

## Chapter 10 Continuing Review

### A. Regulations/Policy

According to federal and institutional regulations, the Institutional Review Board must conduct continuing review of multi-year research projects at intervals appropriate to the degree of risk but not less than once per year. Renewal/approval by the IRB shall occur on or before the one-year anniversary. At the time of initial approval (both expedited and full board), the IRB members vote by ballot (majority rules) and determine whether the study approval is for a 3 month, 6 month, 9 month or one year interval. For continuing renewals receiving full board review, the IRB members again vote by ballot (majority rules) and determine whether the study approval is for a 3 month, 6 month, 9 month or one year interval. The Chair or his/her designee will make that determination for expedited renewals.

The general continuing review guidelines are as follows:

1. The Principal Investigator (PI) will be notified of upcoming continuing review prior to the anniversary date and will be forwarded a letter requesting the “Continuing Review Progress Report”.
2. It is the investigator's responsibility to complete the form and appropriate attachments, and return it to the Office of Research and Grants Administration by the date requested in the notification letter.
3. Failure to fully complete the Progress Report or to return the appropriate forms will result in suspension or closure of the study. A suspension/closure notification letter will be sent to the PI and, if applicable, the funding agency. **(Note: PIs who have an unresolved expired study will not be permitted to submit any new studies for review by the IRB until the expiration matter is resolved.)**

### B. Review Process

1. Continuing Review Procedures
  - a. In general, if a study is initially reviewed under expedited review, then the continuing review may also be conducted under expedited review. The exception to this rule is if a revision changes the risk/benefit ratio of the study from “minimal risk” to “more than minimal risk,” thus requiring full board review for the remainder of the study duration.
  - b. Continuing Review of a study initially reviewed full board is generally reviewed by the full board unless the study status is as follows:
    1. “The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects, OR
    2. No subjects have been enrolled and no additional risks have been identified (NOTE-“no additional risks” applies study-wide for multi-site studies); OR
    3. The remaining research activities are limited to data analysis.”
  - c. “The federal guidelines also permit expedited continuing review of research not

conducted under an investigational new drug application or investigational device exemption, where federal expedited categories two (2) through seven (7) do not apply, but the IRB has determined and documented at a convened meeting that the research involved is no greater than minimal risk and no additional risks have been identified” (see 45 CFR 46.110 or 21 CFR 56.110 and the list of “Categories of Research That May Be Reviewed by the Institutional Review Board Through An Expedited Review” – 63 FR 60367, November 9, 1998).

- d. Revisions to a study will be accepted at the time of renewal as a part of the Continuing Review Progress Report. The last page of the report includes a Modification/Amendment Form. A listing of all Revisions to the study in the past year must also be attached to the Progress Report using the Revision Log.

**Note:** Research activities previously reviewed as "exempt" may have changed or will change based on proposed modifications or amendments. If this should occur, expedited or full-board review for renewal may thereafter be required until study closure.

## 2. IRB Continuing Review Process.

- a. The staff will receive and pre-screen each continuing renewal application. Based upon the type of review required, the staff will either forward the materials to the IRB Chair and/or his/her designee, or prepare the materials for distribution for full-board review.
- b. The reviewers will review the renewal materials for completeness and for planned changes in the conduct of the study that may have an impact on the protection of human subjects. The IRB may contact the PI to obtain clarification of any issue or to obtain incomplete data. **Because the data requested on the progress report are required for audit purposes, all information shall be obtained prior to continuing review approval by the IRB. Failure to attempt to address these items may jeopardize a timely continuation and approval of the study.**
- c. Decisions on renewals that qualify for expedited review will be placed on the Expedited Review List that is sent to the full board at its next convened meeting. Decisions on full board Continuing Reviews will be discussed at the regularly scheduled IRB meeting and included in the minutes for that meeting.
- d. The Board/Chair has the authority to approve the renewal. If after the review of the Continuing Review Progress Report it is determined that additional information is needed or that irregularities have arisen that affect the participation of the human subjects, the IRB may take the following action:
  - Request revisions and/or additional information;
  - Request that the investigator attend the IRB meeting;
  - Suspend approval pending further investigation by the IRB;
  - Terminate IRB approval.

