**IRB:** short for Institutional Review Board. The IRB is required to review all applications that involve research whose results will be disseminated publicly such as dissertations and conference or other presentations.

**IEA:** short for Institutional Effectiveness and Assessment. The IEA is required to review all applications that involve research whose results will be shared only at Asbury Theological Seminary for assessment and accreditation purposes.

**Review type:** Applications, and therefore IRB reviews, fall into three (3) categories called types, and include:

***Exempt Review*** - is a review of a research application that does not include any direct human subject involvement.

***Expedited Review*** - is a review of a research application that includes adult human subjects and minimal risk.

***Full Board Review*** is a review of a research application that includes protected classes of human subjects and higher risk experimental designs and requires an actual physical meeting of the researcher and the IRB.

**Protected classes:** Human subjects that includes children, prisoners, and pregnant women as well as any other vulnerable classes of persons as defined by Federal Law Title 45, Part 46. A copy of which can be accessed at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.

**Supporting Documents (documentation):** This is any document or instrument used in the research process and can include consent forms, surveys, questionnaires, consent forms, interview instruments, letters of approval, debriefing statements or instruments.

**Anonymous:** Anonymous means there is no way for the participant to be identified. If there is a recording of the participant’s voice, they can be identified. Research that is qualitative cannot be anonymous.

**Confidential:** Confidential research means that identifying information may be collected but safeguards are put into place.

***Federal Law*** ***§46.102 Definitions.***

*(found at* [*http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102))

 (a) *Department or agency head* means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

 (b) *Institution* means any public or private entity or agency (including federal, state, and other agencies).

 (c) *Legally authorized representative* means 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 procedure(s) involved in the research.

 (d) *Research* means a 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 this policy, 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.

 (e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

 (f) *Human subject* means 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) Identifiable private information.

***Intervention*** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes 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.

 (g) *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy.

 (h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

 (i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the 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.

 (j) *Certification* means the 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.