

SOP: RR 404 Version No.: 05 Effective Date: 12/3/10	CONTINUING REVIEW – CRITERIA FOR RENEWAL	Supersedes Document Dated: 7/1/08
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1. POLICY

Steering Committee approved 9/19/11

The IRB conducts continuing review of research taking place within its jurisdiction at intervals appropriate to the degree of risk, but not less than once per year.

Specific Policies

Terms used in this policy, but not defined herein shall have the meanings set forth in the Glossary.

1.1. Interval for Review for Purposes of Renewal

The IRB must conduct continuing review of protocols for purposes of renewal of the IRB approval period, at intervals appropriate to the degree of risk. The IRB determines the interval for review, which may not be less than once per year, at the time of initial review. This period is communicated to the Investigator in the approval letter.

Investigators are required to submit a periodic report (see form RR 404-A) prior to the expiration of the study or as requested by the IRB, but at least annually.

1.2. Expiration of Approval Period

There is no grace period extending the conduct of the research beyond the expiration date of IRB approval. Aurora IRB Policy RR 402 (section 1.5) explains how the approval period is determined. Extensions beyond the expiration date will not be granted.

If Continuing Review Report forms and/or other requested progress reports are not received as scheduled, or, for other reasons, the IRB review process is not completed by the expiration date, the Investigator must stop all research activities including recruitment, advertisement, enrollment, consent, interventions, interactions, data collection, and data analysis until reports are reviewed and approved. If the investigator is actively pursuing renewal with the IRB and the IRB believes that it is in the best interest of individual subjects to continue participating in the research interventions or interactions, the IRB may permit the study to continue for the brief time required to complete the review process. The IRB's decision will be communicated to the investigator and appropriate institutional officials via letter (RR 404-E). However, no new subjects may be enrolled. Prospective research data cannot be collected, and no procedures that are being conducted solely for the purposes of the protocol with no benefit to the subjects may be performed until a Continuing Review Report or other progress report is reviewed and approved.

1.3. Criteria for Renewal

See section 1.2. of Policy RR 402 for the criteria for approval.

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Each protocol due for continuing review will receive an initial review by a Research Compliance Analyst (a voting member of the IRB) acting as the Primary Reviewer. The Research Compliance Analyst will perform an initial assessment of the continuing review. If, in the opinion of the Research Compliance Analyst, the risk associated with the study has changed since the previous IRB review and approval, the continuing review form and any other pertinent materials are sent to an IRB Reviewer – the initial Primary Reviewer if available.

1.3.1. Continuing IRB review is required as long as individually identifiable follow-up data are collected or analyzed on subjects enrolled in all protocols. This remains the case even after a protocol has been closed to enrollment at all sites and protocol-related treatment has been completed for all subjects. In these circumstances, these renewal requests may qualify for expedited review.

1.3.2. Continuing review of DSMB-monitored clinical trials: When a clinical trial is subject to oversight by a DSMB whose responsibilities include review of adverse events, interim findings and relevant literature (e.g., DSMBs operating in accordance with the National Cancer Institute Policy for Data and Safety Monitoring of Clinical Trials), the IRB conducting continuing review may rely on a current statement from the DSMB indicating what information was reviewed by the DSMB (e.g., study-wide adverse events, interim findings and any recent literature that may be relevant to the research), the date of review, and the DSMB’s assessment of the information reviewed, in lieu of requiring that information about external adverse events be submitted directly to the IRB. However, the IRB must still receive and review reports of local Unanticipated Problems Involving Risks to Subjects or Others and any other information needed to ensure that its continuing review is substantive and meaningful.

1.3.3. Continuing Review report: For studies receiving full committee continuing review, all IRB members shall receive a copy of the Continuing Review Report form and any additional documentation (including the current informed consent document if applicable) submitted by the Investigator. Additional information (for example, the complete protocol, relevant significant new findings, minutes of the initial review) is available to any IRB member who requests it before or during the IRB meeting, and the complete protocol (including previously approved modifications) is reviewed by at least one IRB member.

1.3.4. Criteria for review more often than annually: Studies may be reviewed by the IRB more frequently if the study is high risk, if the IRB feels that the study population is especially vulnerable, if previous similar studies indicate a high incidence of adverse events, or if the IRB feels that close monitoring is indicated. The IRB may request interim reports at intervals deemed appropriate by the IRB in addition to the required continuing review. The determinations will be made at the fully convened IRB meeting and documented in the minutes.

1.4. Possible Outcomes of Continuing Review

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As an outcome of continuing review, the IRB may require that the research be modified or halted altogether. The IRB may impose special precautions or relax special requirements it had previously imposed on the research protocol.

At the discretion of the IRB, failure to notify the IRB (within time frames established in these policies) of:

- changes in approved research **prior** to implementation of such changes, except where necessary to eliminate apparent immediate hazards to human subjects;
- reportable local adverse events and unanticipated problems;
- reportable significant protocol violations; and/or
- other actions deemed to be in violation of federal regulations or the Aurora policies and procedures;

may result in action to suspend research activities (see Aurora policy RR 407)–and review in accordance with the Noncompliance policy (Policy CO 601).

1.5. Expedited Review for Renewal

A protocol that was originally reviewed using the expedited review procedure (see Policy RR 401) may receive its continuing review on an expedited basis. Additionally, a protocol that received initial full committee review and approval and: 1) is permanently closed to the enrollment of new subjects, all-subjects have completed all research-related interventions, and is active only for long-term follow-up of subjects; 2) where no subjects have been enrolled and no additional risks have been identified; or 3) where the remaining research activities are limited to data analysis may be reviewed using an expedited review. In addition, continuing review may be expedited when the research is neither conducted under an IND or an IDE and no other expedited review category applies but the IRB has determined and documented at a convened meeting that the research involves no more than minimal risk and no additional risks have been identified.

When conducting research under an expedited review procedure, the IRB Chair or designated IRB member conducts the review on behalf of the full IRB using the same criteria for renewal as stated in section 1.3 of this policy. If the reviewer feels that there has been a change to the risks or benefits, he or she may refer the study to the full IRB for review.

1.6. Verification by Third Party

The IRB has the authority to determine that a particular study needs verification from sources other than the investigator that no material changes in the research have occurred since

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the previous IRB review [21 CFR 56.108(a)(2)]. The IRB may consult sponsors, consultants, regulatory agencies, etc. regarding a study in order to determine whether the IRB should approve, modify, halt or place conditions or requirements on the study or investigator in order to ensure the safety of human subjects.

1.7. Notification of IRB Action

Investigators will be notified in writing as soon as possible as to action taken by the IRB for any continuing reviews, including, but not limited to any suspensions or terminations of approved studies (see SOP RR 407), or special conditions placed on the study or enrollment. If the research has been suspended or terminated by the Aurora IRB, the external reporting policy (SOP RR 408) will be followed for notifying other entities.

2. SCOPE

These policies and procedures apply to all research submitted for continuing review.

3. APPLICABLE REGULATIONS, GUIDELINES AND STANDARDS

21 CFR 56.108, 111

45 CFR 46.110, 111

OHRP Guidance on Continuing Review (January 15, 2007)

63 Fed. Reg. 60364-67 (Nov. 9, 1998)

AAHRPP Elements II.2.D.2. and II.2.E.2.

4. REFERENCES TO OTHER APPLICABLE SOPS

SOP 401