

TABLE OF CONTENTS

Purpose	
Policy	
Procedures	
I.	Structure
II.	Chair Responsibilities
III.	Member Responsibilities
IV.	Meetings
V.	Voting
Maintenance Responsibility	
Authorization	
Version/Revision History	

PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to define the structure, members and responsibilities of the North American Consortium for Histiocytosis (NACHO) Executive Committee (EC).

POLICY

The EC is the governing body of NACHO established to provide structure, oversight and consistency to the Consortium's efforts. EC members represent their own institution's interests and commitment to NACHO. All members are encouraged to participate in Consortium activity, but the EC operates as the final decision making body. The NACHO Operations Center is responsible for the day-to-day management and oversight of all administrative responsibilities of the Consortium.

PROCEDURES

I. Structure

- A. Consortium Principal Investigator
 1. The Consortium Principal Investigator will serve as the Chair of the EC.
 2. Any change to the EC Chair will be proposed to and approved by the EC and reported to appropriate granting organizations.
- B. Consortium Co-Principal Investigator
 1. The Consortium Co-Principal Investigator will serve as the Vice Chair of the EC.
 2. The EC Vice Chair will temporarily act in the Chair's role should the Chair be unavailable or unable to fulfill his/her responsibilities.
 3. Any change to the EC Vice Chair will be proposed to and approved by the EC and reported to appropriate granting organizations.
- C. Full Member Institution Principal Investigators
 1. Institutions will be responsible for selecting the individual to serve as their Principal Investigator (PI) who will, in turn, be a member of the EC.
 - a. Proposed PIs will be reviewed and approved by the other members of the EC.
 - b. Any change to the PI will be proposed to and approved by the EC and reported to appropriate granting organizations.
 2. Institutions will identify a second individual to serve as the Alternate PI who will act in the PI's role should the PI be unavailable or unable to fulfill his/her responsibilities.
 - a. Proposed Alternate PIs will be reviewed and approved by the other members of the EC.
 - b. Any change to the Alternate PI will be proposed to and approved by the EC.
- D. Standing Committee Chairs
 1. The Chair of each established standing committee will serve as an EC member.
 2. Standing committees include but are not limited to those listed below.
 - a. Scientific Committee.
 - b. Clinical Studies Committee.

E. Ex Officio Members

1. NACHO Operations Center and Biology Center personnel will serve as non-voting EC members and may include but are not limited to those listed below.
 - a. Project and/ or resource managers.
 - b. Clinical research coordinators.
 - c. Grant management officers.
 2. Other non-voting members may be appointed at the discretion of the EC Chair with majority vote approval of EC members or by majority vote of EC members.
- F. The above will be voting members of the EC unless otherwise noted.
- G. Members will serve three-year terms, with no limit on the number of terms that can be served.
- H. Resignations from the EC should be made in writing to the EC Chair.

II. Chair Responsibilities

The EC Chair will direct and coordinate the work of the Consortium as listed below.

- A. Act as Consortium spokesperson both internally and externally.
- B. Establish the agenda, convene and conduct meetings.
- C. Facilitate the work and responsibilities of the EC and its members by assigning tasks and monitoring the committee's overall progress.
- D. Decide matters where voting has resulted in a tie.
- E. Serve as PI or Co-PI of Consortium-related funding proposals.
- F. Serve as an ex officio member (with a vote) on all standing and ad hoc committees.
- G. Ensure that reports from other committees are submitted to the EC as appropriate.

III. Member Responsibilities

A. Consortium Governance

The EC will provide oversight and deliberation for matters pertaining to NACHO as listed below.

1. Represent the Consortium and its mission and goals.
2. Establish, review, amend and/or approve Standard Operating Procedures.
3. Provide scientific direction for the Consortium.
4. Review and approve new applications for membership as per the process defined in the NACHO Membership, Criteria and Standards SOP.
5. Ensure and/or conduct timely audits of NACHO member institutions.
6. Review Quarterly Institution Activity Reports to assess and evaluate site performance.
7. Review pending membership terminations.
8. Resolve disputes as defined in the NACHO Master Consortium Agreement and any subsequent clinical study riders.
9. Evaluate potential and reported conflicts of interest.
10. Review and approve funding proposal concepts associated with NACHO projects and activities.
11. Review and approve research data before public release.
12. Develop strategic and long range plans to ensure the Consortium's future success.
13. Liaison with and promote productive interaction with groups of similar aims and interests.

B. Clinical Studies Oversight

The EC will have general oversight of Consortium clinical studies as listed below.

