

ANONYMOUS:

Subjects' identities are unknown to the investigator, not requested, and not given. If the only time the investigator asks for a name is for a signature on a consent form, the investigator should use request a waiver of written documentation of consent, to preserve anonymity. The IRB is able to grant these waivers under certain circumstances.

ASSENT:

Agreement by subjects not competent to give legally valid informed consent (e.g., children or cognitively impaired people) to participate in a study.

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.

BENEFIT:

A valued or desired outcome to the study that will be an advantage to the subjects participating. Compensation is not considered a benefit.

BIOMEDICAL RESEARCH:

Studies that are designed to evaluate the safety, effectiveness, or usefulness of an intervention include research on therapies (e.g., drugs, diet, exercise, surgical interventions, or medical devices), diagnostic procedures (e.g., CAT scans or prenatal diagnosis through amniocentesis, chorionic villi testing, and fetoscopy), and preventive measures (e.g., vaccines, diet, or fluoridated toothpaste). It can also include normal human functioning and development, compare the functioning of a particular physiological system at different stages of development (e.g., infancy, childhood, adolescence, adulthood, or old age), or define normal childhood development. It includes records research used to develop and refine hypotheses. Research on specific disease (e.g., research on the biochemical changes associated with AIDS or schizophrenia, or the neurological changes associated with senile dementia of the Alzheimer type) and the human genome and genetic markers fall under biomedical research.

Biomedical research is focused on:

- specific diseases and health conditions (mental or physical), including: detection, cause, treatment, prevention, and rehabilitation
- evaluation and testing of the safety, effectiveness, or usefulness of an intervention, treatment, or therapy
- normal and abnormal physiology, human functioning, and development
- cognitive, emotional, and behavioral responses to real or potential health problems
- the human genome and genetic markers
- the incidence and prevalence of illness and injury among populations, and strategies for prevention and health promotion

CERTIFICATE OF CONFIDENTIALITY:

A Certificate of Confidentiality helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. Any research project that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a Certificate. Federal funding is not a prerequisite for Certificate. For more information:

<http://grants.nih.gov/grants/policy/coc/index.htm>

CERTIFICATION:

Official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

CHILDREN:

Persons who have not 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.

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. 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.

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.

CONFIDENTIAL:

Subjects' names are known to the investigator and are usually coded to a master list and/or kept separately from the data and results. This is usually used, for example, when the investigator must match test results with surveys or if there will be a follow-up survey. The investigator must have a need to know subjects' names.

CONFIDENTIALITY:

Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

CONTINUING REVIEW:

If data gathering continues for more than 12 months, federal regulations require that the project be subject to a “continuing review.” Researchers should use the WIU IRB Review and Monitoring form. This form is also to be used if changes in the research protocol occur within any given 12-month period.

CRIME:

A crime is a wrongdoing which has been classified by the state or federal legislative body as a felony or misdemeanor.

DATA:

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

DATA COLLECTION:

Refers to any research procedure that is intended to elicit from or record the actions, reactions, attitudes, and/or behavioral manifestations of subjects participating in a research project.

DEBRIEFING:

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

DECEPTION:

The protocol is designed to withhold complete information when consent is obtained.

DIRECTLY OR INDIRECTLY IDENTIFIABLE:

Identities of individual subjects are kept by the investigator. If subjects' identities are inseparable from data, then data is **directly** identifiable. If subjects' identities are kept separate from data, with information connecting them maintained by codes and a master list, then data is **indirectly** identifiable. In either case, the investigator must assure that confidentiality will be maintained, and must explain how subjects' identities will be protected.

- *Direct identifiers:* Direct identifiers in research data or records include names; postal address information (other than town or city, state and zip code); telephone numbers, fax numbers, e-mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate /license numbers; vehicle identifiers and serial numbers, including license plant numbers; device identifiers and serial numbers; web universal resource locators (URLs); internet protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full face photographic images and any comparable images.

- *Identifiable data or records:* contains information that reveals or can likely associate with the identity of the person or persons to whom the data or records pertain. Research data or records with direct identifiers removed, but which retain indirect identifiers, are still considered identifiable.
- *In-direct identifiers:* Indirect identifiers in research data or records include all geographic identifiers smaller than a state , including street address, city, county, precinct, Zip code, and their equivalent postal codes, except for the initial three digits of a ZIP code; all elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such age and elements may be aggregated into a single category of age 90 or older.

EDUCATIONAL SETTING:

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management method.

EXEMPT:

The Common Rule codified in 45 CFR 46.101(b) specifies that research activities may be classified as exempt in the policy if human subjects involvement is limited to one of the listed scenarios, including studies involving the collection or study of existing data when those data either are publicly available or are not personally identifiable. To qualify, research must fall into one of six federally-defined exempt categories.

