



MCW Office of Research Standard Operating Procedure

SUBMITTING NEW PROJECTS

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

Applies to: Faculty and Staff involved in human research

PURPOSE:

Investigators must submit all new protocols or projects which involve human subjects as defined by *IRB SOP: Definition and Determination of Human Subject Research* to the MCW IRB for review and approval prior to initiation of research activities. The IRB will determine what type of review is required for the protocol based upon information provided in the submission and any attached documents.

DEFINITIONS:

Designated Reviewer: an individual who has been given the authority by the MCW HRPP Office to make a determination on an assigned submission. This includes IRB members or HRPP staff depending upon the submission type as described below:

1. Projects Reviewed by Convened Committee – designated reviewer refers only to a rostered IRB member
2. Expedited Projects – designated reviewer refers only to a rostered IRB member
3. Non-federally Funded Exempt Projects – designated reviewer refers to either an IRB Staff Member or a rostered IRB member
4. Federally funded Exempt Projects - designated reviewer refers only to a rostered IRB member

Convened IRB Committee Review: Research that involves greater than minimal risk requires review and approval by a convened IRB Committee composed of physicians, scientists, non-scientists, and community members. Risks to research participants should be justified by the anticipated benefits to the subjects or society. Research that requires convened committee review includes but is not limited to:

- Most research that involves children prisoners, pregnant women, fetuses and other vulnerable populations
- Research that involves experimental drugs or devices
- Research that involves invasive procedures
 - Real-Time Review: A mechanism to facilitate review of new IRB submissions by a convened committee within 14-20 days from the date the new submission is received by the IRB. The Principal Investigator and research coordinator must attend the IRB Committee meeting at which the research is scheduled for review. In the event the IRB has requested modifications, these will be communicated to the PI and research coordinator in-person. The project team will be given the immediate opportunity to address the requested modifications and the research is re-presented for a second review during the IRB meeting.

Minimal Risk: means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Expedited Review: means that the review takes place outside of a regularly convened IRB Committee meeting. Reviews are conducted by the IRB Chair and designated expedited reviewers. "Expedited review" does not mean that the review will occur immediately, but rather that the project activities involve no more than minimal risk and meet the criteria of one or more of the nine categories as defined by OHRP and FDA.

Exempt Review: Certain types of research may be classified as "Exempt" from IRB review under federal regulations. Exempt research is human subject research that falls within specifically defined categories. Research that falls into an exempt category still requires submission to the IRB in the eBridge system for final determination.

- **Limited IRB Review:** A condition of exemption for four of the exempt categories. It is required for certain activities in categories 2 and 3. Limited IRB Review may be carried out by the designated reviewer. Limited IRB Review requires the IRB to determine that there are adequate provisions for protecting privacy and confidentiality.

FLEX Review: Certain types of research projects that fall outside of the scope of the MCW FWA and meet the identified criteria, qualify to be reviewed under institutional defined equivalent protections consistent with the Belmont Report. FLEX reviews may be completed by HRPP Staff. Projects which qualify to be reviewed via FLEX review are considered registration projects and are subject to the policies as outlined in *IRB SOP: Registration Projects: Human Subject Research Projects Which Qualify for Flex Review*.

PROCEDURE:

1. Investigators must submit an application for human subject research in eBridge to the MCW IRB for review and approval before beginning the project.
2. To open a new application or submission, Investigators must log into in eBridge. Once logged in, click on the "New Human Research Project" activity on the left to open the eBridge PRO SmartForm, which is the IRB application form. Investigators should complete the necessary fields in the eBridge PRO SmartForm. For all submissions, the Investigator should include the following for the IRB's review, as applicable:
 - a. Protocol
 - b. Complete DHHS-approved protocol
 - c. Consent forms
 - d. DHHS-approved sample consent document
 - e. Data Safety Monitoring Plan or finalized Data Safety Monitoring Board Charter
 - f. Questionnaires, Surveys, Data collection forms
 - g. Additional institutional reviews and Ancillary Review Committee approval letters
 - h. Recruitment materials (advertisements, flyers, radio scripts)
 - i. Safety information (Investigator Brochures, Package Inserts, Safety Reports)
 - j. Documentation of IND/IDE status or exemptions
 - k. Funding documentation
 - i. When submitting a federally funded project for which the grant is awarded to a non-MCW institution, the entire grant must be uploaded into the eBridge SmartForm .

