts to unify, systematize, and explain our moral experience, i.e. our intuitions or judgments about right/wrong, good/bad, etc. See Kantianism, Utilitarianism, Virtue ethics.

Ethical universalism: The view that the same standards of ethics apply to all people at all times.

Ethics (or morals): 1. Standards of conduct (or behavior) that distinguish between right/wrong, good/bad, etc. 2. The study of standards of conduct.

Ethics, applied: The study of ethics in specific situations, professions, or institutions, e.g. medical ethics, research ethics, etc.

Ethics, meta-: The study of the meaning, truth, and justification of ethical statements.

Ethics, normative vs. descriptive: Normative ethics studies the standards of conduct and methods of reasoning that people ought to follow. Descriptive ethics studies the standards of conduct and reasoning processes that people in fact follow. Normative ethics seeks to prescribe and evaluate conduct, whereas descriptive ethics seeks to describe and explain conduct. Disciplines such as philosophy and religious studies take a normative approach to ethics, whereas sociology, anthropology, psychology, neuroscience, and evolutionary biology take a descriptive approach.

Exempt research: human subjects research which is exempted from review by an institutional review board. Some types of exempt research include research on existing human samples or data in which the researcher cannot readily identify individuals and anonymous surveys of individuals.

Exculpatory language: language in an informed consent form, contract, or other document intended to excuse a party from legal liability.

Expedited review: in human subjects research, review of a study by the chair of an institutional review board (or designee) instead of by the full board. Expedited review may be conducted on new studies that pose minimal risks to subjects, for continuing review in which a study is no longer recruiting subjects, or on amendments to approved studies that make only minor changes.

Exploitation: taking unfair advantage of someone else.

***Export Control**: The U.S. Government controls exports of sensitive equipment, software and technology as a means to promote national security interests and foreign policy objectives.

Expression of concern: a journal may publish an expression of concern when a paper has come under suspicion for wrongdoing or is being investigated for possible research misconduct.

F

Fabrication: making up data or results.

***False Claims Act**: "Lincoln's Law"- an American federal law that imposes liability on persons and companies (typically federal contractors) who defraud governmental programs. It is the federal Government's primary tool in combating fraud against the Government.

Falsification: changing, omitting, or manipulating data or results deceptively; or deceptive manipulation of research materials or experiments.

Food and Drug Administration (FDA): a federal agency in charge of approving the marketing of drugs, biologics, medical devices, cosmetics, and food additives. The FDA has adopted human subjects research regulations which are similar to the Common Rule; however, the FDA rules do not allow exceptions from informed consent requirements unless a study qualifies as Emergency research.

Fraud: knowingly misrepresenting the truth or concealing a material (or relevant) fact in order to induce someone to make a decision to his or her detriment. Some forms of research misconduct may also qualify as fraud.

Freedom of Information Act (FOIA): a law enacted in the U.S. and other countries which allows the public to obtain access to government documents, including documents related to government-funded scientific research, such as data, protocols, and emails. Several types of documents are exempt from FOIA requests, including classified research and confidential information pertaining to human subjects research.

G

***Genome Data Sharing (GDS) Policy:** Sharing research data supports the NIH mission and is essential to facilitate the translation of research results into knowledge, products, and procedures that improve human health. To set forth expectations that ensure the broad and responsible sharing of genomic research data, NIH issued the Genomic Data Sharing (GDS) Policy in August 2014 and it became effective on January 25, 2015. **http://gds.nih.gov/**

Good clinical practices (GCPs): rules and procedures for conducting clinical trials safely and rigorously.

Good laboratory practices (GLPs): rules and procedures for designing and performing experiments or tests and recording and analyzing data rigorously. Some types of research are required by law to adhere to GLPs.

Good record-keeping practices (GRKPs): rules and procedures for keeping research records. Records should be thorough, accurate, complete, organized, signed and dated, and backed-up.

Guideline: a non-binding recommendation for conduct.

H

Harassment: repeatedly annoying, bothering, or intimidating someone.

Harassment, sexual: harassment involving unwelcome sexual advances or remarks or requests for sexual favors.

