

THE NORTH SHORE MEDICAL CENTER Institutional Review Board (IRB) POLICIES AND PROCEDURES	IRB Policy Number: 022.0
Title: <i>Continuing Review of Approved Research</i>	Page: 1 of 3
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I. PURPOSE

This policy defines the procedures to be followed for submitting and performing continuing reviews of human-subjects research and clinical investigations under the jurisdiction of the North Shore Medical Center Institutional Review Board (NSMC IRB).

This policy is established to comply in part with the regulatory requirement in 45 CFR 46.103(b)(4)(i) and 21 CFR 56.108(a)(1) requiring IRBs to have "written procedures which the IRB will follow for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution."

II. SCOPE

All investigators conducting human subjects research who use the NSMC IRB are subject to this policy.

III. DEFINITIONS

Continuing Review means review of a protocol conducted for purposes of determining appropriateness of granting continued approval.

Expedited Review means review procedures for research activities that (1) represent no more than minimal risk to human subjects and (2) involve only procedures that meet the criteria for certain categories of research established by the Department of Health and Human Services and/or the Food and Drug Administration which do not require review by a convened quorum of the full IRB (see reference #5). A protocol that initially was reviewed using the expedited review procedures may undergo continuing review under the expedited review procedures. However, research that previously met the criteria for expedited review will require convened IRB review if any submitted changes to the protocol subsequently do not qualify for expedited review.

Convened Board Review means review procedures for research activities that do not meet the criteria for expedited review and must be reviewed by the IRB at a convened meeting. A protocol that initially required convened IRB review and approval will be reviewed by the convened IRB unless the study meets the requirements for expedited review under expedited review categories 8 or 9 (see reference #5).

Minimal Risk means that 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. [45 CFR 46.102(i)][21 CFR 56.102(i)]

Research Activities include, but are not limited to, recruitment and enrollment of subjects, collection of specimens, research on previously collected specimens, review of medical records or other health information, data analysis, and performance of research tests/procedures, treatment or follow-up on previously enrolled subjects.

IV. PROCEDURES

Federal regulations require an IRB to conduct substantive and meaningful continuing review of human subjects research. The purpose of continuing review is to review the progress of the entire study, not just changes in it. With the exception of research that has been certified exempt from IRB review, the IRB will conduct continuing review of all research protocols at intervals appropriate to the degree of risk, but not less than once per year, including research in which the remaining activities are limited to data analysis only. Continuing review of the research is required until the research has been completed or has been closed prior to completion. The investigator must submit the continuing review form to document that the study has been completed or is being closed prior to completion. For multi-site research, the research may be considered completed or may be closed prior to completion when the investigator at this site is no longer collecting, receiving, or analyzing data.

A. Continuing Review Notification to Investigators

Ninety (90), sixty (60), and thirty (30) days prior to expiration of IRB approval, the NSMC IRB Office sends written notice to the Principal Investigator (PI) reminding him/her that continuing review of the research is coming due. The expiration date is the last date that the protocol is approved.

B. Submission Requirements for Continuing Review

For an outline of the materials required for all continuing review submissions, please refer to the *NSMC IRB Continuing Review Submission Checklist*.

C. IRB Continuing Review Requirements

1. Upon receipt of a Continuing Review submission, the IRB Administrator determines if all of the necessary documentation has been submitted. Once complete, the submission is routed for either expedited review or convened IRB review in accordance with this policy.
 - a. Expedited Review:
 - i. The IRB Chair receives a copy of all the required forms and documents submitted by the investigator along with a copy of the current IRB-approved protocol.
 - ii. The IRB Chair is responsible for reviewing and determining whether the research is eligible for review using the expedited review procedure. The reviewing IRB Chair uses a form that documents that the research is minimal risk; meets the criteria for approval; the applicable expedited review categories; and that the consent form includes the basic elements of informed consent or that a waiver or alteration of informed consent is approved.
 - iii. If the IRB Chair determines that continuing review of the research does not warrant review via expedited procedures or proposes to disapprove the research, the continuing review will be scheduled for a convened meeting of the NSMC IRB.
 - b. Convened IRB Review:
 - i. For continuing review submissions reviewed via the convened IRB, a primary reviewer system is used. The primary reviewer(s) receives all submitted materials and a copy of the current IRB-approved protocol, including any modifications previously approved by the IRB.
 - ii. The primary reviewer(s) is responsible for conducting the continuing review and reporting his/her assessment to the convened IRB.
 - iii. All other IRB members receive a copy of all forms and documents submitted by the Investigator. In addition, the complete study file and minutes of meetings at which the protocol was previously reviewed are available to all IRB members upon request.
 - iv. The minutes of convened IRB meetings document the deliberations, actions and votes for each study undergoing continuing review.

c. Review Criteria:

- i. The criteria for continuing review are the same as those for initial review. Therefore, the convened IRB, or IRB Chair for research reviewed under the expedited procedures, must determine that all of the requirements at 45 CFR 46.111 or 21 CFR 56.111 (for FDA regulated research) are satisfied.
- ii. When reviewing the current informed consent document, the convened IRB, or IRB Chair for research reviewed under the expedited procedures, should ensure that the currently approved or proposed consent document(s) are still accurate and complete and any significant new findings that may relate to the subject's willingness to continue participation are provided to the subject in an updated informed consent form or addendum to the informed consent form.

d. Additional Considerations

- i. At the time of initial and/or continuing review, the NSMC IRB will determine whether a research activity requires more than annual review to ensure the protection of the rights and welfare of research subjects. The IRB will consider the nature of the study, the degree of risk involved and the vulnerability of the study subject population in determining the continuing review interval. The continuing review interval will be communicated to the Investigator in writing.
- ii. The NSMC IRB may request independent verification of information provided at continuing review in the following situations, for example: 1) research being conducted by persons who have previously failed to comply with all regulations; 2) as a result of information disseminated via regulatory authorities or other sources; and 3) discrepancies in application materials.

D. Lapse in Approval

1. If a completed continuing review application is not submitted to the IRB, or the IRB has not reviewed and re-approved the research by the expiration date, the current approval expires automatically.
2. The NSMC IRB Office sends written notification to the Investigator in writing that the research has expired and all research activities must stop.
3. If approval has expired but treatment or follow-up of subjects is necessary for subject safety and welfare, the Investigator must request permission of the NSMC IRB to continue previously enrolled subjects on the study. The IRB Chair is responsible for considering these requests on a case-by-case basis and providing the investigator with written documentation of permission, when granted.
4. Such expiration of IRB approval is not considered suspension or termination of research and is not subject to OHRP or FDA reporting.
5. In order for expired research to regain approved status, the IRB must conduct continuing review within 60 days of the study's expiration date and approve the continuation of the research.

V. RELATED POLICIES, REGULATIONS, AND REFERENCES

1. DHHS Regulations: [45 CFR 46.103\(b\)\(4\)](#); [45 CFR 46.109\(e\)](#); [45 CFR 46.111](#);
2. FDA Regulations: [21 CFR 56.108\(a\)](#); [21 CFR 56.109\(f\)](#); [21 CFR 56.111](#);
3. [OHRP Guidance on Continuing Review, January 15, 2007](#)
4. FDA Information Sheets: [Continuing Review After Study Approval, 1998](#).
5. [Categories of Research That May Be Reviewed by the Institutional Review Board \(IRB\) through an Expedited Review Procedure](#)
6. NSMC IRB Continuing Review Submission Checklist