- ii. When submitting an industry sponsored project for which the contract is negotiated between industry and a non-MCW institution, the final contract must be uploaded into the eBridge SmartForm.
 - I. A description of the management and possible reporting process of information that is relevant to the protection of subjects including but not limited to:
 - i. Unanticipated Problems involving Risk to Subjects or others
 - ii. Interim Results
 - iii. Project Modifications
 - m. NIH Data Management and Sharing Plan (e.g. DMPTool)
3. After completing the eBridge PRO SmartForm and uploading all required documents, the Investigator should submit the application in eBridge. Lack of information or incomplete information may result in delays in the process of IRB review and approval.

Other Federal Agencies Requirements

Department of Justice & Bureau of Prisons: For projects supported by Department of Justice being conducted within the Bureau of Prisons; the Investigator must include the following within the eBridge SmartForm

- Description of academic preparation or previous experience in the area of project of the proposed research
- Within the protocol, include a summary statement which includes the following information:
 - Names and current affiliations of the researchers.
 - Title of the project.
 - Purpose of the project.
 - Location of the project.
 - Methods to be employed.
 - Anticipated results.
 - Duration of the project.
 - Number of participants (staff or inmates) required and amount of time required from each.
 - Indication of risk or discomfort involved as a result of participation.
- In addition, the protocol and eBridge SmartForm should include information to address the following areas:
 - Review of related literature.
 - Detailed description of the research method.
 - Significance of anticipated results and their contribution to the advancement of knowledge.
 - Specific resources required from the Bureau of Prisons.
 - Description of all possible risks, discomforts, and benefits to individual participants or a class of participants, and a discussion of the likelihood that the risks and discomforts will actually occur.
 - Description of steps taken to minimize any risks.
 - Description of physical or administrative procedures to be followed to:
 - Ensure the security of any individually identifiable data that are being collected for the project.
 - Destroy research records or remove individual identifiers from those records when the research has been completed.
- Description of any anticipated effects of the research project on organizational programs and operations.

- Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.

ICH-GCP Requirements

The Investigator should indicate if the sponsor of the project or funding agency require the project to be conducted in accordance with ICH-GCP E.6 policies. This will ensure the HRPP and IRB Committees apply these criteria to their review of the project.

Additional Institutional Reviews outside of IRB Review:

Some new protocols may require various administrative or ancillary committees prior to being reviewed by the IRB. Investigators should be aware of these processes when planning to submit a new project to the IRB. The following are examples of administrative committees which may need to review a submission prior to or concurrent to the IRB review:

- **Departmental Review**
 - Individual Departmental Reviewers have been appointed by the department or division (where applicable) to perform these reviews prior to the IRB receiving the submission in eBridge.
- **Children's Wisconsin HRPP Local Context Review**
 - Children's Wisconsin (CW) HRPP reviews all projects which seeks to access, recruit or use CW resources to ensure compliance with CW institutional policies.
- **Emergency Medicine Resource Review Committee:** Required for projects which seek to access, recruit, or use emergency department (ED) resources including if subjects will be recruited from the ED.
- **Office of Clinical Research & Innovative Care Compliance (OCRICC):** Required if the Investigator will utilize any Froedtert Hospital resources, included but not limited to:
 - Medical Records
 - Investigational Pharmacy
 - Space and/or equipment
 - Use of FH staff

Many of the projects conducted at MCW or by MCW faculty include a variety of activities which may require review by ancillary committees for safety or resource availability. Investigators should identify if their projects contain any of the identified activities, procedures, chemicals or human source materials (cells, tissues) in their eBridge SmartForm. Submissions may be delayed if the safety reviews and/or approvals have not been obtained prior to IRB review.

