ECLIPSED PROGRESS REPORTING

Unit: Human Research Protections Program (HRPP), Office of Research
Applies to: MCW/FH Faculty and Staff involved in human research

PURPOSE:
Principal Investigators (PI) who fail to submit and obtain approval for a Continuing Progress Report (CPR) or fail to submit a Study Close-Out Report to the IRB prior to the study's IRB approval expiration fail to comply with one of the PI's primary responsibilities under federal regulation and MCW IRB policies.

DEFINITIONS:
N/A

PROCEDURE:
1. If an Investigator fails to submit and obtain approval for a CPR or submit a study close out report prior to the study's IRB approval expiring; the IRB will not accept or review any new study applications from the PI until:
   • The Investigator has filed a continuing progress or close-out report with the IRB, including an explanation for the lapse and a Corrective Action Plan to prevent any repetitions; and
   • The IRB has reviewed and approved the continuing progress or close-out report.
2. Principal Investigators who leave the institution must have all approved research studies under their name either transferred to another qualified investigator or closed prior to leaving. In these cases the Investigator must:
   • Submit a study amendment to transfer the PI duties to another named Investigator. The amendment must include a PI Agreement of Responsibilities form signed by the new PI. This must be approved by the IRB prior to the PI’s departure, or
   • Submit a final Study Close out Report
3. Failure to complete these activities represents a failure of one of the Principal Investigator’s primary responsibilities under federal regulation and MCW IRB policies.

HRPP Procedures:
1. The Research Support Specialists (RSS) will run a report on expired studies once every week. The RSSs will identify the subsets of expired studies where the PI failed to submit a CPR, failed to obtain IRB approval or submit a final close out study report before the expiration date, and forward that list to the Quality Improvement (QI) team once every week.
2. In addition, the IRB Coordinators and any other IRB Office staff may bring expired studies to the attention of the Quality Improvement group.
3. Upon receipt of the weekly report the QI team will review the list for any errors or duplication and then issue the appropriate “Eclipsed Reporting to the MCW/Froedtert IRB” notification letter to the Principal Investigators identified. This notification will occur once every week, under the name of the HRPP Director, Assistant Dean for Clinical Research. These letters will inform the Investigator of the following:

IRB approval for the study has lapsed… the IRB will not accept any new study applications from the Principal Investigator until:

- The Investigator has filed a continuing progress or close-out report with the IRB, including an explanation for the lapse and a Corrective Action Plan to prevent any repetitions; and
- The IRB has reviewed and approved the continuing progress or close-out report.

4. Copies of the notification letters will be routinely issued to:
   - IRB Manager
   - IRB Operations Director
   - The PI’s Department Chair – or – Division Chief
   - RSSs

5. The RSSs will maintain a list of all the notification letters sent (by PI, PRO #, Study Title, and IRB Committee #), and will upload a copy of the notification letter into the study eBridge file.

6. The RSSs will compare every newly-received IRB study application with the list of “Eclipsed” investigators, and if the PI’s name appears on the “Eclipsed” list, will notify the investigator that the IRB application may not advance until a CPR for the eclipsed study has been approved by the IRB. The RSSs will also post a copy of the updated “Eclipsed” list on a weekly basis on a common bulletin board in the IRB office, and provide copies to:
   - IRB Manager
   - Operations Director

7. RSSs will review the list on a weekly basis and update the information every time the IRB reviews and approves the outstanding Continuing Progress Report or receives a final close out study report for one of the “eclipsed” investigator. The matter will not be considered resolved until the IRB has either approved or closed a study.

8. For those studies that remain expired after initial contact, the HRPP Director will send an email annually to all Department Chairs/Chiefs and investigators requesting the resolution of studies that are in an expired state.

EXCEPTIONS:

1. In addition, the IRB Coordinators and any other IRB Office staff may bring expired studies to the attention of the Quality Improvement group, so long as the expiration occurred after the effective date of this policy (August 1, 2008).

2. For studies with Investigators who leave the institution prior to submitting a close out study report or having a change in PI approved, a letter will be sent to the Department Chair or Division Chief informing him/her of the matter, and providing instruction on how to resolve the matter.

REFERENCES: N/A
ATTACHMENTS:
Eclipsed Email Notification Templates

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