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

Exempt Review: Certain types of research may be classified as "Exempt" from IRB review under federal regulations. Exempt research is human subject research that involves very little, if any, associated risk and 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 IRB Chair or by one or more experienced members of the IRB using the expedited review procedure(s). 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 fall outside of the scope of MCW FWA which 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 and will not require additional review by the IRB committee or a designated reviewer. 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

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 an Detailed description of th Prisons:

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**
  - o

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

---

Effective Date:	04/28/2023
Version number:	10.0
Previous Version/date:	9.0, 06/15/2018
Responsible Office:	HRPP Office
Approval Date:	04/13/2023

Approved By
HRPP Authorized Official: Ryan Spellecy, PhD, Director, HRPP
Human Research Protections Program (HRPP)
Office of Research
Medical College of Wisconsin