MCW Office of Research
Standard Operating Procedure

SIX (6)-YEAR RENEWALS

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

Applies to: Faculty and Staff involved in human research

PURPOSE:
Since 2005, MCW IRB has relied upon the eBridge system to process IRB applications and projects. As projects evolve over time, MCW IRB requires the review of non-exempt human subject research that continues beyond six years from the initial date of approval.

DEFINITIONS:
6-Year Renewal: The eBridge process which allows the Investigator to update their IRB approved project via a combined annual progress report and a modified eBridge SmartForm

POLICY:
For any non-exempt human subject research, MCW IRB requires a 6-year renewal submission every six year for ongoing projects, unless the project's activities fit one of the exceptions to this policy. A 6-year renewal submission may not be required when a project meets one of the following criteria:

- The project team's activities are limited only to data, sample, or image analysis or for a multi-site project, the activities of an analysis or reading center.
- The project team's activities are limited only to long-term follow-up of participants (e.g., collection of information about clinical health status and survival).

Regardless of the status of the project, MCW IRBs may require project closure and re-submission of a new IRB application.

In 2010, the MCW IRB began the process of converting all on-going non-exempt human subject projects into an updated version of the eBridge SmartForm. A 6-year renewal date was calculated at the time the conversion was approved.

Projects which received initial approval after 2010, the 6-year renewal date was calculated to be within 6 calendar years from date of initial IRB approval.

PROCEDURE:
1. Investigators will receive notifications that a specific project must submit a 6-Year Renewal application.
    a. Reminders will be communicated via eBridge to the project team to complete a 6-Year Renewal application or submit a Final Report.
2. To submit a 6-Year Renewal application in eBridge, the investigator or project team must login to eBridge, locate the approved project from My Home page, and click on "6-Year Renewal".
    a. This button/activity will not be available if the project has an amendment or CPR open and/or in process of being reviewed.

3. Investigators should complete the CPR form, click finish and then select the activity "View/Edit" to begin renewing their project.
4. New questions should be answered and addressed as they come up in the SmartForm. Project teams should use the "continue" button to move through the branching of the SmartForm.
5. The entire eBridge SmartForm should be reviewed for accuracy and sections or questions updated if necessary to reflect the conduct of the project.
6. Investigators should identify within the 6-Year Renewal application
    a. where the project began in terms of objectives and aims,
    b. what has been completed and/or objectives met,
    c. what remains to be done for the project.

    Along with responding to these questions, Investigators should identify changes made to the project that have not been previously reported to the IRB. Responses to the above questions, along with any changes should be described in the SmartForm.
7. In addition, the project team should review all the currently uploaded documents in eBridge and "delete" any documents or outdated revisions they are no longer using for the project.
8. After changes have been made to the eBridge SmartForm and a review of the uploaded documents, the Investigator should review the application to ensure its accuracy and then click the "Submit" button.
9. Once the IRB approves the 6-Year Renewal application, an archive copy of the previous eBridge SmartForm version along with all uploaded documents will be created and will be accessible to the project team under the "Archived SmartForm" project links which is in the eBridge Project workspace.

IRB Review

1. When a 6-Year Renewal application is received via eBridge by the IRB, the HRPP office will review the 6-Year Renewal application and attached documents for completeness, and determine the type of IRB review the project would qualify for based upon initial review the project received. The HRPP Office will also determine if continuing review is no longer required. If review is required, the IRB will review a 6-Year Renewal application under the following categories:
    a. Expedited Review
    b. Convened Committee Review

    For the IRB to re-approve a project, the basic criteria as described in the federal regulations must be met and reconfirmed. The determination that all criteria are met will be based upon information provided in the 6-Year Renewal application and any attached documents.
2. The IRB will notify investigators of its decision to approve or table the 6-Year Renewal application, or of modifications required to secure continued IRB approval. If the IRB decides to disapprove a 6-Year Renewal application, it will include in its written notification a statement of the reasons for its decision.
3. 6-Year Renewal applications are assigned to the IRB Committee which conducted the initial review and approval of the project.
4. By accessing the project in eBridge, the PI and project personnel will be able to see which Committee will review the 6-Year Renewal application, the name and contact information for the IRB Coordinator II (C2) responsible for the Committee, the meeting date at which the 6-Year Renewal application will be reviewed, and the results of the review. The IRB C2 should be contacted for questions related to a 6-Year Renewal application or its review. The submission number (CPR#) assigned to the project in eBridge should be referenced when requesting assistance.

Lapse of Project Approval:

If an Investigator does not provide a 6-Year Renewal submission to the IRB or the IRB has not approved the 6-Year Renewal application and project prior to the expiration date:

1. All research activities stop.
2. Interventions and interactions on current subjects stop, unless the IRB finds an over-riding safety concern or ethical issue involved such that it is in the best interests of individual subjects to continue participating.
3. New enrollment of subjects is not allowed to occur

REFERENCES:
N/A

SUPPORTING DOCUMENTS:
N/A

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