DEFINITION OF RESEARCH

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: MCW/FH Faculty and Staff involved in human research

PURPOSE:
N/A

DEFINITIONS:
Research – (45 CFR 46.102(d)) 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.

Clinical Investigation (21 CFR 50.3(c)) – means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies.

PROCEDURE:
Research is an original investigation undertaken to acquire knowledge and understanding. It typically involves inquiry of an experimental or critical nature driven by hypotheses or intellectual positions capable of rigorous assessment. It is an independent*, creative, cumulative and often long-term activity conducted by specialists with knowledge about the theories, methods and information concerning the field of inquiry. Research findings must be open to scrutiny and formal evaluation by others in the field, which may be achieved through publication or public presentation.

Research includes contributions to the knowledge base of subjects and disciplines. It also includes the experimental development of solutions, as well as investigation that leads to new or substantially improved materials, devices, products or processes.
The following activities are excluded from the definition of research:

- preparation for teaching;
- the provision of advice or opinion, except where it is consistent with the definition of research;
- scientific and technical information services;
- standardization and routine testing;
- feasibility studies (except into research and experimental development projects);
- routine medical care;
- a single-case presentation based on retrospective (not pre-planned) review of routine medical care;
- the commercial, legal and administrative aspects of patenting, copyrighting or licensing activities;
- routine computer programming, systems work or software maintenance (but research and experimental development of applications software, new programming languages and new operating systems is research); and
- any other routine professional practice

*The interpretation of "independent" does not exclude collaborative research.

REFERENCES:
45 CFR 46.102(d)
21 CFR 50.3(c)

ATTACHMENTS:
N/A

Effective Date: 5/20/2004
Revision History: 06/29/2009
Supersedes Policy: 05/20/2004
Review Date: 09/10/2009
Approved By: [Signature]

David Clark, PhD, Assistant Dean for Clinical Research and Director, HRPP
Human Research Protections Program (HRPP)
Office of Research
Medical College of Wisconsin