

APPENDIX A: DEFINITIONS RELATED TO THE IRB PROCESS

Ashford University Institutional Review Board

Archival Data	Also known as existing data . This is data which has already been collected for purposes other than the proposed research. It is complete and available to the primary investigator at the time of the IRB application.
Exempt Review	Research in this category involves risks or stressors that are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations.
Existing Data	Also known as archival data . This is data which has already been collected for purposes other than the proposed research. It is complete and available to the primary investigator at the time of the IRB application.
Expedited Review	An accelerated evaluation of a research proposal. Research that poses only minimal risk to adult human participants, and does not deal with sensitive or personal aspects of the participant's behavior, may be granted an expedited review under certain conditions.
Full Review	Research involving more than minimal risk or vulnerable human participants must undergo a full IRB review.
Human Participant	A living individual about whom an investigator (whether professional or student) conducting research obtains data or identifiable private information through intervention or interaction with the individual.
Informed Assent	A minor participant's affirmative agreement to participate in research.
Informed Consent	An adult participant's affirmative agreement to participate in research, or the affirmative agreement for one's child to participate in research.
Interaction	Communication or interpersonal contact between investigator and participant.
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.

<p>Private Information</p>	<p>Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. It also includes that which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the participant 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 participants.</p>
<p>Protected Health Information (PHI)</p>	<p>Defined as individually identifiable health information that a health care provider, health plan, health care clearinghouse or employer creates or receives. This includes information about the past, present or future physical or mental health of a person, the provision of health care to a person, or the payment for the provision of care to that person.</p>
<p>Research</p>	<p>A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to the development of generalizable knowledge. Activities that meet this definition constitute research, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.</p>
<p>Vulnerable Persons/ Participants</p>	<p>Those who are relatively (or absolutely) incapable of protecting their own interests. Vulnerable participants include children under 18 years, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, persons not proficient in the language of the research study, and any participants likely to be vulnerable to coercion or undue influence.</p>