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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the institutional audit process of the expected standards of performance of the North American Consortium for Histiocytosis (NACHO) Full Member and Associate Member institutions.

POLICY

The NACHO Operations Center (NACHO OC) is responsible for establishing and implementing mechanisms to assure the clinical trials conduct, performance standards, and the scientific contributions of the Full and Associate Member institutions are met. It is the policy of NACHO that all Full and Associate Member Institutions will comply with the standard performance requirements established by the Executive Committee (EC). Audits will be performed remotely unless otherwise dictated. (Refer to SOP: Membership Categories, Criteria and Standards).

PROCEDURES

I. Required Documentation from NACHO Institution

- A. Patient Screening Logs
 - 1. Completed and submitted to the NACHO OC on a quarterly basis
- B. IRB Approvals
 - 1. Timely submission of approvals and continuing reviews to Coordinating Centers

II. Reports Compiled by the NACHO OC

- A. Institution Activity Reports
 - 1. Generated quarterly on January 1st, April 1st, July 1st, and October 1st of each year
 - 2. Summarizes the following information
 - a. Executive committee meeting attendance (for Full members)
 - b. Number of study riders approved
 - c. Number of NACHO studies activated
 - d. Patient screening
 - e. Patient accrual
 - f. Protocol compliance
 - g. Study meeting attendance
- B. Timeliness of Data Entry
 - 1. A review of the study databases will be performed by each Study Coordinator as needed per study demands, but at least monthly.
- C. Site PI review
 - 1. The site PI will review and sign the quarterly reports
 - 2. The signed report will be sent to the NACHO OC at NACHO.OperationsCenter@stjude.org and placed in the electronic site file.

III. Audit Review and Reporting Period

- A. The review date for the annual institutional performance audit will cycle on July 1st of each year.
- B. All of the above documentation and reports for the previous year will be reviewed remotely by the NACHO OC during the performance audit
- C. Any queries will be sent to the institutional Principal Investigator and appropriate study staff
 - 1. Queries will be responded to within ten (10) business days

IV. Institutional Audit Summary

- A. The NACHO OC will compile the Institutional Audit Summary.
- B. The report will be sent to the EC for review, recommendations, and approval.
- C. A copy of the final report will be sent to the institution PI for review.
- D. The report will be filed in the electronic institutional File at the NACHO OC.

MAINTENANCE RESPONSIBILITY

The NACHO SOP Ad Hoc Committee is responsible for the annual review of this SOP. Suggested changes must be proposed to and approved by the NACHO EC.

AUTHORIZATION

This SOP was developed by the SOP Ad Hoc Committee and reviewed and approved by the NACHO EC.

VERSION/REVISION HISTORY

Approval Date	Version	Version/Revision Summary
12/18/2018	V 1.0	Original documentation/publication.