HARRISBURG UNIVERSITY INSTITUTIONAL REVIEW BOARD

IS THIS RESEARCH? Guidance Sheet

Office of Human Protection (OHRP) and National Institute of Health (NIH), as well as government agencies like the Food and Drug Administration (FDA), provide guidance in determining which studies qualify as research. The following general guidance will help determine if a study qualifies as research at Harrisburg University of Science and Technology (HU). *Note: final determination rests with the IRB. Email IRB@HarrisburgU.edu for more information.

DEFINITIONS

OHRP's Revised Common Rule defines research as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. *

- **Systematic investigation** means a detailed or careful examination that has or involves a prospectively identified approach to the activity based on a system, method, or plan.
- **Generalizable knowledge** means the information is expected to expand the knowledge base of a scientific discipline or other scholarly field or study and yield one or both of the following:
 - Results that are applicable to a larger population beyond the site of data collection or the specific subjects studied
 - Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.

KEY POINTS

The design and methodology, not the size and scope, is used in the determination of research.

- Preliminary and pilot studies are still considered research if they meet the above definitions or are part of a larger study that also meets the above definitions.
- Quality improvement or quality assurance (QI/QA) studies may be considered research if they are designed to promote general knowledge across an industry or program.
- Focus groups, surveys, or interviews intended only to evaluate and improve programs or services provided by the institution or to assess its needs are not research.
- Focus groups, surveys, or interviews used to generalize findings are considered research.
- Class research, capstones, and class projects are not considered research if the data collected is **not intended for use outside** of the classroom. Those intended for use outside may be considered research according to the above definitions.
 - Thesis and Dissertations are generally classified as research.
- Methodologies designed to understand behaviors, beliefs, customs, and practices with findings applied to a community or group, and not just the individuals from whom the information was collected, is considered research. This may include case studies, ethnography.

*https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/lesson-2-what-is-human-subjects-research/index.html