



MCW Office of Research Standard Operating Procedure

DEPARTMENTAL REVIEW

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

Applies to: Faculty and Staff involved in human research

PURPOSE:

Under federal regulations, the MCW IRB has a responsibility to determine whether a project is designed so that the risks to subjects are minimized, whether the potential benefits of a project justify the potential risks and if the necessary resources are available to the Investigator to conduct the project. These directives obligate the IRB to consider the project design and overall scientific quality of each project under review.

The MCW IRB delegates this responsibility to the Department/Division/Institute and requires that a representative of the Investigator's department, division, or institute to certify that a review of these elements had been completed.

DEFINITIONS:

Department: For purposes of this policy, may mean a Department, Division, or Institute.

Departmental Reviewer: Individual in the Department, Division, or Institute who is designated to review and attest that certain criteria are met before the project can move to Ancillary or IRB review.

POLICY:

When a new IRB eBridge SmartForm application is submitted, the application is first routed to the designated departmental reviewer. The IRB is not able to begin their review of a submission until the designated departmental reviewer indicates approval on behalf of their department, division and/or institute.

The departmental reviewer's approval form includes an attestation addressing the following elements as these elements must be evaluated as part of the department, division or institutes review process:

- The Principal Investigator is a faculty member or adjunct faculty member in good standing in his/her Department/Division/Institute.
- The Principal Investigator's commitment of time and effort to the project is endorsed.
- The indicated commitment of departmental or divisional funds for this project is endorsed.
- The research project as submitted in the eBridge SmartForm and supporting documents has scientific merit.
- The eBridge SmartForm application is complete and coherent.

In cases where an external review of scientific quality has taken place, the Departmental Reviewer may recognize and accept that external review (e.g., section review for NIH grants, foundation review). In all other cases, Departments, Divisions, and Institutes should define their own scientific review processes and who will complete those.

Faculty members who are members on the research under review may not participate in the departmental review process to avoid potential conflicts of interest. Due to this possible conflict, it is recommended that the Chair, Chief or Director of a Department/Division/Institute appoint two Departmental Reviewers.

PROCEDURE:

1. A PI submits a new project within the eBridge system in accordance with *IRB SOP: Submitting New Projects*.
2. The new eBridge SmartForm is routed to the designated Departmental Reviewer.
3. The designated Departmental Reviewer reviews the eBridge SmartForm application according to their own department's procedures. Each department's process should evaluate and attest that the following conditions are satisfied:
 - a. The Principal Investigator is (i) a faculty member or adjunct faculty member in good standing in his/her Department/Division/Institute.
 - b. The Principal Investigator's commitment of time and effort to the project is endorsed.
 - c. The indicated commitment of departmental or divisional funds for this project is endorsed.
 - d. The research project as submitted in the eBridge SmartForm has scientific merit.
 - e. The eBridge SmartForm is complete and coherent.
4. When the Departmental Reviewer documents their approval in eBridge, the SmartForm is routed to Ancillary Review (if required), then to the IRB.

REFERENCES:

N/A

SUPPORTING DOCUMENTS:

IRB SOP: Submitting New Projects

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Approved By	
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