Helsinki Declaration: ethical guidelines for conducting medical research involving human subjects research adopted by the World Medical Association.

Honesty: the ethical obligation to tell the truth and avoid deceiving others. In science, some types of dishonesty include data fabrication or falsification, and plagiarism.

Human subjects research: research involving the collection of data through interaction with a living individual or collection of private information concerning a living individual. See also Research Subject.

I

Incidental finding: information inadvertently discovered during medical treatment or research which was not intentionally sought. For example, if a research subject receives an MRI as part of brain imaging study and the researcher notices an area in the fontal cortex that appears to be a tumor this information would be an incidental finding.

Individualized research results: in human subjects research, results pertaining to a specific individual in a study, such as the subject's pulse, blood pressure, or the results of laboratory tests (e.g., blood sugar levels, blood cell counts, genetic or genomic variants). Individualized results may include intended findings or incidental findings. There is an ongoing ethical controversy concerning whether, when, and how individualized research results should be shared with human subjects research. Some argue that individualized results should be returned if they are based on accurate and reliable tests and have clinical utility, because inaccurate, unreliable, or uncertain results may be harmful. Others claim that the principle of autonomy implies that subjects should be able to decide whether to receive their results.

Informed consent: the process of making a free and informed decision (such as to participate in research). Individuals who provide informed consent must be legally competent and have enough decision-making capacity to consent to research. Research regulations specify the types of information that must be disclosed to the subject. See also Assent.

Informed consent, blanket (general): a provision in an informed consent document that gives general permission to researchers to use the subject's data or samples for various purposes and share them with other researchers.

Informed consent, documentation: a record (such as a form) used to document the process of consent. Research regulations require that consent be documented; however, an institutional review board may decide waive documentation of consent if the research is minimal risk and 1) the principle risk of the study is breach of confidentiality and the only record linking the subject to the study is the consent form or 2) the research involves procedures that normally do not require written consent outside of the research context.

Informed consent, specific: a provision in an informed consent document that requires researchers to obtain specific permission from the subject prior to using samples or data for purposes other than those that are part of the study or sharing them with other researchers.

Informed consent, tiered: provisions in an informed consent document that give the subject various options concerning the use and sharing of samples or data. Options may include blanket consent, specific consent, and other choices.

Informed consent, waiver: in human subjects research, the decision by an institutional review board to waive (or set aside) some or all of the informed consent requirements. Waivers are not usually granted unless they are necessary to conduct the research and pose minimal risks to the subjects.

Institutional Animal Care and Use Committee (IACUC): a committee responsible for reviewing and overseeing animal research conducted at an institution. IACUCs usually include members from different backgrounds and disciplines, with institutional and outside members, scientists and non-scientists.

***Institutional Biosafety Committee (IBC)**: a committee responsible for reviewing and overseeing research involving recombinant DNA (rDNA) or synthetic DNA as described in the **NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules**, and non-recombinant DNA research involving infectious agents classified as Risk Group 2, 3, and 4 in the NIH Guidelines, Appendix B.

Institutional Review Board (IRB): a committee responsible for reviewing and overseeing human subjects research. An IRB may also be called a research ethics committee (REC) or research ethics board (REB). IRBs usually include members from different backgrounds and disciplines, with institutional and outside members, scientists and non-scientists.

Intellectual property: legally recognized property pertaining to the products of intellectual activity, such as creative works or inventions. Forms of intellectual property include copyrights on creative works and patentson inventions.

J

Justice: 1. treating people fairly. 2. An ethical principle that obligates one to treat people fairly. Distributive justice refers to allocating benefits and harms fairly; procedural justice refers to using fair processes to make decisions that affect people; formal justice refers to treating similar cases in the same way. In human subjects research, the principle of justice implies that subjects should be selected equitably. See also Belmont Report.

***Just in time (JIT)**: a notice of impending award success from NIH that requires verification of certain compliance elements before the award can be fully executed.

K

Kantianism: An ethical theory developed by German philosopher Immanuel Kant (1724-1804), which holds that the right thing to do is to perform one's duty for duty's sake. One's duty is defined by an ethical principle known as the categorical imperative (CI). According to one version of the CI, one should act according to a maxim that could become a rule for all people. According to another version, one should always treat people as having inherent moral value (or dignity) and never only as objects or things to be used to achieve some end.

