



MCW Office of Research Standard Operating Procedure

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.

DEFINITIONS:

Principal Investigator:

- any individual who leads or directs a research project involving human subjects
- any individual who performs activities that engage MCW, Froedtert Health (FH), or Versiti in anyone else's research project
- any individual that uses MCW, Froedtert Health (FH), or Versiti resources; including lab equipment, physical space, or services
- any individual who brings research data onto the campus
- any individual who performs any research activity on MCW, Froedtert Health (FH), or Versiti campus

A Principal Investigator has overall responsibility for the conduct of a research project, including all technical, programmatic, financial, compliance, and administrative aspects. The Principal Investigator is responsible for controlling the technical direction and academic quality of the project, and will ensure that the project is carried out in compliance with the terms, conditions, and policies of the institution and sponsor, when applicable.

Project Personnel: all individuals who contribute substantially to the scientific development and/or the execution of a project.

POLICY:

Investigators are responsible for being knowledgeable regarding their roles and responsibilities as an Investigator. With each submission to the IRB, the Investigator is required to affirm that they agree to uphold the protection of the rights and safety of human research subjects through adherence to federal, state, tribal, and local laws, MCW IRB policies and procedures, and institutional policies.

The affirmation is found on the *Agreement of Investigator Responsibilities* page at the end of the eBridge submission.

Investigator Responsibilities

1. The Investigator is responsible for reviewing all submissions to the IRB and conduct the research project in compliance with all federal, state, tribal, and local laws as well as institutional rules and regulations related to research involving humans and, if applicable, to the Good Clinical Practice Guidelines.
 2. The Investigator is responsible for knowing and conducting the research project in compliance with all MCW corporate policies and MCW IRB policies and procedures.
 3. The Investigator may not initiate any research involving humans or enroll any research subject into a project without prior IRB review and approval.
 - a. In addition, the Investigator may not amend or change an approved protocol without prior IRB review and approval, except where necessary to eliminate apparent immediate hazard to the subject. For more information see *IRB SOP: Amendments*.
 4. The Investigator is responsible for conducting the informed consent process in accordance with *IRB SOP: Informed Consent and Documentation for Human Subjects Research*.
 5. The Investigator is responsible for ensuring that research subjects are kept fully and promptly informed of any new information that may affect their willingness to continue to participate in the research project.
 6. The Investigator is responsible for maintaining current and accurate records of research data, outcomes, and adverse events.
 7. The Investigator will ensure the privacy of subjects and maintain confidentiality and security of the data in accordance with *IRB SOP: Privacy and Confidentiality* and other applicable institutional policies.
 8. The Investigator is responsible for submitting the project in a timely manner (as required by the IRB) for the Continuing Progress Review (CPR) in order to obtain IRB renewal/approval. The Investigator is responsible for being aware that failure to do so will result in a lapse of project approval, and all activities must halt. For more information see *IRB SOP: Continuing Progress Reports*.
 9. The Investigator is responsible for following the protocol as approved by the MCW IRB. All protocol deviations will be reported to the IRB in accordance with *IRB SOP: Reporting Requirements to the IRB*. Documentation of protocol deviations will be kept in the project regulatory files, and if applicable, in the research subject files.
 10. The Investigator is responsible for reporting to the IRB in a timely manner, all reportable events according to *IRB SOP: Reporting Requirements to the IRB* and make a reasonable effort to ensure that subjects who have suffered an adverse event associated with research participation receive adequate care to correct or alleviate the consequences of the adverse event to extent possible.
 - a. The Investigator must report to the IRB, Data and Safety Monitoring Boards, sponsors and appropriate federal agencies any unanticipated problems involving risks to subjects or others that occur in the course of the project.
 11. The Investigator is responsible for ensuring that project coordinators, co-investigators, and other research staff understand their association with and role in the project. The Investigator will provide access to a copy of the protocol for the project coordinator(s), co-investigator(s), and other research staff. The Investigator will also ensure that all members of the research team have completed appropriate human subjects research protections (HSRP) training. For more information see *IRB SOP: Human Subject Research Protections Training Requirements*.
 12. The Investigator is responsible for completing MCW HSRP training requirements and to remain up-to-date with federal regulations, state, tribal, and local laws, institutional and MCW IRB policies and procedures, and compliance expectations. For more information see *IRB SOP: Human Subject Research Protections Training Requirements*.
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Investigator and Project Personnel Conflicts of Interest

1. Investigators are responsible for disclosing all actual or perceived conflicts of interest as defined by following *MCW Corporate policies* and *IRB SOP: Investigator Conflicts of Interest* to the institution and to the MCW IRB.
2. Investigators are responsible for ensuring all actual or perceived conflicts of interest as defined by institutional policy are reviewed and a determination rendered by the MCW Financial Conflicts of Interest in Research Committee.

Funding Proposals

1. Investigators are responsible for ensuring that the IRB application contains any and all current funding.
2. Funding may be linked within the eBridge SmartForm, or should be uploaded as a supporting document.