## Continuing Review

## **C. Study Closure**

A "Final Report" should be submitted to the IRB Chairperson as soon as possible after completion or termination of the study. The Continuing Review Progress Report may be used as the Final Report by adding the word "FINAL" to the top of the page as instructed on the form. In addition, a final study summary will need to be included with the progress report (see the item requesting "summary" on the Continuing Review Progress Report). A copy of the Continuing Review Progress Report may be obtained by contacting the Office of Research and Grants Administration.

(Revised 2/22/04)

**CONTINUING REVIEW PROGRESS REPORT  
CAMC/WVU Institutional Review Board**

**SECTION I – Update Study Information**

PI: \_\_\_\_\_  
(Please print name of Principal Investigator - PI)

H.S.#: \_\_\_\_\_  
(Place the IRB study number here)

Study Title:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

(Please submit the attached modification/amendment form for study title changes not yet approved by the IRB.)

MOST RECENT VERSION DATE: Protocol: \_\_\_\_\_ Consent: \_\_\_\_\_ Investigator’s Brochure:  
\_\_\_\_\_

**1. Please list below all present investigators/research assistants participating with the PI on this study. IF THERE HAS BEEN A CHANGE IN INVESTIGATOR(S) THAT HAS NOT YET BEEN REPORTED TO THE IRB, YOU MUST COMPLETE THE ATTACHED MODIFICATION/AMENDMENT FORM AND SUBMIT IT ALONG WITH THIS REPORT. If additional space is needed to list investigators, please attach a separate sheet.**

Investigator(s):  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**2. Please list below all present study coordinators participating with the PI on this study. List the primary study coordinator first. IF THERE HAS BEEN A CHANGE IN STUDY COORDINATORS THAT HAS NOT YET BEEN REPORTED TO THE IRB, YOU MUST COMPLETE THE ATTACHED MODIFICATION/AMENDMENT FORM AND SUBMIT IT ALONG WITH THIS REPORT. If additional space is needed, please attach a separate sheet.**

Study Coordinator(s):  
\_\_\_\_\_  
\_\_\_\_\_

**3. If any demographic information has changed for the Principal Investigator, any other investigator, research assistant or study coordinator since the last IRB review, please update that information now. You may attach additional pages as necessary. Check One – [ ] Changes included below [ ] Changes included below and attached [ ] No changes:**

Name(include preferred salutation):

Title:

Degree:

Department:

Specialty Area:

Role in study:  Investigator,  Research Assistant,  Study Coordinator,  Other

Division:  CAMC,  WVU-Charleston,  CAMC Institute,  Other: \_\_\_\_\_) Check all that apply.

Address:

City:

State:

Zip:

Work Telephone:

Pager #:

Fax #:

Email Address:

## CONTINUING REVIEW PROGRESS REPORT

### SECTION II – Continuing Review Category

**Please check one box below and then complete either part 1 or 2 as indicated:**

Initial study review was **EXPEDITED** (minimal risk) – please complete **Part 1** below.

Initial study review was **FULL BOARD** (more than minimal risk) – please complete **Part 2** below.

**(If you do not find a category in Part 1 or 2 that fits your study, please contact the IRB Office at 304-388-9971.)**

#### **Part 1. RENEWAL FOR STUDIES INITIALLY REVIEWED AS EXPEDITED:**

For continuing review categories A through F below, submit an **original** continuing review packet with **one** copy of the most recent, stamped, consent/authorization form *and one* clean, unstamped copy—on letterhead—of the current consent/authorization form. If you request a change to the consent, submit **one** clean, unstamped copy—on letterhead—of the revised consent/authorization form along with one highlighted copy showing the changes requested, and a copy of the most recent, stamped approved consent. If you request a change to the protocol, submit a highlighted copy of the revised protocol showing the changes along with a clean copy of the new protocol. For both consent and protocol changes, you also need to complete the attached Modification/Amendment form.