L

Law: a rule enforced by the coercive power of the government. Laws may include statutes drafted by legislative bodies (such as Congress), regulations developed and implemented by government agencies, and legal precedents established by courts.

Legal authorized representative (LAR): a person, such as a guardian, parent of a minor child, health care agent, or close relative, who is legally authorized to make decisions for another person when they cannot make decisions for themselves. LARs may also be called surrogate decision-makers. See Competence, Decision-making capacity.

M

Material transfer agreement (MTA): an agreement between institutions for the transfer and use of research materials, such as cells or reagents.

Media embargo: a policy, adopted by some journals, which allows journalists to have access to a scientific paper prior to publication, provided that they agree not to publicly disclose the contents of the paper until it is published. Some journals will refuse to publish papers that have already appeared in the media.

***Mentee**: See Mentor below.

***Mentor**: someone who provides education, training, guidance, critical feedback, or emotional support to a student or trainee (i.e., mentee). In science, a mentor may be the student's advisor but need not be.

Minimal risk: a risk that is not greater than the risk of routine medical or psychological tests or exams or the risk ordinarily encountered in daily life activities.

***Misconduct**: See Research misconduct. Corporate misconduct is not necessarily research misconduct and vice versa.

Mismanagement of funds: spending research funds wastefully or illegally; for example, using grant funds allocated for equipment to pay for travel to a conference. Some types of mismanagement may also constitute fraud or embezzlement.

***Montreal Statement**: The Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations was developed as a follow-up to the Singapore Statement at the 3rd World Conference on Research Integrity, 5-8 May 2013, in Montréal, as a global guide to the responsible conduct of research. See Singapore Statement.

Morality: See Ethics.

N

National Science Foundation (NSF), Office of Inspector General (OIG): an NSF office that oversees the integrity of NSF-funded research. OIG reviews reports of research misconduct inquiries and investigations conducted by institutions and investigations of other problems, such as mismanagement of funds.

Nazi research on human subjects: heinous experiments conducted on concentration camp prisoners, without their consent, during World War II. Many of the subjects died or received painful and disabling injuries. Experiments included wounding prisoners to study healing; infecting prisoners with diseases to test vaccines; and subjecting prisoners to electrical currents, radiation, and extremes of temperature or pressure.

Negligence: a failure to follow the standard of care which results in harm to a person or organization. In science, research that is sloppy, careless, or poorly planned or executed may be considered negligent.

Non-**compliance**: the failure to comply with research regulations, institutional policies, or ethical standards. Serious or continuing non-compliance in human subjects research should be promptly reported to the institutional review board and other authorities. See Compliance.

Nuremberg Code: the first international ethics code for human subjects research, adopted by the Nuremberg Council during the war crimes tribunals in 1947. The code was used as a basis for convicting Nazi physicians and scientists for war crimes related to their experiments on concentration camp prisoners.

O

Objectivity: 1. The tendency for the results of scientific research to be free from bias. 2. An ethical and epistemological principle instructing one to take steps to minimize or control for bias.

Observer (or Hawthorne) effect: the tendency for individuals to change their behavior when they know they are being observed. Some social science experiments use deception to control for the observer effect.

Openness: the ethical obligation to share the results of scientific research, including data and methods.

Office of Human Research Protections (OHRP): a federal agency that oversees human subjects research funded by the Department of Health and Human Services, including research funded by the National Institutes of Health. OHRP publishes guidance documents for interpreting the Common Rule, sponsors educational activities, and take steps to ensure compliance with federal regulations, including auditing research and issuing letters to institutions concerning non-compliance.

Office of Research Integrity (ORI): a U.S. federal agency that oversees the integrity of research funded by the Public Health Service, including research funded by the National Institutes of Health. ORI sponsors research and education on research integrity, and reviews reports of research misconduct inquiries and investigations from institutions.

