RESPONSIBILITIES FOR INVESTIGATORS CONDUCTING HUMAN SUBJECT RESEARCH

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

Applies to: Faculty and Staff involved in human research

PURPOSE:
It is the policy of the Medical College of Wisconsin (MCW) Institutional Review Board (IRB) that Investigators conduct human subject research in accordance with federal regulations, state, tribal, and local laws as well as institutional policies and procedures.

It is an Investigator's responsibility to be aware of the expectations, training requirements, and oversight responsibilities prior to conducting or engaging in human subject research.

2. The Investigator is responsible for assuring that accurate and updated information regarding the use of FDA approved and/or investigational agents is communicated to subjects when used in the context of the project, if applicable.
    a. This information may come from new adverse events, FDA alerts and warnings or other sources, and may require modifications to IRB approved documents.

Additional Committee/Institution Approvals

1. Investigators are responsible for seeking review and approval from other MCW, FH or Versiti Committees as required, prior to the initiation of any project. See *IRB SOP: Submitting New Projects*.
2. MCW IRB may require approval from the following committees and/or institutions before final IRB approval will be granted depending on the activities proposed in the research.
    a. Departmental Review
    b. Clinical and Translational Science Institute (CTSI/TRU)
    c. Safety Committees (e.g.,Radiation Safety, MRI, IBC)
    d. Emergency Medicine Resource Review Committee
    e. CW HRPP Local Context Review

3. If additional approvals are required, it is the Investigator's responsibility to obtain approval from any other institutions before initiating the project. For more information see *IRB SOP: Reliance Agreements for Multi-Site Projects.*

REFERENCES:

N/A

SUPPORTING DOCUMENTS:

MCW Corporate Policy: MCW Participation as Research Subject Policy (RS.HS.030)
MCW Corporate Policy: Conflicts of Interest - General (AD.CC.030)
MCW Corporate Policy: Financial Conflicts of Interest in Research (RS.GN.020)
IRB SOP: Human Subject Research Protections Training Requirements
IRB SOP: Submitting New Projects
IRB SOP: Amendments
IRB SOP: Continuing Progress Reports (CPR)
IRB SOP: Reporting Requirements to the IRB
IRB SOP: Privacy and Confidentiality
IRB SOP: Research Involving Prisoners
IRB SOP: Research Involving Pregnant Women and Fetuses
IRB SOP: Use of Human Fetal Tissue in Research
IRB SOP: Research Involving Children
IRB SOP: Research with Subjects likely to Manifest or Develop Decreased Decisional Abilities

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Office of Research
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