1. Review and approve new clinical studies, ensuring alignment with NACHO's mission.
2. Determine the desirability of banking biological samples.
3. Oversee requests for use of clinical studies data.
4. Place studies on hold, if/when necessary.

C. Institution Management

1. EC members serving as institution PIs will be responsible for all NACHO activities at their institution as listed below.
 - a. Directly supervise the performance and administration clinical studies.
 - 1) Ensure compliance with protocol documents.
 - 2) Identify investigators and personnel to ensure timely and efficient work.

- b. Circulate information about and from NACHO to all pertinent personnel.
- D. Committee Development and Oversight
 - 1. The EC will establish, restructure and/or eliminate standing and ad hoc committees at its discretion by majority vote.
 - a. A standing committee is a permanent work group that addresses a particular area of ongoing issues, ensures consistency of practices, and serves as organizational memory.
 - b. An ad hoc committee is a temporary work group formed for a specific task or objective, and with the intent to dissolve after the completion of the task or achievement of the objective.
 - 1) An ad hoc committee can be reclassified as a standing committee as the EC deems appropriate and by majority vote.
 - 2. Upon creation, the EC will define in writing the structure, role, responsibilities, composition and/or expectations of each committee.
 - 3. The EC will review the progress of each committee at least twice annually, based on activity and reports provided by committee chairs.
 - 4. Committee members may include representatives from Full or Associate Member Institutions that volunteer or accept nomination.
 - 5. Committees will select a chair from among its members, by majority vote, within four (4) weeks of a committee being established.
 - a. Chairs will be responsible for leading the committee as listed below.
 - 1) Ensure committee efforts align with EC directives for the group.
 - 2) Monitor participation of committee members.
 - 3) Establish the agenda, convene and conduct meetings.
 - 4) Decide matters where voting has resulted in a tie.
 - 5) Provide the EC with regular progress updates.

IV. Meetings

- A. Regular meetings of the EC will be integrated with the monthly group teleconferences and one in-person meeting (hereafter referred to collectively as “meetings”) as outlined in the Membership, Criteria, and Standards SOP unless otherwise noted or announced.
 - 1. Participation in meetings is open to PIs and/or Alternate PIs from both Full and Associate Member Institutions, as well as other members of the EC; other participants may be invited at the discretion of the EC.
 - a. The institution PI or Alternate PI for is expected to attend and participate in no fewer than 50% of meetings during a six (6) month period of time.
 - 2. The presence of a majority of EC members constitutes a quorum.
 - 3. Meeting dates, times, and location, if applicable, will be communicated at least 30 days in advance of the event.
 - 4. Unless otherwise stated, the monthly group teleconference will take place on the same time each month, using the same dial-in number and passcode.
- B. An executive session solely for EC member participation may be called during group meetings.
- C. Special meetings of the EC may be called by the EC Chair or at the request of a majority of EC members.
 - 1. Notices of special meetings will be sent at least seven (7) days in advance of the event and will state the reason that such meeting has been called.
- D. NACHO Operations Center personnel are responsible for organizing meetings that support the business of the Consortium.

V. Voting

- A. EC members eligible to vote on Consortium matters, as defined in Section I of this SOP, include the Chair, Vice Chair, Full Member Institution PIs or Alternate PIs, and standing committee chairs.
- B. Votes may take place during teleconferences, at in-person meetings, and/or via an electronic mechanism.

- C. The presence and/or participation of a majority of EC members constitute a quorum for voting.
 - 1. A positive vote of more than half of that majority is required to pass a measure unless otherwise noted or announced.
- D. Only the institutional PI will have the right to vote if both he/she and the Alternate PI from the same institution participate in a meeting/vote.
- E. Individuals eligible to serve on the EC due to multiple roles within the Consortium may only cast one vote.
- F. Voting via proxy is not permitted.

MAINTENANCE RESPONSIBILITY

The EC is responsible for the annual review of this SOP; any amendments or changes must be approved by a majority of EC members.

AUTHORIZATION

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

VERSION/REVISION HISTORY

Approval Date	Version	Version/Revision Summary
08/14/2015	V 1.0	Original documentation/publication.
11/11/2015	V 2.0	Reference to location of operations center removed (policy section); non-voting member appointment process clarified (I.E.2); proposal concept, rather than full proposal, to be approved (III.A.10).
10/07/2016	V 3.0	Change to using the term "Associate" members, rather than "Affiliate" Members to avoid confusion with St. Jude "Affiliate" sites.