Supervision and Monitoring of Research Process

1. Investigators are responsible for ensuring that all procedures associated with the research are performed, with the appropriate level of supervision, only by individuals who are licensed or otherwise qualified to perform them under the laws of Wisconsin and the policies of Medical College of Wisconsin, Froedtert Health and Versiti.
2. Investigators must ensure adherence to the IRB approved project protocol and monitor the informed consent process. Investigators must also ensure there are appropriate facilities and resources to conduct the research.
3. Investigators are responsible for regularly reviewing and documenting their research processes and address any deficiencies identified.
4. When overseeing a multi-site project, it is the responsibility of the Investigator to routinely monitor external performance sites and assure adequate staff, resources, and pharmacy practices.

Confidentiality

1. The conditions for maintaining confidentiality of the subjects' records are required for the life of the data. These rules apply equally to any and all projects conducted or assisted by students, staff, and faculty.
2. Records for projects conducted with Food and Drug Administration (FDA) regulated articles must be kept in accordance with current FDA regulations.
3. Investigators are responsible for ensuring subject privacy and confidentiality according to HIPAA guidelines as well as Institutional and IRB policies and procedures. See *IRB SOP: Privacy and Confidentiality* for more information.

Additional Requirements for Activities Involving Vulnerable Populations

1. Investigators are responsible for identifying the involvement of a vulnerable population in their projects and for implementing any additional safeguards protect these populations. Special considerations are provided in the federal regulations and/or the MCW IRB policies and procedures for the following populations:
 - a. Pregnant Women, Human Fetuses, Neonates, and Transplantation of Fetal Tissue: For research activities involving pregnant women, human fetuses, neonates and transplantation of fetal tissue, the Investigator must adhere to *IRB SOP: Research Involving Pregnant Women and Fetuses* and/or *IRB SOP: Use of Human Fetal Tissue in Research*
 - b. Prisoners: All research activities involving the use of prisoners as subjects require both MCW IRB approval and OHRP approval and be conducted in accordance with *IRB SOP: Research Involving Prisoners*.
 - c. Children: All research involving minors must be conducted in accordance with *IRB SOP: Research Involving Children*.

- d. Decreased Decisional Ability: Research activities involving individuals who are or who may experience decreased decisional abilities must be conducted in accordance with *IRB SOP: Research with Subjects likely to Manifest or Develop Decreased Decisional Abilities*.
 - e. MCW faculty members, fellows, staff members, and students: No MCW faculty member, fellow, or exempt staff member may participate as a subject in any MCW research project during the employee's regularly scheduled working hours. No MCW non-exempt staff member may claim as hours worked time spent participating as a subject in any MCW research project.
 - a. No MCW faculty member may solicit or knowingly permit MCW faculty member, fellow, staff member, or student over whom the investigator has a Reporting or Evaluative Relationship to participate as a subject in any MCW research project for which the MCW faculty member is an Investigator. Investigators are responsible for being in compliance with *MCW Corporate Policy: MCW Participation as Research Subject Policy (RS.HS.030)*
 - f. Non-English proficient subjects: Research activities involving individuals who are Limited-English proficient and/or Non-English proficient must be conducted in accordance with *IRB SOP: Recruitment and Enrollment of Non-English or Limited-English Proficient Subjects*.
2. The IRB may also determine that other target populations such as Native American tribes or individuals who are economically or educational disadvantaged, identified in the project are vulnerable and may impose additional protections not outlined in the federal regulations. See *IRB SOP: Research involving Native American or Alaskan Native Tribes* and *IRB SOP: Research Involving Economically or Educationally Disadvantaged Persons*.

Project Records

1. At a minimum, Investigators must maintain project records for at least ten (10) years from the date the project is closed with the MCW IRB, per *IRB SOP: Project Closure*
2. Beyond ten (10) years, requirements for record retention vary with the type of project conducted and provisions of the Investigator's funding source. It is the Investigator's responsibility to have a clear understanding of the retention requirements of a sponsor and/or the FDA as applicable.
3. All project records must be accessible for inspection by authorized representatives of the institution, the MCW IRB, federal regulatory agency representatives, and the department or agency supporting the project.
4. In the event the Investigator moves to another location and leaves MCW, FH, Versiti, or CW, the MCW IRB must be notified prior to leaving the institution. The Investigator may either have another MCW, FH, Versiti, or CW Investigator assume Principal Investigator responsibilities, close each of his or her projects with the IRB, or take the project to the new location.
 - a. The Investigator must also notify the MCW IRB via an amendment submission of the plan for either moving the data to another institution or transferring the data to another MCW, FH, Versiti or CW PI.

Use of Investigational Drugs and/or Investigational Devices

1. The Investigator is responsible for contacting the FDA and, if necessary, obtaining an Investigational New Drug (IND) or Investigational Device Exemption (IDE) from the FDA in accordance with Federal regulations. See *IRB SOP: Use and Storage of Investigational Drugs or Biologics* and *IRB SOP: Use and Storage of Investigational Devices*.

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 HRP 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

IRB SOP: Research Involving Economically or Educationally Disadvantaged Persons

IRB SOP: Research Involving Native American or Alaskan Native Tribes

IRB SOP: Use and Storage of Investigational Drugs or Biologics

IRB SOP: Use and Storage of Investigational Devices

IRB SOP: Project Closure

IRB SOP: Informed Consent Process for Human Subject Research

IRB SOP: Informed Consent Document for Human Subject Research

IRB SOP: Investigator Conflicts of Interest

IRB Form: Agreement of Investigator Responsibilities

IRB SOP: Recruitment and Enrollment of Non-English or Limited-English Proficient Subjects

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