**Check Appropriate Item(s) – [NOTE: this section is for studies initially reviewed as expedited]:**

A. **Enrollment of subjects/collection of data has begun and will continue beyond the renewal date.**

B. **Project is open to enrollment/data collection; however, there has been NO enrollment of subjects/NO data collected at this site, and no changes to the protocol or consent form are requested.**

C. **Project is open to enrollment/data collection, there has been NO enrollment of subjects at this site/NO data collected at this site, BUT, changes to the protocol or consent form are requested.**

D. **Project is closed to enrollment, but subjects are either in treatment or in follow-up, or, data collection is completed and no further data will be accrued.  
This project closed to accrual on \_\_\_\_\_ (date).**

E. **Contact with human subjects/data records will not continue beyond the expiration date, subject or record**

**follow-up is completed and DATA ANALYSIS is underway.**

- F. **Funding or start of research is pending. Please keep this file active.** (Attach a letter to explain the “pending” issue. Do not complete the rest of the packet.)
- G. **Data analysis is completed. Please close this file.** (If your project is completed, submit this original completed Continuing Review Packet and all the requested materials). **Please add the word “FINAL” to the top of this page of the Continuing Review Progress Report.**
- H. **The project has been terminated. Please close this file.** (Submit this original completed Continuing Review Packet with a brief explanation of the study termination circumstances).
- I. **Project was never begun. Please close this file.** (Please include a brief cover letter explaining why the project was never begun. Do not complete the rest of the packet).

**(continued – Part 2 full board categories are listed on the next page)**

**Part 2. RENEWAL FOR STUDIES INITIALLY REVIEWED AS FULL BOARD:**

**Check Appropriate Item(s) – [NOTE: this section is for studies initially reviewed full board]:**

In general, studies which underwent initial full board review are required to have full board review for renewal with a few exceptions as outlined in Federal Register 63 FR 60364-60367. Please follow the instructions for each category below. If you request a change to the protocol or consent with this full board renewal, please complete the attached Modification/ Amendment form and follow the instructions on that form for the number of copies needed.

- A. **Enrollment of subjects/collection of data has begun and will continue beyond the renewal date.**  
(Complete and submit this original packet and **17** copies of this entire Continuing Review Packet, **17** copies of the most recent, stamped, consent/authorization form *and one* clean, unstamped copy —on letterhead—of the current consent/authorization form. If a Modification/Amendment is included, see the attached form for further instructions.)
- B. **Project is open to enrollment; however, there has been NO enrollment of subjects and no amendments/changes to the protocol or the consent form are requested.**  
(Complete and submit the **original and one full copy** of the completed Continuing Review Packet and include a copy of the most recent, stamped, consent form with both. Include only **one** clean, unstamped copy – on letterhead – of the current consent form with the original. Also **submit 16 copies of this page.**)
- C. **Project is open to enrollment/data collection, there has been NO enrollment of subjects at this site/data collected at this site, BUT, changes to the protocol or consent form are requested.**  
(Complete and submit this original packet and **17** copies of this entire Continuing Review Packet, **17** copies of the most recent,

stamped, consent/authorization form *and one* clean, unstamped copy —on letterhead—of the current consent/authorization form.)

- [ ] D. **Project is closed to enrollment, but some subjects are receiving study treatment/research related intervention.**  
(Note: In this category, some subjects may be in follow-up or finished with treatment while others are still on treatment).  
**This project closed to accrual on \_\_\_\_\_ (date).**  
(Complete and submit this original packet and **17** copies of this entire Continuing Review Packet, **17** copies of the most recent, stamped, consent/authorization form *and one* clean, unstamped copy – on letterhead – of the current consent/authorization form.)
- [ ] E. **Project is closed to enrollment, all subjects have completed research-related interventions, and subjects are in long-term follow-up only.** (This category qualifies for expedited renewal)  
**This project closed to accrual on \_\_\_\_\_ (date).**  
(Complete and submit this original completed Continuing Review Packet, **one** copy of the most recent, stamped, consent/authorization form, *and one* clean, unstamped copy – on letterhead – of the current consent/authorization form.)
- [ ] F. **Contact with human subjects/data records will not continue beyond the expiration date, subject or record follow-up is completed and DATA ANALYSIS is underway.** (This category qualifies for expedited renewal) (Submit this original completed Continuing Review Packet, **one** copy of the most recent, stamped, consent/ authorization form, *and one* clean, unstamped copy – on letterhead – of the current consent/authorization form.)
- [ ] G. **Funding or start of research is pending. No changes are requested. Please keep this file active.**  
(Submit this original completed Continuing Review Packet, **one** copy of the most recent, stamped, consent/ authorization form, *and one* clean, unstamped copy – on letterhead – of the current consent/authorization form. In addition, include in a cover letter an update on the funding issue or an explanation of why the research has not yet begun.)
- [ ] H. **Data analysis is completed. Please close this file.** (If your project is completed, submit this original completed Continuing Review Packet and all the requested materials). **Please add the word "FINAL" to the top of this page of the Continuing Review Progress Report.**
- [ ] I. **The project has been terminated. Please close this file.**  
(Submit this original completed Continuing Review Packet with a brief explanation of the study termination circumstances).
- [ ] J. **Project was never begun. Please close this file.** (Please include a brief cover letter explaining why the project was never begun. Do not complete the rest of the packet).

