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| Policy/Procedure Title | Continuing Renewal of Approved Research |
| Version | 2 |
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PURPOSE

To define all research that meets federal, state, local and/or institutional requirements for continuing renewal at least annually. To define circumstances under which continuing renewal is required more often than annually.

POLICY

To ensure the appropriate IRB review is completed as required by federal, state, local and/or institutional requirements.

SCOPE

This policy covers all human subject research that is conducted under any CAMC Health Systems, Inc. facility, involving any CAMC Health Systems, Inc. patient, or under any agreement in place for review by the CAMC/WVU-Charleston Division IRB.

RESPONSIBILITY

The **Principal Investigator** is responsible to ensure all Continuing Renewals are submitted to the IRB through the Research and Grants Administration Office within the required time frame.

The **IRB Chairperson and/or Vice-Chairperson** is responsible for ensuring the appropriate type of continuing review is completed as required by federal, state, local and/or institutional requirements.

The **IRB Members** are responsible for ensuring the continuing reviews are completed appropriately, ethically and within the requirements of federal, state, local and/or institutional requirements.

Research and Grants Administration staff is responsible for maintaining documentation of continuing review activities and reporting all continuing review information at convened IRB meetings. **Research and Grants Administration staff** is responsible to ensure all Board members receive paperwork to allow adequate time for review prior to meetings and due dates.

TYPES OF CONTINUING REVIEW

Expedited Continuing Review

Studies qualifying for expedited continuing review according to federal regulations found in 45CFR46.110.

Expedited continuing review may be conducted by the IRB Chairperson or his/her designee.

Expedited continuing reviews will be reported to the next convened IRB meeting by means of the Review of Expedited, Exempt and Closed Activities list.

Full Board Continuing Review

Studies meeting the requirements for full board continuing review according to federal regulation found in 45CFR46.109.

IRB may determine full board continuing review is required for a study previously meeting the requirements for expedited continuing review for reasons included but not limited to concerns found regarding the study, investigator and/or research staff.

PAPERWORK REQUIRED FOR CONTINUING RENEWAL REVIEW

The following paperwork must be submitted for all continuing renewals by the Principal Investigator:

- CAMC/WVU-Charleston Division IRB Continuing Renewal Application
- Copy of current approved protocol
- Copy of current approved consent form (if applicable)
- Clean copy of consent form for approval (if applicable)
- Tracking logs (revision, adverse event and deviation if applicable)
- Additional information as provided by study sponsors

SUBMISSION PROCESS

All continuing renewals should be submitted via the online submission process through www.irbplus.com.

DEADLINES FOR SUBMISSIONS

Expedited Continuing Review

Principal Investigators must submit all continuing renewal paperwork to the IRB office no later than 10 business days prior to the expiration date of the study for review and processing.

Full Board Continuing Review

Principal Investigators must submit all continuing renewal paperwork to the IRB office no later than the first business day of the month in which the study must be reviewed by the IRB.

TIMING OF CONTINUING RENEWAL

Federal regulations, found in 45CFR46.109, require continuing renewal of all active studies be completed at least annually.

More often than annual continuing renewal

IRB may determine continuing review is required for a study more often than annually for reasons including but not limited to 1) any investigator-initiated treatment study; 2) concerns found regarding the study, investigator and/or research staff; 3) procedures not previously used in humans; 4) more than minimal risk with prospect of benefit to study participants; 4) high likelihood study participants will expire due to study procedures.

IRB may determine continuing review more often than annually by means of setting a time period (3 month, 6 month, 9 month, etc.) or by setting a limit on the number of study participants to enroll by documenting via paper ballot or through documented discussion in meeting minutes. IRB's determination of continuing review more often than annually will be documented in the IRB meeting minutes and detailed in the prepared letter provided to the Principal Investigator.

REVIEW PROCESS

The Research and Grants Administration Office staff will conduct an initial review of all submitted Continuing Renewals, sending the continuing renewal through the appropriate review process.

Expedited Continuing Review

The IRB Chairperson or his/her designee will conduct a review of all information submitted by the Principal Investigator for continuing renewal.

Full Board Continuing Review

The Primary Reviewer will receive and conduct a review of all information submitted by the Principal Investigator for continuing renewal, including but not limited to the renewal application with a summary of the study status, the current protocol, the current consent form, the proposed "clean" consent form. The Primary Reviewer will also receive and review all paperwork that has been received, reviewed, approved and/or disapproved, notes to file, etc. since the last continuing renewal. The Primary Reviewer will complete a checklist and present a summary of his/her findings to the Board during the convened meeting.

The Board members and alternate members present for the convened meeting will receive and conduct a review of all information submitted by the Principal Investigator for continuing renewal, including but not limited to the renewal application with a summary of the study status, the current protocol, the current consent form, the proposed “clean” consent form.

DECISION OF THE BOARD FOR CONTINUING RENEWAL

Expedited Continuing Review

The IRB Chairperson or his/her designee may make the following determinations regarding submitted continuing renewals:

Approved – Study may continue as approved for the period of time determined (not to be changed from previous determination without approval of the full board).

Refer for Full Board Review – Study renewal will be placed on the next full board IRB agenda. Disapproval for continuation of any study may not be determined by the Chairperson or his/her designee alone. Studies with concern will be placed on the next full board IRB agenda.

Full Board Continuing Review

The Board may make the following determination regarding submitted continuing renewals during a convened meeting:

Approved – Study may continue as approved for the period of time determined. Period of renewal may be changed if determined necessary by the Board.

Approved Pending Receipt of Information – Additional information has been determined to be needed by the Board. Once the Principal Investigator provides all appropriate requested information to the Research and Grants Administration Staff the study will be approved for continuation.

Approved Pending Requested Changes – Changes have been requested by the Board. Once the Principal Investigator provides all appropriate requested changes to the Research and Grants Administration Staff the study will be approved for continuation.

Tabled – The Board had an inability to review and make determination for the continuation of a study. Additional information will be gathered as requested by the Board. The study will be placed on the next scheduled meeting agenda.

Disapproved – The Board determined the study should be terminated within our institution. Reasons for disapproval may include but not limited to 1) increased risk to study participants; 2) concern with the science of the study; 3) concerns with the principal investigator and/or research staff; 4) concerns with the conduct of the study.

NOTIFICATION OF DECISIONS OF THE BOARD

All decisions of the Board are provided to the Principal Investigator and Lead Study Coordinator (if so listed in the initial application) via letter.

LENGTH OF APPROVAL

The expiration date stated on the IRB approval letter and/or consent form is the date the study expires. Study procedures may be conducted and the consent form may be used the day of expiration.

FAILURE TO SUBMIT CONTINUING RENEWAL REVIEW OF APPROVAL STUDY

If a Principal Investigator fails to submit continuing renewal paperwork by the deadline the following actions will be promptly taken:

Suspension – A 30 day suspension will be implemented on the study the day of expiration. This suspension immediately requires no further actions may take place with this study, including but not limited to data collection, patient contact, treatment of subjects enrollment of subjects, etc. If the Principal Investigator feels there is a safety issue for subjects to continue study medications or treatments contact the IRB, through the Office of Research and Grants Administration staff, immediately. The renewal paperwork must be submitted during this time period for the study to continue.

Closure – After the 30 day suspension, if renewal paperwork has not been received, the study will be closed. If the study is closed for failure to complete continuing renewal paperwork the closure will be reported to the Office of Human Research Protection.

APPEAL OF DECISION OF THE BOARD FOR CONTINUING RENEWAL

The Principal Investigator may appeal the decision of the convened Board through the appeals process outlined in the Appeal of Decision of the Board Policy and Procedure.