

What is a Human Subject?

The Human Assurance Committee (HAC) utilizes the Office for Human Research Protections (OHRP) definitions of Human Subjects.

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 [Federal Policy §____.102(f)] (available at http://www.hhs.gov/ohrp/irb/irb_glossary.htm)

There may be some circumstances where the definition may be amended to include the definition of the United States Food and Drug Administration (FDA) and/or the Office of Civil Rights (OCR) with regards to the Health Insurance Portability and Accountability Act (HIPAA) of 1996 regulations:

FDA HUMAN SUBJECTS: Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. (available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?FR=56.102>)

OCR HUMAN SUBJECTS: Protections extend to decedents

There are also cultural or ethnic groups whose beliefs are such that they may object to the use of any samples of human tissue for research. One must be aware of these boundaries and respect them.