SECTION III – Continuing Review Data

**Instructions:** Attach a separate sheet for any item as needed. If any question is not applicable, put N/A next to the number for that question. **Failure to answer all questions completely will result in the return of this report and possible suspension/closure of this study. (Caution: Always refer to your initial application/last renewal packet submitted to the IRB before completing this section. Your year-to-year data should be consistent. If there is a discrepancy from the previous report, please explain the issue in a cover letter and attach it to this report.)**

1. Below, indicate the number of subjects enrolled/records reviewed at this site **total since the project began:**

	<u>Children</u>			<u>Adults</u>		
	Male	Non-pregnant Female	Pregnant Female	Male	Non-pregnant Female	Pregnant Female
Caucasian	_____	_____	_____	_____	_____	_____
African-American	_____	_____	_____	_____	_____	_____
Hispanic-American	_____	_____	_____	_____	_____	_____
Native-American	_____	_____	_____	_____	_____	_____
Asian-American	_____	_____	_____	_____	_____	_____
Other:_____	_____	_____	_____	_____	_____	_____
	<b>TOTAL</b> _____			<b>TOTAL</b> _____		

a. Total number of subjects (children & adults) enrolled at this site since this project began: \_\_\_\_\_

\*For multi-site studies, the number you state should be for subjects enrolled at CAMC/WVU Charleston Division sites.

b. Total number of subjects (children & adults) enrolled at this site since the last IRB review: \_\_\_\_\_

c. Current Number of living subjects in study: \_\_\_\_\_  
Breakdown: Number in treatment \_\_\_\_\_; Number in follow-up \_\_\_\_\_

d. Number of subjects deceased \_\_\_\_ (Provide a brief description of cause of death if other than disease related):

e. Have any subjects dropped out (or transferred)?  Yes  No If yes, how many and why? \_\_\_\_\_

2.If this is a multi-site study, at this time how many subjects are enrolled total study-wide: \_\_\_\_\_

3.What was the original projected enrollment/number of records to be reviewed at this site? \_\_\_\_\_  
If the number of subjects enrolled/records reviewed is significantly above or below the initial projection, briefly explain.

4. a. Have all subjects signed a consent or assent form?  Yes  No  
If no, was consent or assent waived for this project?  Yes  No  
b. Have there been any problems obtaining consent or assent? If yes, Explain  Yes  No  
c. Are all signed forms on file and available for review? If no, Explain  Yes  No

5. Have activities involving human subjects during the past year followed procedures as described in the approved protocol?  Yes  No If no, attach a listing of any protocol deviations/violations

**Continuing Review**

and a brief explanation of the resolution for each. (note: serious protocol deviations/violations should be reported to the IRB at the time of occurrence)

6. Were any grievances or complaints received about this study?  Yes  No If yes, please explain:
7. Adverse Events – Attach an up-to-date copy of the **AE Tracking Log** (See Instructions for Reporting Adverse Events)  
If none, mark this box –  No adverse events, no log attached.
8. **For clinical drug or device studies:** Since the initial protocol submission, has there been any change to the FDA status of the experimental drug or device for this protocol?  Yes  No  N/A If yes, please explain:
9. **For clinical drug or device studies:** Has your research protocol been audited by the FDA since the last IRB review?  Yes  No  N/A  
If Yes, was an FDA 483 issued?  Yes  No If yes, please attach a copy with this form.
10. If applicable, attach a copy of the most recent Data Safety Monitoring Board (DSMB) report for this study.  
 Report attached dated: \_\_\_\_\_  None available  Not applicable  
(NOTE: The IRB requires that you contact your sponsor/cooperative group and request this report. The only time “none available” should be checked is if the DSMB has not yet issued a report.)
11. Attach the **Revision Log** listing all revisions/amendments/modifications to this study reviewed by the IRB.  
If none, mark this box –  No revisions, no log attached.  
(Note: No changes to the study can be made without prior IRB review and approval.)
12. Have any significant findings developed during the course of the research which may affect the risk/benefit ratio to subjects?  Yes  No If yes, please explain.
13. **Summarize** the study activities, data trends and/or preliminary results to date. (**Attach separately, if needed.**)  
**\*\*\*Some type of brief update summary is required – “none or n/a” is not acceptable\*\*\***  
(Some ideas to consider addressing: How are your subjects doing in the study? What have you learned so far? If no subjects have been enrolled/records reviewed to date, why? If the research is a data collection study, have records been obtainable and are the variables listed on your data collection form available? Are you seeing any trends? Any favorable comments? Do you have any concerns to date? If available, also attach the most recent study summary from the sponsor/cooperative group. If this is a study closure, provide a final report.)
14. **Attach a summary of recent literature, if any, that suggests new information that supports continuance of this project. (e.g., new reactions, new treatments, etc.)**