- **Clinical and Translational Science Institute (CTSI/TRU)**
 - This review is required for projects which seek to use TRU resources.
- **MCW Ancillary Safety Committees**
 - **MRI Safety Committee:** Required if the project procedures will include any MRI scanning procedures that are 1) not routinely performed for similar patients not enrolled in a project, 2) not performed for this project at FH Radiology, 3) and not billed to the patient(s) insurance as routine care cost.
 - **Hazardous Chemical Committee:** Required if the project procedure will include using chemicals classified as one of the following; carcinogens, acutely toxic, reproductive hazardous, highly reactive, Homeland Security

Chemical of Interest, untested substances or any of the chemicals cited on their PHS list

- **Radiation Safety Committee:** Required if the project procedures will include Irradiators, CT, X-Rays, DEXA scans, Fluoroscopy, and/or Unsealed Radioactive materials.
 - If the project will be conducted solely at the Blood Center of Wisconsin (BCW) and all project staff are BCW employees, research staff should not check “Radiation Safety Committee” in the eBridge SmartForm. A letter from the BCW Radiation Safety Officer should be uploaded into the eBridge SmartForm in section 52.
- **Institutional BioSafety Committee:** Required if the project procedures will include the use of toxins, pathogens, recombinant DNA, or synthetic nucleic acids.
 - If the project will be using human source material such as human blood, tissues, or human cell lines, Investigators must complete and submit to the IBC the IBC Human Source Material Registration form.
- **Human Stem Cell Committee** – Required if the project seeks to use the following types of human stem cells
 - Human embryonic stem cells (hESCs)
 - Induced pluripotent stem cells (iPSC) regardless of source
 - Human pluripotent stem cells (hPSCs) in vitro expected to yield gametes
 - Transplantation of hPSCs or multipotent human neural stem cells into animals

IRB Review

1. When a new project is received by the IRB, the HRPP office will review the submission and attached documents for completeness and determine the appropriate type of IRB review based upon the risks and types of activities involved. The IRB reviews new research under the following categories:

- FLEX Review
- Exempt Review
- Expedited Review
- Convened Committee Review

In order for the IRB to approve a project, basic criteria as described in the **federal regulations** must be met. The determination that all criteria are met will be based upon information provided in the submission and any attached documents.

2. New projects are assigned to Convened IRB Committees on a rotating basis. All projects which qualify for either expedited, exempt, or FLEX review are assigned to one of the Minimal Risk Committees. Changes may be made to Committee assignments due to expertise, workload, or quorum issues however; typically the protocol once reviewed by a Committee will remain with that Committee for the life of the project.
3. The IRB will notify Investigators of its decision to approve or disapprove the proposed research project, or of modifications required to secure IRB approval of the research project. If the IRB decides to disapprove a research project, it will include in its written notification a statement of the reasons for its decision.

4. Investigators and project staff are notified of the disposition of a protocol within 5 business days following an IRB Committee meeting.
5. A schedule of IRB meetings is posted on MCW HRPP's website.
6. By accessing the project in eBridge, the PI and project team will be able to see which Committee will review the protocol, the name and contact information for the IRB Coordinator II (C2) responsible for the Committee, the meeting date at which the protocol will be reviewed, and the results of the review.
 - The IRB C2 should be contacted for questions related to the protocol or its review. Please reference the submission number (PRO#) assigned to the project in eBridge when requesting assistance.

REFERENCES:

N/A

SUPPORTING DOCUMENTS:

IRB SOP: Definition and Determination of Human Subject Research

IRB SOP: Registration Projects: Human Subject Research Projects Which Qualify for Flex Review

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