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.

Routine Review Selection
Registration Projects may be selected by the MCW HRPP QA/QI team for a routine review. Investigators will be notified in advance that the project was selected along with a description of what will be reviewed as part of the routine review visit.

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 changes to a Registration project.

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