DEFINITION OF HUMAN SUBJECTS

Unit: Human Research Protections Program (HRPP), Office of Research
Applies to: MCW/FH Faculty and Staff involved in human research

PURPOSE:
It is the responsibility of the Institutional Review Board (IRB) staff and committee members to ensure the proper application of the definition in reviewing submissions. It is the responsibility of principal investigators to ensure the proper application of the definition to their research projects and submit an application to the IRB for its review.

DEFINITIONS:
1. Human subjects
   a. (45 CFR 46.102) means a living individual about whom an investigator (whether professional or student) conducting research obtains
      i. Data through intervention or interaction with the individual, or
      ii. Identifiable private information.
      Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject 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 subjects.
   b. (21 CFR 56.102) 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.

PROCEDURE:

Review of research involving human subjects:
Research which involves human subjects as defined per the federal regulations must be reviewed by an IRB. MCW/FH IRBs must review all human subjects research initiated by MCW faculty, staff or students as defined in MCW/FH Institutional Review Board Standard Operating Procedures and MCW Corporate Policy Research Involving Human Subjects and/or their Private Identifiable Information.
Review of research regarding decedents:
Research projects involving decedents shall be reviewed by an MCW Privacy Board. The principal investigator will submit research projects involving decedents to the IRB using the required application for review and determination.

Research protocols involving decedents do not require IRB review; however, based upon federal regulations at 45 CFR 46.160 and 164, a review by the Institution's Privacy Board is required.

MCW/FH IRBs also serve as the MCW Privacy Boards. There is a separate process for Privacy Board review submissions.

REFERENCES:
21 CFR 56.102(e)
45 CFR 46.102(f)
45 CFR 46.160 and 164
MCW Standard Operating Procedures
MCW Corporate Policy – Research Involving Human Subjects and/or their Private Identifiable Information

ATTACHMENTS: N/A

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Approved By: __________________________
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