P

Paternalism: restricting a person's decision-making for their own good. In soft paternalism, one restricts the choices made by someone who has a compromised ability to make decisions (see Decision-making capacity); in hard paternalism, one restricts the choices made by someone who is fully autonomous (see autonomy).

Patent: a right, granted by a government, which allows the patent holder to exclude others from making, using, or commercializing an invention for a period of time, typically 20 years. To be patented, an invention must be novel, non-obvious, and useful. The patent holder must publicly disclose how to make and use the invention in the patent application.

Peer review: The process of using experts within a scientific or academic discipline (or peers) to evaluate articles submitted for publication, grant proposals, or other materials.

Peer review, double-blind: a peer review process in which neither the authors nor the reviewers are told each other's identities.

Peer review, open: a peer review process in which the authors and reviewers are told each other's identities.

Peer review, single-blind: a peer review process, used by most scientific journals, in which the reviewers are told the identities of the authors but not vice versa.

Placebo: a biologically or chemically inactive substance or intervention given to a research subject which is used to control for the Placebo effect.

Placebo effect: a person's psychosomatic response to the belief that they are receiving an effective treatment. Researchers may also be susceptible to the placebo effect if they treat subjects differently who they believe are receiving effective treatment. See also Double-Blinding.

Plagiarism: misrepresenting someone else's creative work (e.g., words, methods, pictures, ideas, or data) as one's own. See also Research misconduct.

Plagiarism, self: reusing one's own work without proper attribution or citation. Some people do not view self-plagiarism as a form of plagiarism because it does not involve intellectual theft.

Politics: 1. Activities associated with governance of a country. 2. The science or art of government. 3. The study of government.

Precautionary Principle (PP): an approach to decision-making which holds that we should take reasonable measures to prevent, minimize, or mitigate harms which are plausible and serious. Some countries have used the PP to make decisions concerning environmental protection or technology development. See also Risk/benefit analysis, Risk management.

Preponderance of evidence: in the law, a standard of proof in which a claim is proven if the evidence shows that it is more likely true than false (i.e., probability > 50%). Preponderance of evidence is the legal standard generally used in research misconduct cases. This standard is much lower than the standard used in criminal cases, i.e. proof beyond reasonable doubt.

Privacy: a state of being free from unwanted intrusion into one's personal space, private information, or personal affairs. See also Confidentiality.

Proprietary research: research that a private company owns and keeps secret.

Protocol: a set of steps, methods, or procedures for performing an activity, such as a scientific experiment.

Protocol, deviation: a departure from a protocol. In human subjects research, serious or continuing deviations from approved protocols should be promptly reported to the institutional review board.

Publication: the public dissemination of information. In science, publication may occur in journals or books, in print or electronically. Abstracts presented at scientific meetings are generally considered to be a form of publication.

Publication bias: bias related to the tendency publish or not publish certain types of research. For example, some studies have documented a bias toward publishing positive results.

Q

Quality control/quality assurance: processes for planning, conducting, monitoring, overseeing, and auditing an activity (such as research) to ensure that it meets appropriate standards of quality.

Questionable research practices (QRPs): research practices that are regarded by many as unethical but are not considered to be research misconduct. Duplicate publication and Honorary authorship are considered by many to be QRPs.

R

Randomization: a process for randomly assigning subjects to different treatment groups in a clinical trial or other biomedical experiment.

Randomized controlled trial (RCT): an experiment, such as a clinical trial, in which subjects are randomly assigned to receive an experimental intervention or a control.

Regulation: 1. A type of law developed and implemented by a government agency. 2. The process of regulating or controlling some activity.

Reliance agreement: an agreement between two institutions in which one institution agrees to overseehuman subjects research for the other institution for a particular study or group of studies.

Remuneration: in human subjects research, providing financial compensation to subjects.

Reproducibility: the ability for an independent researcher to achieve the same results of an experiment, test, or study, under the same conditions. A research paper should include information necessary for other scientists to reproduce the results. Reproducibility is different from repeatability, in which researchers repeat their own experiments to verify the results. Reproducibility is one of the hallmarks of good science.

Research: A systematic attempt to develop new knowledge.

Research compliance: See Compliance.

