

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:

- x 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.
- x 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. 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