MCW Office of Research
Standard Operating Procedure

DEFINITION AND DETERMINATION OF HUMAN SUBJECTS RESEARCH

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

Applies to: Faculty and Staff involved in human research

PURPOSE:
It is the responsibility of the MCW Institutional Review Board (IRB), staff and committee members to ensure the proper application of the definition of human subjects research and to provide investigators with guidance regarding this definition.

It is the responsibility of principal investigators to ensure the proper application of the definition to their human subjects research projects and apply to the IRB for its review.

Investigators must submit to the IRB for review prior to initiating the research regardless of whether their activities involve human subjects. Investigators may not independently make the determination whether an activity involves research; the IRB will make the independent determination regarding human research subject involvement.

DEFINITIONS:
Research: 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.

Systematic Investigation: A project which:

Attempts to answer research questions (e.g., attempts to prove a hypothesis).
Is methodologically driven, i.e., it collects data or information in an organized and consistent way.
Analyzes information quantitatively and/or qualitatively.
Draws conclusions from the results.

Generalizable Knowledge: Knowledge which contributes to a theoretical framework of an established body of knowledge. Results are expected to reflect a larger population beyond the studied population and are expected to be replicable in other settings.

Human subject:

A living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

An individual who is or becomes a participant in research, either as a recipient of

Decedent Research: Research that uses *only* human cadavers, cadaveric tissues, or the data/specimens of deceased individuals. This research is often considered "Not Human Subjects Research."

Not Human Subjects Research (NHSR): Projects that do not fit the definition of research, do not actively involve human subjects, do not access private, identifiable human data, and are not purposed to support the marketing of an FDA-regulated drug, biologic, or device product.

POLICY:
Investigators can consult with the MCW Human Research Protection Program (HRPP) Office regarding their project at any time before, during, or after review. All official determinations made by the IRB are delivered in determination letters via eBridge.

Review of research involving human subjects:
The MCW HRPP Office must review all human subjects research in which we are engaged in accordance with MCW IRB policies and MCW Corporate Policy *RS.HS.040 – Human Research Protection Program*. Investigators must submit all research to the HRPP Office for review via the eBridge system. Human subjects research activities may not begin until the project team receives the official IRB determination letter via eBridge.

The IRB will make the ultimate determination regarding whether a human subjects research project requires review at a convened IRB meeting or whether it can be processed via one of the minimal risk pathways or may qualify for an exempt determination.

For a human subjects research project to qualify as minimal risk, all research activities must qualify under federal determinations of Exempt or Expedited research (45 CFR 46.104 fice4 0at99termination.

Review of research involving human fetal tissue:
All research using human fetal materials must be submitted to the IRB via eBridge. See *IRB SOP: Use of Human Fetal Tissue in Research* for further information.

REFERENCES:
45 CFR 46.102
45 CFR 46.104
45 CFR 46.110
45 CFR 46.160
45 CFR 46.164
21 CFR 50.3(c)
21 CFR 56.102
21 CFR 58
Federal Food, Drug, and Cosmetic Act Sections 505(i) and 520(g)

SUPPORTING DOCUMENTS:
MCW Corporate Policy RS.HS.040 – Human Research Protection Program
IRB SOP: Registration Projects: Human Subject Research Projects which Qualify for FLEX Review
IRB SOP: Use of Human Fetal Tissue in Research

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