CHAPTER 2: DEFINITION OF RESEARCH
Per 45 CFR 46.102, 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.

In some cases, the HU IRB must review pilot research and protocol development, including but not limited to the following activities:

- Development and testing of instruments or measures on human subjects* (even if it is just one subject);
- Testing of research procedures on human subjects*;
- Procedures done on human subjects* for the purpose of refining research design.
- Data collected that will be used solely or in combination with other data for purposes of publication, reports or presentation;
- Development and testing procedures on human subjects* involving needles, catheters, radiation, drugs or devices that are swallowed or inserted in an orifice require IRB approval.

*Please note that the Office for Human Research Protections (OHRP) considers the Principal Investigator as well as all research personnel to be human subjects if testing procedures are to be conducted on them. Therefore, even when pilot tests are conducted on study personnel, the protocol must be reviewed and approved by the IRB prior to initiation.

Pilot studies should be identified as such in applications to the IRB. The informed consent process must explain to subjects that the research is a pilot study. Procedures that are not considered to be pilot research and do not need to be reviewed by the IRB include, but may not be limited to, the following:

- Training programs designed to teach proven methods that will be used during the conduct of research (i.e., blood drawing training, interview techniques training);
- Refining data collection procedures or preparation of an instrument, such as a survey. For instance, "How could this survey question be misunderstood?", or "In what order should survey instruments be distributed?" This type of study development does not contribute to generalizable knowledge, and therefore is not considered research and does not require IRB review. Such data cannot be used in publications or reports.