Research ethics: 1. Ethical conduct in research. 2. The study of ethical conduct in research. See Responsible conduct of research (RCR).

Research integrity: following ethical standards in the conduct of research. See Research ethics.

Research institution: an institution, such as a university or government or private laboratory, which is involved in conducting research.

Research Integrity Official (RIO): an administrator at a research institution who is responsible for responding to reports of suspected research misconduct.

Research misconduct: intentional, knowing, or reckless behavior in research that is widely viewed as highly unethical and often illegal. Most definitions define research misconduct as fabrication or falsification of data or plagiarism, and some include other behaviors in the definition, such as interfering with a misconduct investigation, significant violations of human research regulations, or serious deviations from commonly accepted practices. Honest errors and scientific disputes are not regarded as misconduct.

Research misconduct, inquiry vs. investigation: If suspected research misconduct is reported at an institution, the Research integrity official may appoint an inquiry committee to determine whether there is sufficient evidence to conduct an investigation. If the committee determines that there is sufficient evidence, an investigative committee will be appointed to gather evidence and interview witnesses. The investigative committee will determine whether there is sufficient evidence to prove misconduct and make a recommendation concerning adjudication of the case to the research integrity official.

Research sponsor: an organization, such as a government agency or private company, which funds research.

Research subject (also called research participant): a person who is the subject of an experiment or study.

Respect for persons: a moral principle, with roots in Kantian philosophy, which holds that we should respect the choices of autonomous decision-makers (see Autonomy, Decision-making capacity) and that we should protect the interests of those who have diminished autonomy (see Vulnerable subject). See also Belmont Report.

***Respondent**: a person(s) accused of alleged research misconduct by a complainant. See Complainant.

Responsible conduct of research (RCR): following ethical and scientific standards and legal and institutional rules in the conduct of research. See also Research ethics, Research integrity.

Retraction: withdrawing or removing a published paper from the research record because the data or results have subsequently been found to be unreliable or because the paper involves research misconduct. Journals publish retraction notices and identify retracted papers in electronic databases to alert the scientific community to problems with the paper. See Correction.

Right: a legal or moral entitlement. Rights generally imply duties or obligations. For example, if A has a right not be killed then B has a duty not to kill A.

Risk: the product of the probability and magnitude (or severity) of a potential harm.

Risk/benefit analysis: a process for determining an acceptable level of risk, given the potential benefits of an activity or technology. See also Risk Management, Precautionary Principle.

Risk management: the process of identifying, assessing, and deciding how best to deal with the risks of an activity, policy, or technology. See also Precautionary Principle.

Risk minimization: in human subjects research, the ethical and legal principle that the risks to the subjects should be minimized using appropriate methods, procedures (such as Subject selection rules), or other safety measures (such as a Data and safety monitoring board).

Risks, reasonable: in human subjects research, the ethical and legal principle that the risks to the subjects should be reasonable in relation to the benefits to the subjects or society. See Risk/benefit analysis, Social value.

S

Salami science: dividing a scientific project into the smallest papers that can be published (least publishable unit) in order to maximize the total publications from the project. See Questionable research practices.

Scientific (or academic) freedom: the institutional and government obligation to refrain from interfering in the conduct or publication of research, or the teaching and discussion of scientific ideas. See Censorship.

Scientific validity (or rigor): processes, procedures, and methods used to ensure that a study is well-designed to test a hypothesis or theory.

Self-deception: in science, deceiving one's self in the conduct of research. Self-deception is a form of bias that may be intentional or unintentional (subconscious).

Self-regulation: regulation of an activity by individuals involved in that activity as opposed to regulation by the government. See also Law.

Singapore Statement: an international research ethics code developed at the 2nd World Conference on Research Integrity in Singapore in 2010. See Montreal Statement.

Social responsibility: in science, the obligation to avoid harmful societal consequences from one's research and to promote good ones.

Social value: 1. the social benefits expected to be gained from a scientific study, such as new knowledge or the development of a medical treatment or other technology. 2. The ethical principle that human subjects research should be expected to yield valuable results for society.