\_\_\_\_\_  
Principal Investigator's Signature

\_\_\_\_\_  
Date

**Continuing Review**

**10-10**

Form B

Received: \_\_\_\_\_

This Form also serves as SECTION III of the Continuing Renewal Progress Report

H.S.#: \_\_\_\_\_

Revised 2/22/04

Office use only

**MODIFICATION/AMENDMENT FORM**  
**(TO BE USED FOR ALL STUDY REVISIONS)**

H.S. #: \_\_\_\_\_ Principal Investigator: \_\_\_\_\_

Study Title: \_\_\_\_\_

Revision Description or Protocol Amendment/Modification Number and Date: \_\_\_\_\_

Initial Study Review was (check one): [ ] Expedited [ ] Full Board

**NOTE:** Add all study Revisions/Amendments/Modifications to the **Revision Log**. Submit a copy of the log with each new revision submission and at the time of continuing renewal. A sample of the log is attached.

1. DESCRIBE **MINOR** CHANGES IN THE PROTOCOL and/or CONSENT: Minor changes include administrative or minor editorial changes, study location change, closure to accrual, data issues, updated investigator brochure, addition or deletion of sub-investigator or study coordinator etc. [Minor changes will receive expedited review. Submit one copy of the original document (e.g. consent, protocol) and one copy of the document with highlighted changes and a new version date. Also, for a minor consent change, submit one clean copy of the revised consent on letterhead with the new version date.]

2. DESCRIBE **MAJOR** CHANGES THAT WILL AFFECT ELEMENTS of the PROTOCOL or INFORMED CONSENT (Purpose, Risks or Discomforts, Benefits, Alternative Procedures, Confidentiality of Records, Cost/Compensation, Voluntary Participation, etc.): Note: Some major scientific changes do not require a consent form change. Please note "NO CONSENT FORM CHANGE REQUIRED" if this is the case. *A change in the Principal Investigator for a study initially reviewed as full board is considered a major change.* [All major changes will require full-board review unless the study was initially reviewed as expedited. If the study was initially reviewed full board, attach 17 copies of the IRB approved consent form or protocol, 17 copies of the revised consent form and/or protocol with changes highlighted, and supporting paperwork for the requested change. If the study was initially reviewed expedited, submit this original form and one copy of the approved consent or protocol and a highlighted consent and/or protocol with changes – no additional copies are necessary for expedited review. For consent form changes for both expedited and full board studies, submit one clean copy of the revised consent on letterhead with a new version date for approval.]

3. IF A NEW Investigator/Research Assistant/Study Coordinator is added, THAT PERSON MUST COMPLETE THE NIH TRAINING AND PROVIDE CONFIRMATION WITH THIS FORM. Also submit a brief bio-sketch of the person's qualifications for his/her role with the study and have the person sign below indicating his/her willingness to be added to the study. In addition, attach a Financial Disclosure Form 12 and FDA Form 1572, if applicable to your study.

\_\_\_\_\_  
Print name of Person being added to the study

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Principal Investigator's Signature: \_\_\_\_\_ Date: \_\_\_\_\_

CAMC/WVU IRB Approval: \_\_\_\_\_ Date: \_\_\_\_\_

**Continuing Review**

(Chair or Chair's Designee)

Submit with Revision Log to: CAMC/WVU IRB, Room 3283, WVU Building, 3110 MacCorkle Ave, SE  
Charleston, WV 25304