MCW IRB Committee Procedures

INITIAL REVIEW PROCESS: PRIMARY AND SECONDARY REVIEWER RESPONSIBILITIES

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

Applies to: Institutional Review Board Committees

PURPOSE:
This procedure outlines the steps taken when a new project will be reviewed by the convened IRB Committee and the expectations of the IRB members assigned as primary and/or secondary reviewers.

MCW IRB has two (2) IRB committees focused on the review of minimal risk research. Initial review of projects which appear to qualify for expedited review, or an exempt determination is outlined in *IRB Member SOP: Review of Exempt or Expedited Review.*

DEFINITIONS:
N/A

POLICY:
N/A

PROCEDURE:
INITIAL REVIEW

1. At the time of initial review, the IRB Committee considers the proposed eBridge PRO submission in accordance with regulatory and institutional requirements.
2. The IRB Committee will review and examine the Principal Investigator (PI) and project staff to ensure that their expertise and training is appropriate to conduct the project.
3. The standards for the review of a new project and/or consent form are outlined in the *IRB Member Form: New Protocol Review Checklist* which includes the federal regulations criteria for approval (45 CFR 46.111 and/or 21 CFR 56.111).
    - These forms are available to members via HRPP website, and during the meeting.
4. The IRB Committee must determine the following criteria are clearly met for initial approval according to criteria for approval (45 CFR 46.111 and/or 21 CFR 56.111).
    a. Risk to subjects is minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk and whenever appropriate, by using procedures already being performed on the subject for diagnostic or treatment purposes
    b. Risks are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may be expected to result.
    c. Selection of subjects is equitable
    d. Informed consent will be sought from each subject or the subject's legally authorized representative. See *IRB Member SOP: Informed Consent for Human Subject Research* for more information.

e. Informed consent will be appropriately documented, or if approved by the IRB, waived. See *IRB Member SOP: Informed Consent for Human Subject Research* for more information.
f. When appropriate, data will be monitored to ensure the safety of subjects. *See IRB SOP: Data and Safety Monitoring Plans*
g. Privacy and confidentiality protections are in place where appropriate. See *IRB Member SOP: Privacy and Confidentiality* for more information.
h. The project has the resources necessary to protect subjects including but not limited to:
    i. Adequate time for the researchers to conduct and complete the project
    ii. Adequate number of qualified staff
    iii. Adequate facilities to conduct the project
    iv. Access to a population that will allow the recruitment of the necessary number of subjects
    v. Availability of medical or psychosocial resources that subjects may need as a consequence of the project.
    vi. For projects where other sites are relying upon the MCW IRB to serve as the IRB of Record, the Committee should review the information regarding resources provided with the IRB submission.
        - This will include a CV of the investigator from the relying site and a description of available resources in the protocol or in an addendum to the protocol, along with the local context form for each location.

5. Additional criteria and checklists must be used for the review of projects which may involve minors, prisoners, pregnant women and fetuses or individuals who may be decisionally impaired are applied as set forth in the following procedures:
    - *IRB Member SOP: Research Involving Prisoners*
    - *IRB Member SOP: Research Involving Pregnant Women and Fetuses*
    - *IRB Member SOP: Research Involving Children*
    - *IRB Member SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability*

    The specific criteria are made available to all members via the HRPP website and during the meeting.

6. If the project is funded or supported by one of the following federal agencies as noted below; either the Primary or Secondary Reviewer must complete the *IRB Member Form: Additional Federal Agencies Requirements Checklist*.
    - Department of Defense (DoD), or a component of the DoD
    - Environmental Protection Agency (EPA)
    - Department of Justice (DoJ) and/or Bureau of Prisons (BoP)
    - Department of Education (DoEd.)
    - Department of Energy (DoE)

7. If the project requires the IRB and the Investigator to comply with ICH-GCP E.6 criteria, the Primary and Secondary Reviewer should work with the IRB Coordinator II (C2) to ensure the necessary criteria have been met for the review of the project and complete the *IRB Member Form: ICH-GCP E.6 Requirements Checklist*.

Convened Meetings and the Primary Reviewer System

1. When the MCW IRB Committee reviews an initial submission in eBridge at a convened meeting, the IRB C2 provides all members with sufficient information to evaluate whether the proposed project fulfills the criteria for approval.
2. All MCW IRB members have access to the same information, including the investigator's brochure (if applicable).

3. The MCW IRB Committees use a “primary reviewer” system to promote a thorough review of the initial submission at a convened meeting.
4. With this system, the IRB C2 assigns the initial submission in eBridge to one or two IRB member(s) who are responsible for leading the discussion when the Committee reviews the submission in accordance with *IRB Member SOP: Assigning Reviewers and the Use of Consultants* and complete the *IRB Member Form: New Protocol Review Checklist*. These resources are available via the HRPP website.
5. The assigned Primary and Secondary Reviewers perform an in-depth review of all the information and documents included in the eBridge PRO SmartForm including, but not limited to, the following (when applicable):
    a. Protocol
    b. Complete DHHS-approved protocol (if applicable)
    c. Proposed MCW Consent Form
    d. DHHS-approved sample consent document (if applicable)
    e. The investigator brochure, package insert or Device manual
    f. Any grant application or contract

    The review is conducted according to the standards outlined in the *IRB Member Form: New Protocol Review Checklist* as appropriate.

6. All other IRB committee members are expected to review key documentation the eBridge submission to the extent necessary to be prepared to participate in the discussion of the regulatory criteria for approving research. *See IRB Member SOP: Conduct and Expectation of IRB Members* for more information.
    a. For initial review of a submission “key documentation” includes the following:
        i. SmartForm application
        ii. Consent Form(s)
        iii. Recruitment materials (if provided)

7. If the assigned Primary Reviewer, the IRB Chair or the HRPP Director determines that additional expertise is needed for the review of the proposed project, an appropriate consultant will be invited to assist in the review in accordance with *IRB Member SOP: Assigning Reviewers and Use of Consultants.*
8. Following the presentation, the Primary and Secondary Reviewers will make a motion for the IRB Committee’s vote as outlined in *IRB Member SOP: IRB Actions* and opens the floor for discussion among the members. At the end of the discussion the IRB Chair will call for a vote.
    a. The motion will include the length of approval for the project. The Primary and Secondary Reviewer will review the criteria for identifying projects which may require review on a more frequent basis as outlined in this procedure.

Research Reviewed more than Annually

While the IRB Committee is required to review a project once per year, at a minimum, the Primary Reviewer or other Committee members may recommend a shorter frequency of review for the research in that:

a. The risk-benefit ratio is such that the IRB committee should review project data and progress at a shorter interval to determine if the project is still acceptable or
b. High-risk of harm and/or a high likelihood that harm will occur sooner than one year.

REFERENCES:

45 CFR 46.111
21 CFR 56.111

SUPPORTING DOCUMENTS:

IRB SOP: Data and Safety Monitoring Plans

IRB Member SOP: Informed Consent for Human Subject Research
IRB Member SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability
IRB Member SOP: Privacy and Confidentiality
IRB Member SOP: Research Involving Prisoners
IRB Member SOP: Research Involving Pregnant Women and Fetuses
IRB Member SOP: Research Involving Children
IRB Member SOP: Conduct and Expectation of IRB Members
IRB Member SOP: IRB Actions
IRB Member SOP: Assigning Reviewers and Use of Consultants.
IRB Member Form: New Protocol Review Checklist
IRB Member Form: ICH-GCP E.6 Requirements Checklist
IRB Member Form: Additional Federal Agencies Requirements Checklist

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