EXPEDITED REVIEW:

Review of proposed research by the IRB Administrator 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 (see page 9).

FULL BOARD REVIEW:

Review of proposed research at a convened meeting at which a majority of the membership of the IRB 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.

GENERALIZABLE KNOWLEDGE:

Knowledge that could be applied to populations outside of the population served by the covered entity. This definition can vary.

Examples of activities that typically are not generalizable include:

- biographies
- oral histories that are designed solely to create a record of specific historical events
- service or course evaluations, unless they can be generalized to other individuals

- services, or concepts where it is not the intention to share the results beyond WSU or any agency supporting the research
- classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices
- quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the WSU community

GUARDIAN:

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

HIPPA:

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

HUMAN SUBJECTS:

Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the 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.

INFORMED CONSENT:

- 1) The knowing, legally effective consent of any individual or the individual's legally authorized representative; such consent can be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- 2) 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.

INTERPRETER/ TRANSLATER:

An agent of the researcher(s), whom assists in the facilitation of communication between the researcher(s) and participants who are not fluent in the language of the researcher(s).

INSTITUTIONAL REVIEW BOARD:

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.

INTENTIONALLY IDENTIFIED:

Subjects' names are identified in connection with the data when the research results are presented to the public. This procedure is common for journalistic-type interview studies, where subjects are public figures or in oral histories. In these cases, the investigator should seek explicit consent from the subjects for the use of their names in connection with their data.

INTERACTION:

Includes communication or interpersonal contact between investigator and subject.

INTERVENTION:

Includes both physical procedures by which data is gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

IRB APPROVAL:

The determination by the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and other Institutional and federal requirements.

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. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

MONITORING:

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

NEONATE:

Newborn (viable or non-viable).

NON EXEMPT:

The Common Rule codified in 45 CFR 46.110 specifies that research activities may be eligible for expedited review if the protocol involves only minimal risk or a previously reviewed protocol is receiving modifications that are only minor. Non Exempt review is carried out by the Compliance Specialist, IRB Chair or the Chair's designee. Such expedited reviews have the force of full reviews, except that if the protocol is found not acceptable, then it must receive review by the full committee; the chair or designee alone cannot reject a proposal. Expedited reviews are reviewed as the packets are received and will take approximately 15-20 working days for review once they have arrived at the IRB office. Full board applications are reviewed at the next scheduled IRB meeting.

ORAL HISTORY:

Tape-recorded historical information obtained in interviews concerning personal experiences and recollections. Often, the intention is that these tapes become available to the public at a specified future time in order to convey historical insight.

NONAFFILIATED 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, homemaker).

PERMISSION:

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

PERSONALLY IDENTIFIABLE HEALTH INFORMATION:

Health or medical data or information that can be linked manifestly or inferentially to an individual.

POPULATION:

A group of people in society meeting certain criteria to be eligible as subjects in a project's protocol.

PRINCIPAL INVESTIGATOR:

The individual with primary responsibility for the design and conduct of a research study.

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; and (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 [45 CFR 46.303(c)].

PRIVACY:

Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

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:

individually identifiable Health information recorded in any form or medium that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

PROTOCOL:

The formal design or plan of a study's activity; specifically, the plan submitted to an IRB for review and to an agency for support. The protocol includes a description of the 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.

PUBLICLY AVAILABLE DATA:

Public sources of data, such as census data.

RESEARCH:

Systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of the WSU IRB, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

- Research includes all theses, dissertations, publications, and/or presentations.
- The term "research" designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).
- Research generally does not include operational activities such as practice activities in medicine, psychology, social work, and public health (e.g., routine outbreak investigations and disease monitoring) and studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, marketing studies, or contracted-for services. It generally does not include journalism or political polls. However, some of these activities may include or constitute research in circumstances where there is a clear intent to contribute to generalizable knowledge.

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."

SIGNIFICANT RISK:

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

SUBSTANCE ABUSE:

Substance abuse refers to the use of substances when said use is causing detriment to the individual's physical health or causes the user legal, social, financial or other problems, up to, and including, endangering their lives or the lives of others. Substance abuse is not specific to illegal substances. Substance abuse also includes the abuse of legal substances which are legitimately purchased or prescribed.

SYSTEMATIC:

Step-by-step, methodical procedure presented or formulated as a coherent body of ideas or principles.

VOLUNTARY:

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

VULNERABLE POPULATIONS:

Refers to subjects such as children, prisoners, pregnant women, persons with disabilities, economically or educationally disadvantaged persons, or any other population that may be relatively or absolutely incapable of protecting their interests through the informed consent process