CHAPTER 10: DEFINITIONS

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 implied consent, to preserve anonymity.

APPLICATION: 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 application 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.

ASSENT: Agreement by subjects not competent to give legally valid informed consent (e.g., children or cognitively impaired people) to participate in a study. Refers to a child’s affirmative agreement to participate in the research. Mere failure to object should not, absent affirmative agreement, be construed as assent. “Children” are persons who have not attained the legal age for consent to treatment or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. § 46.402 From Informed Consent A Guide to the Risks and Benefits of Volunteering for Clinical Trials (Kenneth Getz & Deborah Borfitz, 2002): p. 130, “Children aren’t expected to give their consent, but they’re often asked to give their assent.” “IRBs consider parental permission sufficient if the research is going to be done on young children (vaguely defined as somewhere under the age of seven to 11) who lack the intellectual and emotional ability to understand what they’re agreeing to.”

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:

1. specific diseases and health conditions (mental or physical), including: detection, cause, treatment, prevention, and rehabilitation;
2. evaluation and testing of the safety, effectiveness, or usefulness of an intervention, treatment, or therapy;
3. normal and abnormal physiology, human functioning, and development;
4. cognitive, emotional, and behavioral responses to real or potential health problems;
5. the human genome and genetic markers;
6. 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 research 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 or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

COMMON RULE: A large majority of Federal Agencies simultaneously published a regulation or "Common Rule" on June 18, 1991 to regulate the conduct or support of human subject research. The rule is set forth in 45 CFR Part 46, Subpart A. Subpart A consists of 45 CFR 46.101 to 46.124.

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.

CONTINUING REVIEW: Approved research will undergo review until the completion or termination of the research, including scheduled continual reviews of research that will occur at least annually.

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.

DECEPTION: Deception is the intentional misleading of subjects or the withholding of full information about the nature of the experiment. Misleading or omitted information might include the purpose of the research, the role of the researcher, or what procedures in the study are actually experimental. Deception increases ethical concerns, because it interferes with the ability of the subject to give informed consent. However, deception is arguably necessary for certain types of behavioral research. Because humans act differently depending on circumstances, full knowledge by the subject might bias the results.

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.

- **Indirect 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 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. Exempt determinations are evaluated by IRB staff and will take approximately 10 working days for certification once they arrive at the IRB Office.

**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 HU 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 HU community

**HIPAA:** Health Insurance Portability and Accountability Act (HIPAA) 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 SUBJECT:** A living individual about whom an investigator (whether professional or student) conducting research obtains a) data through intervention or interaction with the individual, or b) identifiable private information.

**INFORMED CONSENT:** 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.

**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 (IRB):** A committee formed to facilitate the protection of human subjects in 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 study is 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 differ somewhat from that given for non-institutionalized adults.

**NEONATE:** Newborn (viable or non-viable).

**NON-EXEMPT:** The Common Rule 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 three IRB Members. 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 12 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.

**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 research’s protocol.

**PRINCIPAL INVESTIGATOR (PI):** The individual with primary responsibility for the design and conduct of a research study.
PRISONER: A prisoner is defined by federal regulations as any individual involuntarily confined or detained in a penal institution and/or individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to incarceration.

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.

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 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;
- 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);
- 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;
- generally does not include journalism or political polls.
- However, some of the above 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 study. Both the probability and magnitude of possible harm may vary from minimal to significant.

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.