Speciesism: the idea defended by philosopher Peter Singer that treating human beings as morally different from animals is a form of discrimination similar to racism. Singer argues that since all animals deserve equal moral consideration, most forms of animal experimentation are unethical. See Value, scale of.

Standard operating procedures (SOPs): rules and procedures for performing an activity, such conducting or reviewing research.

Statistical significance: a measure of the degree that an observed result (such as relationship between two variables) is due to chance. Statistical significance is usually expressed as a p-value. A p-value of 0.05, for example, means that the observed result will probably occur as a result of chance only 5% of the time.

Subject selection: rules for including/excluding human subjects in research. Subject selection should be equitable, i.e. subjects should be included or excluded for legitimate scientific or ethical reasons. For example, a clinical trial might exclude subjects who do not have the disease under investigation or are too sick to take part in the study safely. See Risk minimization, Justice.

Surrogate decision-maker: see Legal authorized representative.

T

Testability: the ability to test a hypothesis or theory. Scientific hypotheses and theories should be testable.

Therapeutic misconception: 1. The tendency for human subjects research in clinical research to believe that the study is designed to benefit them personally; 2. The tendency for the subjects of clinical research to overestimate the benefits of research and underestimate the risks.

Three Rs: ethical guidelines for protecting animal welfare in research, including **R**eduction (reducing the number of animals used in research), **R**eplacement (replacing higher species with lower ones or animals with cells or computer models), and **R**efinement (refining research methods to minimize pain and suffering) – developed by Russell and Burch in 1959.

Transparency: in science, openly disclosing information that concerned parties would want to know, such as financial interests or methodological assumptions. See also Conflict of interest, management.

Tuskegee Syphilis Study: a study, sponsored by the U.S. Department of Health, Education, and Welfare, conducted in Tuskegee, Alabama from 1932-1972, which involved observing the progression of untreated syphilis in African American men. The men were not told they were in a research study; they thought they were getting treatment for "bad blood." Researchers also steered them away from clinics where could receive penicillin when it became available as a treatment for syphilis in the 1940s.

U

Unanticipated problem (UP): an unexpected problem that occurs in human subjects research. Serious UPs that related to research and suggest a greater risk of harm to subjects or others should be promptly reported to institutional review boards and other authorities.

Undue influence: taking advantage of someone's vulnerability to convince them to make a decision.

Utilitarianism: An ethical theory which holds that the right thing to do is to produce the greatest overall happiness for the greatest number of people. Act utilitarians focus on happiness resulting from particular actions while rule utilitarians focus on happiness resulting from following rules. See also Consequentialism, Ethical theory.

V

Value: something that is viewed as worth having or desiring, such as happiness, knowledge, justice, or virtue.

Value, instrumental: something that is valued for the sake of achieving something else, e.g. a visit to the dentist is valuable for dental health.

Value, intrinsic: something that is valued for its own sake, e.g. happiness, human life.

Value, scale of: the idea that some things can be ranked on a scale of moral value. For example, one might hold that human beings are more valuable than other sentient animals; sentient animals are more valuable than non-sentient animals, etc. Some defenders of animal experimentation argue that harming animals in research can be justified to benefit human beings because human beings are more valuable than animals.

Virtue: a morally good or desirable character trait, such as honesty, courage, compassion, modesty, fairness, etc.

Virtue ethics: an ethical theory that emphasizes developing virtue as opposed to following rules or maximizing good/bad consequences.

Voluntariness: the ability to make a free (un-coerced) choice. See Coercion, Informed consent.

Vulnerable subject: someone who has a compromised ability to make decisions or advocate for his/her interests. Vulnerability may be based on age, mental disability, institutionalization, language barriers, socioeconomic deprivation, or other factors. See Decision-making capacity, Informed consent.

W

Whistleblower: a person who reports suspected illegal or unethical activity, such as research misconduct or non-compliance with human subjects or animal regulations. Various laws and institutional policies protect whistleblowers from retaliation.

Withdrawal: removing a human subjects research form a study. Subjects may voluntarily withdraw or be withdrawn by the researcher to protect them from harm or ensure the integrity of the study. Subjects who withdraw from a study may request to have their samples removed from the study (i.e., destroyed).