MCW Office of Research
Standard Operating Procedure

SUBMISSION OF CONTINUING PROGRESS REPORTS (CPR)

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

Applies to: Faculty and Staff involved in human research

PURPOSE:
In accordance with federal regulations and institutional policy, a continuing progress report (CPR) must be submitted for review and approval at intervals appropriate to the degree of risk. Factors for making the decision about the frequency of review include the federal regulations, the level of risk, location of the project, institutional requirements and any other factors that might affect the welfare of the subjects. Frequency of review is determined by the IRB upon review.

DEFINITIONS:
Convened Committee Review: Research that involves activities greater than minimal risk requires review and approval by a convened IRB Committee.

Minimal Risk: 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 reviewed 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 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 they 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 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 bears the ultimate responsibility for knowing the expiration date issued when the project received approval.
    a. The deadline for submission of CPRs to the IRB is 90 days prior to the project expiration date.
2. CPRs must be submitted in eBridge using the eBridge CPR SmartForm.
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:
    a. the number of subjects accrued/enrolled to the project since the last IRB review
    b. the number of subjects withdrawn from the project since the last IRB review and a summary of the reasons for withdrawal
    c. a summary of any complaints about the project since the last IRB review
    d. a summary of any recent literature that may be relevant to the project
    e. any amendments or modifications to the project since the last IRB review
    f. any relevant multi-center project reports
        i. If the Investigator is the lead PI of a multi-site project, additional information is required as described in the *IRB SOP: Multi-site Projects and Investigator Responsibilities.*
    g. a summary of available information regarding any internal and external (if applicable) related and unexpected serious adverse events, protocol deviations, and/or any unanticipated problems.
    h. a monitoring report commensurate with the data and safety monitoring plan approved by the IRB
    i. any other relevant information, especially information about risks associated with the project
    j. 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. See *IRB SOP: Amendments* for more information.

Suspension or Termination at the Time of Continuing Review:
Suspension or termination of a project may occur at any point throughout the life of a project, including at the time of continuing review.

If a project is suspended or terminated by the IRB, Investigators have the right to appeal as described in *IRB SOP: IRB Actions*.

Lapse of IRB Approval

1. IRB approval may lapse if
    a. an Investigator does not provide a CPR to the IRB prior to the expiration date; or
    b. submits to the IRB without enough time to review and approve the CPR prior to the expiration date; or
    c. the IRB approves the CPR with modifications, and these are not reviewed and approved prior to the expiration date
2. If IRB approval lapses, the following actions must occur:

a. All research activities must stop.
b. Interventions and interactions on current subjects must stop, unless the IRB finds an overriding safety concern or ethical issue involved such that it is in the best interests of individual subjects to continue participating.
c. New enrollment of subjects is not allowed to occur

3. Any research activity on an expired, suspended or terminated project would constitute unapproved human research and is considered serious noncompliance with MCW policies and procedures regarding the conduct of human subject research.
    a. Findings of serious noncompliance would be reported by the IRB Committee to Institutional Officials, 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, they should re-submit the CPR to the IRB for review.
6. 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.

Research that Does Not Require Continuing Review

1. Research meeting the following requirements does not require continuing review unless otherwise determined by the IRB:
    - Research eligible for expedited review under 45 CFR 46.110
    - Research eligible for exempt determination and reviewed by limited IRB review
    - Research that involves only one or both of the following in accordance with the IRB-approved project:
        - Data analysis, including analysis of identifiable private information or biospecimens
        - Accessing follow-up clinical data from procedures that are part of routine care
2. If the IRB determines that continuing review is required even though a project meets the above conditions, the IRB chair or designated reviewer will document the rationale for conducting continuing review on the *CPR Reviewer Checklist*.
3. If the CPR required convened committee review, the rationale will also be recorded in the minutes.

REFERENCES:
45 CFR 46.110

SUPPORTING DOCUMENTS:
IRB SOP: Amendments
IRB SOP: IRB Actions
IRB SOP: Multi-site Projects and Investigator Responsibilities

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