SUBMISSION OF CONTINUING PROGRESS REPORTS (CPR)

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

Applies to: MCW/FH Faculty and Staff involved in human research

PURPOSE:
In accordance with Federal regulations and institutional policy for the Medical College of Wisconsin (MCW) and Froedtert Hospital (FH) Institutional Review Board (IRB), a continuing progress report must be submitted for review and approval at intervals appropriate to the degree of risk, but not less than once per year. Factors for making the decision about the frequency of review include the level of risk, location of the project, and any other factors that might affect the welfare of the subjects. Frequency of review is determined by the IRB upon review.

DEFINITIONS:
Full Committee Review: Research that involves anything more than minimal risk requires review and approval by a full convened IRB Committee composed of physicians, scientists, non-scientists, and community members. Risks to research subjects should be justified by the anticipated benefits to the subjects or society.

Minimal Risk: means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Expiration Date: the last date of the IRB approval period. For example, if a project is approved from 10/02/2012 to 10/01/2013, the project activities may continue until midnight on 10/01/2013 when IRB approval expires.

Expedited Review: Research that is judged to represent minimal risk and also falls within one or more of the "expedited review categories" defined by DHHS may be accomplished by means of expedited review. Expedited review means that the review takes place outside of a regularly convened IRB Committee meeting. Reviews are conducted by the IRB Chair and designated Expedited reviewers.

Accrual/Enrollment: MCW/FH IRB defines any subject who signs a consent form as "accrued" or "enrolled" to the project. The number of subjects accrued or enrolled should include all individuals who signed a consent form regardless of whether or not they participated in the project.

- If a project involves multiple consent forms (e.g., for different types of subjects, or for different phases of the project, or a "screening" and a separate "project" consent form), the number of subjects accrued/enrolled should include everyone that signed
a consent form, but do not count the same individual twice if he/she signed two consent forms.

- If the project does not involve subjects signing a consent form, count the number of individuals of whom biospecimens or data and/or private health information was collected.

PROCEDURE:

1. It is the Investigator's responsibility to ensure that a Continuing Progress Report (CPR) is completed and submitted to allow the IRB adequate time to conduct continuing review of the project before the expiration date. While eBridge will issue a series of electronic reminders to remind the Investigator of the approaching CPR deadline, the Investigator is still responsible for knowing the expiration date issued when the project received approval. The deadline for submission of CPRs to the IRB is 60 days prior to the project expiration date.

2. CPRs must be submitted in eBridge using the form provided. Exceptions include studies that remain in "paper" with IRB permission, specific CIRB protocols, etc. The CPR template for paper submissions can be found on the IRB web site, Continuing Progress Report (CPR) -Paper Form.

3. Federal regulations require that continuing review of research be substantive and meaningful. During the continuing review, the IRB will determine if the research project continues to meet all criteria set forth by federal regulations in order for the IRB to approve research.

4. In order for the IRB to comply with these regulations, the Investigator must provide complete information in the CPR submission, including:
   - the number of subjects accrued/enrolled to the project since the last IRB review
   - the number of subjects withdrawn from the project since the last IRB review and a summary of the reasons for withdrawal
   - a summary of any complaints about the project since the last IRB review
   - a summary of any recent literature that may be relevant to the project
   - any amendments or modifications to the project since the last IRB review
   - any relevant multi-center trial reports
   - a summary of available information regarding any internal and external (if applicable) unanticipated problems and adverse events
   - any other relevant information, especially information about risks associated with the project
   - a copy of the current informed consent document(s)

Any changes to the consent form or to the project must be submitted using an amendment.

Lapse of IRB Approval

- If an Investigator does not provide a CPR to the IRB prior to the expiration date or with enough time to review the CPR prior to the expiration date; OR
- If the IRB approves the CPR with modifications and these are not reviewed and approved prior to the expiration date:
  - All research activities must stop.
• Interventions and interactions on current subjects must 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.

• New enrollment of subjects is not allowed to occur

• 3. Any research activity on an expired project would constitute unapproved human research and, is considered serious noncompliance with MCW/FH policies and procedures regarding the conduct of human subject research. This finding would be reported by the IRB Committee to the Medical College of Wisconsin Institutional Official, and applicable federal agencies.

4. The HRPP Office should be contacted immediately if it is in the best interest of accrued/enrolled subjects to continue treatment or to continue being evaluated so they can safely complete the project. The Investigator may no longer use further data about the subjects for research purposes.

5. If the Investigator wishes to reactivate the project, he/she should contact the IRB Coordinator II responsible for the Committee providing oversight for the project. If the Investigator does not re-activate the project within six months of expiration, the IRB will require the Investigator to submit a new project submission.

REFERENCES:
45 CFR 46.109(e)
21 CFR 56.109(f)

SUPPORTING DOCUMENTS:
Continuing Progress Report (CPR) -Paper Form
Guideline for Completion of the eBridge CPR Smart Form

Effective Date: 10/21/2013
Version number: 4.1
Previous Version/date: 4.0, date 11/20/2010
Responsible Office: HRPP Office
Approval Date: 10/14/2013

Approved By

[Signature]

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