

Human Research Protection Program Glossary

<p>Adverse Event – An undesirable and unintended, although not necessarily unexpected, result of experimental interventions.</p>
<p>Assent – An agreement by an individual not competent to give legally valid informed consent (e.g., a child or a cognitively impaired adult) to participate in research.</p>
<p>Assurance – A formal, written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.</p>
<p>Autonomy – Personal capacity to consider alternatives, make choices, and act without undue influence or the interference of others.</p>
<p>Belmont Report – A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.</p>
<p>Beneficence – An ethical principle 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 no harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.</p>
<p>Benefit – A valued or desired outcome; an advantage.</p>
<p>Best Practice – The methods and procedures employed by those institutions and/or individuals who are most experienced in a field and are the recognized leaders in terms of the quality of what they do. In terms of human subjects protection, best practice refers to the models which should be emulated in designing research experiments that best protect the rights, privacy and dignity of the subjects or participants.</p>
<p>Children – Persons who have not attained the legal age for consent to the procedures involved in research, as determined under the applicable law of the jurisdiction under which research is conducted.</p>
<p>Cognitively impaired – Having either a psychiatric disorder (psychosis, dementia, etc.) or a developmental disorder (retardation) that affects cognitive or emotional functions to the extent that the capacity for judgment and reasoning is significantly diminished. Others, including those 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.</p>
<p>Competence – Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.</p>
<p>COMMON RULE: Another term for 45 CFR 46 Federal Policy for the Protection of Human Subjects (Basis DHHS Policy for the Protection of Human Research Subjects).</p>
<p>Debriefing – Giving subjects 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 standard English usage, in which debriefing involves obtaining rather than imparting information.)</p>
<p>Deception – Withholding of information about a research project that might affect the subjects' decision to participate in the study. In its mildest form, deception may involve simply withholding the research hypothesis from the subjects to avoid biasing the results. More severe forms of deception may involve deceiving subjects about the purpose of the study, deceiving them about the status of other individuals who they believe to be subjects (confederates), and deceiving them about the status of individuals supposedly outside of the experiment. In its most extreme form, subjects are not even made aware that they are participating in a research project until the experiment has concluded. All forms of deception violate the fundamental principle of autonomy—the individuals right to self-determination, that is, to freely make a decision to participate or not participate based on full information about the nature of the research. The IRB approves deception research only if its use is carefully justified and when specified conditions are met that restore the autonomy to the individual by the conclusion of the experiment.</p>
<p>Equitable – Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed.</p>

<p>Exempt - A project that does not require further review after initial consideration by the IRB or its designated review body. The “Exempt” status is granted based on criteria specified in the federal regulations. Research that is categorized as exempt by the IRB review includes research that does not involve directly or indirectly human subjects or any data about human subjects. Unforeseeable risk includes “research involving the collection or study of <i>existing data</i>, documents, records, pathologic specimens, or diagnostic specimens, if these sources are <i>publicly available</i> or if the information is recorded by the investigator in such a manner that the <i>subjects cannot be identified, directly or through identifiers linked to the subjects</i> [emphasis added]” (Title 45 Code of Federal Regulations, Part 46 Protection of Human Subjects).</p>
<p>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.</p>
<p>Full Board Review – Review of proposed research at a convened meeting at which a majority of the membership of the IRB is present, including at least one member whose primary concerns are in non-scientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.</p>
<p>Guardian – An individual who is authorized under applicable state or local law to give permission on behalf of a child to participate in research.</p>
<p>Focus Groups¹ – A form of structured interviews, typically with 6-12 subjects, who are part of a data collection effort to explain, understand, and capture opinions, beliefs, opinions, and characteristics of a particular issue or subject.</p>
<p>Human Subjects – Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under federal regulations, human subjects are defined as: living individuals about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.</p>
<p>Informed Consent – A person’s voluntary agreement, based upon an 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.</p>
<p>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.</p>
<p>IRB – See Institutional Review Board.</p>
<p>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.</p>
<p>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, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedures involved in the research.</p>
<p>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, physiological or psychological examinations or tests.</p>
<p>OHRP – Office of Human Research Protections – An office within the U.S. Department of Health and Human Services.</p>
<p>OPRR – Office for the Protection from Research Risks – A former office within the U.S. Department of Health and Human Services that was elevated to the Office of Human Research Protections (OHRP) within the Office of Public Health and Science (OPHS) in 2000.</p>
<p>Principal Investigator – The scientist or scholar with primary responsibility for the design and conduct of a research project.</p>

¹ Cooper, D. R., & Schindler, P. S. (2003), *Business Research Methods*. New York, NY: The McGraw-Hill Companies, Inc..

<p>Prisoner – An individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial or sentencing; (3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution.</p>
<p>Privacy – Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.</p>
<p>Protected Population – The scope of the IRB extends to of all members of the US Naval Academy community, military and civilian, who are subjects or potential subjects of research that is sanctioned or authorized by USNA. This includes, but is not limited to:</p> <ol style="list-style-type: none"> 1. The Brigade of Midshipmen; 2. All faculty, including resident, visiting faculty, civilian, and military; 3. All civilian employees in all pay grades; 4. All military personnel assigned to the USNA Complex; 5. All civilian contract employees who are engaged in work connected to or in support of USNA activities; 6. All permanent residents of USNA, including their families; 7. Candidates, sponsor families, and any other guests who are participating in USNA sectioned activities or functions; 8. Any population connect to or associated with USNA who are not otherwise covered by IRB protections from other DoD/DoN research
<p>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 experimental procedures, and the proposed methods of analysis that will be performed on the collected data.</p>
<p>Research – A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge.</p>
<p>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.</p>
<p>Review (of Research) – The concurrent oversight of research on a periodic basis by an IRB. In addition to reviews at least annually, as mandated by federal regulations, reviews may also, if deemed appropriate, be conducted on a continuous or periodic basis.</p>
<p>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.”</p>
<p>Survey² – A survey is a form of data collection that asks subjects about attitudes, opinions, perceptions, and characteristics generally used as a part of a larger research study.</p>
<p>Voluntary – Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject’s decision to participate, not participate, or to continue to participate in a research activity.</p>

² Wiersma, W., & Jurs, S. G. (2005). *Research Methods in Education*. Boston, MA: Pearson Education, Inc.