MCW Office of Research
Standard Operating Procedure

REGISTRATION PROJECTS: HUMAN SUBJECT RESEARCH PROJECTS WHICH QUALIFY FOR FLEX REVIEW

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

Applies to: Faculty and Staff involved in human research

PURPOSE:
Effective 01/27/2017 MCW as an institution opted to limit the scope of its Federal Wide Assurance (FWA) to apply to federally funded and/or FDA-regulated research. With the revised common rule, MCW has elected that certain research projects not funded by federal sources, and/or not regulated by the FDA, fall outside of the scope of the FWA, may qualify to be reviewed under institutional equivalent protections consistent with the Belmont Report.

This policy is limited to projects which meet the following criteria:

1. All project activities are no greater than minimal risk.
2. The project has not received or been supported by federal agencies. This includes project team members where a student, resident, or fellow is supported via a federal training grant or other federal funding including support from Faculty Advisor's federal funding.
3. Projects with contractual obligations or restrictions that preclude eligibility with this policy. For example, the sponsor's contract requires the project to be reviewed under FDA or HHS regulations.
4. Project does not involve prisoners as subjects
5. Project does not have an executed Inter-Institutional Reliance Agreement in place
6. Project is not a local bank
7. Project may not include international site(s) under the supervision of the PI
8. Project does not include CW resources, patients and/or staff.

Under no circumstances will federally funded or FDA regulated research projects qualify for review under this policy.

DEFINITIONS:
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.

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

POLICY:
As defined above, all registration projects must meet the above criteria to qualify for review under the equivalent protections and processes (FLEX Review) as defined and outlined in this policy.

Registration Categories
This policy creates new MCW-specific registration categories which are not defined in the federal regulations for research projects. These categories will only be applied to research projects which fall outside of the scope of MCW FWA.

Special Note: If your project involves the use of any Froedtert Health resource such as, space, staff services, supplies/equipment, or any ancillary services - lab, pharmacy, radiology, protected health/billing information or specimen requests, OCRICC approval is required before beginning any research activity at those sites. It is recommended that you contact OCRICC before submitting to the IRB.

- Category 1: Evaluation or comparison of educational techniques or instructional curriculum
- Category 2: Conducting surveys, questionnaires, focus groups, or interviews
- Category 3: Use of specimens that has been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis)
- Category 4: Taste and Food Quality evaluations
- Category 5: Blood draws via venipuncture, finger, heel or ear stick*
- Category 6: Prospective collection of biospecimens via non-invasive procedures
- Category 7: Prospective collection of data via non-invasive procedure
- Category 8: Research involving materials (i.e. data, documents, or records) that has been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
- Category 9: Collection of images, video or recordings for solely for research
- Category 10: Psychosocial interventions

*Category 5 has specific criteria which must be met to qualify under this category such as limits on amount of blood collected depending upon the subject population to be included.

IRB Approval Periods
Registration projects reviewed and determined to qualify for FLEX review as defined by this policy will not be required to submit a continuous progress report (CPR) for the life of the project unless the project is modified in such a way that it no longer qualifies for FLEX review.

Consent
Registration projects may involve a variety of activities, and the research team should consider several factors regarding consent, including:

- If there will be direct contact or interaction with subjects.
- The nature of the research activities.

No Consent Required:
For projects which do not have direct contact with subjects such as those that propose to review records or access biospecimens not created for the research

project, teams may indicate “None of the above” in consent section of the eBridge SmartForm, and then select the option indicating no direct contact.

- This is like the pathway for projects under federal regulations which may qualify for an exempt determination.

Informational Letter or Consent Scripts:
Projects looking solely at the following activities:

- Evaluating educational curriculum, instructional techniques,
- Distributing surveys, or questionnaires,
- Conducting interviews and focus groups

These activities may involve varied levels of contact with subjects and may qualify to use an informational letter or a consent script to explain the research to subjects, participation is voluntary, the risk of the research activities, benefits and who to contact if they have any questions.

MCW HRPP has an informational letter template which teams may use for their registration projects.

Minimal Risk Consent Form:
For projects which may include activities such as blood draws, MR scans, imaging, non-invasive collection of biospecimens, or psychosocial interventions, the MCW HRPP recommends the use of the minimal risk consent form which also has HIPAA authorization language incorporated into the document.

PROCEDURE:

1. Investigators must complete and submit an eBridge PRO application in accordance with *IRB SOP: Submitting New Projects*.
2. Projects which may qualify for FLEX review will follow the same process of undergoing departmental and applicable ancillary, and safety committee reviews prior to being received by the HRPP Office. Investigators must secure all the applicable department/institutional approvals prior to their project being reviewed by the IRB.
3. HRPP Office will review the project and confirm the project qualifies for FLEX review and identify the applicable Registration categories.
4. During the review, the assigned IRB Coordinator will review and may request changes to ensure the following criteria have been met:
    a. This project meets the following ethical requirements:
        i. The research holds out no more than minimal risk to subjects.
        ii. The selection of subjects is equitable
        iii. If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.
    b. If the project involves interaction with subjects, a **consent process and form (if applicable)** has been reviewed and discloses the following information:
        i. That the activity involves research.
        ii. A description of the procedures.
        iii. That participation is voluntary.
        iv. Name and contact information for the researcher.
        v. There are adequate provisions to maintain the privacy interests of subjects.
5. After the review is complete, and any requested changes have been completed, the HRPP Office will issue determination letter in accordance with *IRB SOP: IRB Approval Documents.*

Modifications to a Registration Project

1. It is the responsibility of the Principal Investigator to secure IRB approval prior to implementation of substantial revisions to a Registration project.
2. Examples of changes requiring approval include but are not limited to:
    - PI change
    - Addition of federal or for-profit funding
    - Addition of new activities or project phases
    - Changes that trigger FDA jurisdiction (e.g. you are now planning to report research results to a drug/device manufacturer for the purpose of FDA application)
    - Addition of completely new project population
    - Addition of site that requires execution of a reliance agreement with our IRB
    - Addition of international sites
3. See *IRB SOP: Amendments* for more information regarding Amendments.
4. Submitted changes may alter a project's qualification for FLEX review. If changes disqualify a project from FLEX review, the project will be assigned to an IRB Committee for review and reclassified under the applicable HHS and/or FDA regulations.

Reclassification of Projects which qualify under FLEX review

1. Investigators with currently approved minimal risk projects, approved prior to 2017 and classified as Expedited or Exempt under HHS regulations may have their projects reclassified as Registration projects. This may occur during the review of an amendment or 6-year Renewal in eBridge.
2. The HRPP office will confirm if the project qualifies for FLEX review.
3. Investigators will be notified of this reclassification with their IRB approval letter

Closing Registration Projects

1. The PI is responsible for notifying the IRB when a Registration project is complete. If the IRB is not notified that the project is complete, the project remains in an active state.
2. To close a Registration project, project teams should navigate to the eBridge Protocol Workspace and perform the action to report project closure and move the project to a "Completed" state.
3. Registration projects can close during data analysis / manuscript preparation activities.
4. As with all research projects, once a Registration project is closed, it cannot be re-opened, so data collection, participant enrollment, etc. must be complete prior to closure.

REFERENCES:

N/A

SUPPORTING DOCUMENTS:
Belmont Report
Inter-institutional Reliance Agreement
IRB SOP: IRB Approval Documents
IRB SOP: Submitting New Projects
IRB SOP: Amendments
MCW Informational Letter Template
MCW Informed Consent Templates

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