



Policy Name: Full Board Continuing Review Policy and Procedures			
Approved			Date: 11/01/08
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Replaces Policy: N/A			Dated: N/A

I. POLICY

A. Introduction

Full Board review and approval is required for studies that initially went through review at a convened meeting of the IRB except in the following circumstances:

1. Research is permanently closed to the enrollment of new subjects; (a) all subjects have completed all research-related interventions; and no subjects remain in long-term follow-up; or (b) no subjects have been enrolled and no additional risks have been identified; or (c) the remaining research activities are limited to data analysis.
2. Unless the IRB or sponsor required full review: continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories 2 through 8 of the expedited review categories do not apply and the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified..

B. IRB Continuing Review

The IRB will conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. The same criteria used for initial review of protocols will be followed during protocol renewal review. This evaluation will include study accrual, revisions, unanticipated toxicities, subject complaints, and any new information or findings relating to the risk/benefit assessment. Based on these findings, the informed consent process or document will also be reviewed to determine if it is still acceptable or whether new information that may have been obtained during the course of the study needed to be added.

C. VA Studies

Continuing review of research that are VA studies will address requirements of VHA 1200.5.

II. PROCEDURES

A. Notification to Principal Investigator

Prior to the protocol's expiration date, the IRB staff will send the Principal Investigator a timely reminder of approval expiration.

B. Regulatory Compliance Review

1. IRB Administration

- a) When received, the continuation application is assigned to the appropriate IRB Coordinator who:
 - (1) Documents receipt of the application in the continuing review logbook, and
 - (2) Reviews the application for completeness, accuracy, regulatory compliance and congruency with previous applications. If the application is incomplete, the IRB Coordinator will contact the Principal Investigator/Study Coordinator regarding the deficiencies.

2. University Compliance

- a) Study personnel listed on the application are checked against the Compliance Office database to ensure that the required institutional training has been completed.
- b) If any study personnel have not completed the required training, University Compliance will notify the IRB Administrator.
- c) The IRB will notify Principal Investigator in writing that continuation approval will not be released until documentation is received by the IRB that the training has been completed.

C. Materials Provided to the IRB Board

1. The Continuing Review Application and any additional documents uploaded by the PI in support of the renewal application are sent to all members of the board. Using the designated review procedure, the completed application is given to the primary reviewer (the Chair, Vice-Chair or the Chair's Designee).
 - a) Request for Continuing Review Application,
 - b) The initial application and previous continuing review applications,

- c) Study protocol,
 - d) A summary of all adverse events reports,
 - e) Data safety monitoring reports,
 - f) Investigator drug brochures,
 - g) The current consent document, and
 - h) Any newly proposed consent document, if applicable.
2. The IRB Reviewer Checklist for Continuing Review Full Board and expedited Protocols is sent to the primary reviewer for reference in completing the review.

D. Review by the Primary Reviewer

1. The Primary Reviewer accesses the entire IRB file that includes the initial application, all amendments, all adverse event reports, data safety monitoring reports, investigator drug brochures, informed consents and all previous continuing review applications.
2. If the Primary Reviewer has questions or concerns, he/she may contact the Principal Investigator or ask the IRB Coordinator to contact the Principal Investigator.
3. The Primary Reviewer will review the Principal Investigator responses: 1) if responses are satisfactory, the Primary Reviewer will sign the continuation application in preparation for the Board's review; 2) if the primary reviewer is unable to resolve issues with the study team, the Principal Investigator will be invited to attend the Board meeting.

E. Convened IRB

1. The continuation application submitted by the principal investigator and reviewed by the primary reviewer is included in the agenda distribution. The entire protocol file and minutes at which the protocol was reviewed are available to all members upon request.
2. During the meeting, each continuation application is presented by the chair and/or primary reviewer(s), discussed and voted on individually. The chair and/or primary reviewer will present additional pertinent information regarding the studies applying for continuation such as recent published events. The principal investigator will be present if requested by any Board member or if the chair/Administrator thinks the investigator needs to be present to clarify issues/concerns.
3. The Board may approve, table, or disapprove or require modifications to secure continued. The Board may table a

continuation application if they request an independent audit of the study, require additional information regarding any of the principal investigator's responses on the application, and/or require substantive changes to the protocol. If approved, the Board will stipulate the frequency of future continuation review.

4. If the Board needs clarification on something which does not substantially impact the risk/benefit analysis, the Board may approve the continuation contingent on final review and approval by the Chair or the Chair's Designee. No required changes to the informed consent document will be deferred to the Chair's or Chair's Designee approval unless the Board has stipulated the wording of these changes.
5. Changes that are substantive in nature must be brought back to the full Board at a convened meeting. The Board can approve the study for one month and have the modifications come back to the next convened meeting. The PI can also be contacted by telephone during the meeting to answer any questions.

F. Post-IRB Meeting

1. If the continuation is approved without substantive changes, the IRB staff will prepare the approval for release.
2. If modifications are substantive in nature or if the Board tables or disapproves the study, the Chair will notify the principal investigator in writing that the continuation of the study has not been approved and to stop enrollment and all research related activities unless currently enrolled subjects will be placed at risk; the Board will decide if stopping all research related activities will place the currently enrolled subjects at risk.
3. If the continuation application requires further modifications that are minor in nature, the Administrator will notify the Principal Investigator and Study Coordinator in writing. When revisions are received in the IRB office, the Coordinator and the Chair will review them; if acceptable, the Chair will sign the approval and the Administrator will release the approval.

G. Expiration of IRB Approval If the Principal Investigator does not submit a continuation application prior the protocol expiration date or does not address the IRB's concerns, the IRB approval of the study expires.

1. The IRB Administrator will send written notification to the Principal Investigator (Letter of Expiration) informing the Principal Investigator that the IRB approval has expired and all research activities must stop, including recruitment, advertisement,

screening, enrollment, consent, interventions, interactions, and collection of private identifiable information. The Associate provost for Research and the Department Chair will be copied on this correspondence. If applicable, notification will be made to the local district FDA (21 CFR 56.113).

2. The notification to investigators will include a request to submit immediately to the IRB chair, a list of participants for whom stopping research activities would cause harm.
3. Interventions and interactions on current participants may continue only when the IRB, the IRB Chair or designee finds an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants.
4. The Principal Investigator is requested to sign the letter indicating receipt of notification of approval expiration. If the Principal Investigator wishes to continue the study, he/she must submit a continuation application for review at the next convened meeting.

H. VA Protocols

1. **Continuing Review Information Provided by PI** In addition to the above information, the continuing review will include
 - a) The number of participants considered as members of specific vulnerable populations and
 - b) An assurance that all serious adverse events and unexpected adverse events have been reported as required.
2. **Expiration of IRB Approval** If an investigator does not provide continuing review information to the IRB or the IRB has not approved a protocol by the expiration date:
 - a) The IRB notifies the investigator to submit immediately to the IRB chair, a list of participants for whom stopping research activities will cause harm.
 - b) Interventions and interactions on current participants may continue only when the IRB or IRB Chair, in consultation with the local VA Chief of Staff, finds an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants.
 - c) The VAMC R&D Committee will notify the expiration to the sponsor.

III. REFERENCES

- A. [IRB Reviewer Checklist for Continuing Review Full Board and Expedited Protocols](#)