Useful Definitions

**45 Code of Federal Regulations Part 46:** The federal policy that provides regulations for the involvement of human subjects in research. The Policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that takes appropriate administrative action to make the Policy applicable to such research. Also referred to as 45 CFR 46

**Adverse event:** an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention

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

**Children:** persons who have not attained the legal age for consent to treatments or procedures involved in the research, 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

**Disseminated:** the material will be shared beyond the local setting. Obvious examples of disseminated information are publication in a scholarly journal, presentation at a professional conference, or placement of a report in a library.

Examples that are not disseminated information include oral presentation to a departmental group in fulfillment of a university requirement, sharing of results with an agency that cooperated in information collection, or internal presentation for utilization and review purposes.

**Exempt review:** Categories of research that do not require IRB continuing review

**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

**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:** investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population) or inform policy. For conclusions to be generalizable, they must actually be disseminated for research purposes (or be part of a program of
investigation that will be disseminated). A useful definition of dissemination is that the material will be shared beyond the local setting.

**Human Subject:** a “living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) obtains identifiable private information” (see 45CFR46.102(d))

**Individually identifiable:** the identity of the participant is or may be readily ascertained by the investigator or is associated with the information

**Interaction:** includes communication or interpersonal contact between investigator and subject (For more information, see 45 Code of Federal Regulations 46.102(f)) (e.g., surveys, focus groups, interviews)

**Intervention:** includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the participant or the participant’s environment that are performed for research purposes

**IRB (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 social/behavioral research

**Minimal risk:** A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults – Risk of physical or psychological harm that is no greater in probability and severity than that ordinarily encountered in the daily lives, or in the routine medical, dental, or psychological examinations of healthy persons

**OHRP (Office for Human Research Protections):** An administrative unit within the Department of Health and Human Services (DHHS). The OHRP’s functions include implementation of the DHHS Regulations for the Protection of Human Subjects (45 CFR 46), and the guidance on ethical issues in biomedical or social/behavioral research

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

**Private information:** includes information about behavior that occurs in a context in which a participant can reasonably expect that no observation or recording is taking place, information for specific purposes by an individual, and which the individual can reasonably expect will not be made public such as a medical record

**Systematic Investigation:** attempts to answer research questions, collects data in an organized or consistent way, the data is analyzed in some way (i.e., quantitative or qualitative), and conclusions are drawn from the results

**Voluntary:** Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject’s decision to participate (or to continue to participate) in a research activity