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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to identify the categories, criteria, and performance standards of membership in the North American Consortium for Histiocytosis (NACHO) and to define the membership application process.

POLICY

NACHO is the first multi-institutional consortium for Langerhans cell histiocytosis (LCH) and other histiocytic disorders in North America with a solid scientific agenda and the research infrastructure necessary for the development and effective implementation of clinical and translational studies and biological research for LCH. Parties interested in opening a NACHO study must apply for membership in NACHO to facilitate the contracts and opening of NACHO studies.

PROCEDURES

I. Membership Categories

A. Full Member Institution

1. NACHO's original Full Member Institutions were identified as the founding 12 members of the consortium. Those Full Member Institutions will remain as such when in compliance with NACHO membership standards and the conditions set forth in the Master Consortium Agreement executed between the Operations Center institution and NACHO site institutions.
    a) Additional full memberships may be granted at the discretion of and/or via a process established by the NACHO Executive Committee (EC), the governing body of the consortium.
2. Each Full Member Institution must identify one individual from their institution to serve as the Principal Investigator (PI) for NACHO studies and activities.
    a) The PI will serve as a member of the NACHO EC.
    b) An Alternate PI must be identified to serve in the PIs role should the PI be unavailable or unable to perform his/her duties.
    c) All PIs must be proposed to and approved by the other members of the NACHO EC.

B. Associate Member Institution

1. Institutions will be considered for Associate membership when meeting at least one (1) of the criteria below, in addition to the criteria listed in Section II of this SOP.
    a) The institution is interested in opening and enrolling patients on a NACHO study.
    b) The chair of a study approved for development by the NACHO EC is at that institution.
    c) The institution provides significant scientific input for the development of a NACHO study.
    d) The institution provides laboratory resources for correlative studies for a NACHO study.

e) Other special reasons as determined by the NACHO EC.

2. Membership applications must be submitted following the process outlined in Section VII
3. Associate members are considered temporary memberships and will continue based on the guidelines set forth in the NACHO Master Consortium Agreement and any subsequently engaged Clinical Study Protocol Riders.
4. Each Associate Member Institution must identify one individual from their institution to serve as the PI for NACHO studies and activities; the PI will be responsible for:
    a) Directly supervising the performance and administration of NACHO clinical trials, ensuring compliance with protocol documents and identifying investigators and personnel to ensure timely and efficient work, and
    b) Circulating information about and from NACHO to all pertinent personnel.
5. An Alternate PI must be identified to serve in the PI's role should the PI be unavailable or unable to perform his/her duties.
6. Associate Member Institutions are not eligible to serve on the NACHO EC or to receive consortium infrastructure funding.
7. Associate Member Institutions may be considered for Full Membership Institution status at the discretion of and/or via a process established by the NACHO EC.

II. Membership Criteria

All institutions interested in NACHO membership must meet the criteria listed below.

A. Have an investigator with clinical trials and/or scientific research experience who has the availability and desire to act as a PI for that institution.
B. Demonstrate and/or have evidence of the infrastructure necessary to perform clinical studies.
C. Be committed to prioritizing NACHO protocols and to providing complete and timely data, including follow-up information. It is understood that this does not prohibit members from engaging in other research activities.
D. Be willing and able to comply with:
    1. NACHO performance audits.
    2. Federal Drug Administration (FDA) requirements and/or other local, regional, state, and national government regulations, as applicable, for conduct of clinical trials.
    3. NACHO regulatory requirements and SOPs.

III. Member Institution Application Process

Institutions meeting the requirements of membership outlined in this SOP may apply for Associate membership with NACHO following the process below. Applications will be accepted on an ongoing basis.

A. Interested parties will complete a membership application and submit other requested materials to the NACHO Operations Center.
    1. Application instructions will be available on the NACHO website and/or by contacting the NACHO Operations Center.
    2. Applicants will be sent notification that an application has been successfully received.
B. Applications will be reviewed by the NACHO Membership Committee and considered for approval by the NACHO EC.
    1. A positive majority vote of NACHO EC members is needed to approve membership.
    2. Voting may take place via teleconference, in-person meeting or electronically.
C. Membership Applications will be approved biannually.
    1. Applicants will be notified via email of their acceptance status within 4 weeks of decision
D. Failure to execute the NACHO Master Consortium Agreement within six (6) months of receipt may result in rejection of application.

IV. Membership Requirements

NACHO institutions agree to the stipulations and activity listed below.

A. Comply with all provisions outlined in the written NACHO Master Consortium Agreement for the duration of membership in NACHO, including the confidentiality clause.
B. Execute individual Clinical Study Protocol Riders, as applicable, for each NACHO study within nine (9) months of receipt.
C. Report to the NACHO EC any conflicts of interest for the PI, Alternate PI and all sub-investigators as

per the policy established by the NACHO EC.

D. Comply with NACHO clinical trials monitoring, as applicable.
E. Comply with FDA requirements and/or other local, regional, state, and national government regulations, as applicable, for conduct of clinical trials.
F. Adhere to NACHO regulatory requirements and SOPs.
G. Participate in NACHO teleconferences and in-person meetings.

V. Performance Standards for Member Institutions

The guidelines below define participation levels needed from Member Institutions to maintain membership in good standing with NACHO. Participation requirement can be met by Clinical Trials or Scientific Contribution.

A. Performance evaluations/audits
    1. Performance will be evaluated each calendar year.
    2. The annual performance period will be based on the start date of January 1.
    3. Institution Activity Reports will be generated annually and distributed to sites.
B. Member Institutions remain in good standing by meeting one of the following criteria:
    1. Clinical Trials Participation
        a) Have at least one NACHO Clinical Research Study activated, and
        b) Compliance with Clinical Studies Committee expectations for site study performance
    2. Scientific Contribution
        a) Site PI or designee is Member of a NACHO Clinical Trial Protocol Team
        b) Site PI or designee participation in a NACHO Committee
        c) Site PI or designee has significant scientific contribution to NACHO Clinical Trials development
C. Regular (over 50%) attendance of NACHO Consortium Meetings (in person or virtual) by the Site PI or designee is expected to remain in good standing
    1. NACHO Meetings include:
        a) NACHO Annual Meetings
        b) Study Meetings
        c) Committee or Working Group Meetings

VI. Membership Probation and Termination

After annual membership performance evaluation, a warning notice will be issued to institutions that do not meet the standards above

A. A probation period of six (6) months will be applied to institutions that received a warning notice. Institutions may appeal the probation decision one time with submission of an action plan to the NACHO Membership Committee. After the 6-month probation, the action plan will be reviewed and the site will be evaluated for their compliance. The site may apply for an extension of their probation in some cases. Before the end of the probation period, institutions must meet the membership standards or membership will be terminated.
B. Membership in NACHO can also be terminated for:
    1. Failure to comply with the confidentiality clause in the NACHO Master Consortium Agreement.
    2. Failure to comply with federal and/or other local, regional, state, and national government regulations, as applicable, for conduct of clinical trials.
    3. Failure to disclose conflicts of interest that affects NACHO research and/or goals.
    4. An audit that identifies serious problems in clinical trials conduct as determined by the NACHO EC.
C. The NACHO EC will review membership terminations prior to notices being issued.

VII. Benefits of Membership

Member Institutions can become involved in NACHO's work in the ways listed below.

A. Open and enroll patients on active NACHO clinical studies.
B. Have restricted user access to the NACHO website.
C. Participate in NACHO teleconferences and meetings.
D. Assist in the development of future NACHO clinical studies.
E. Serve as a member of NACHO committees.
F. Receive guidance, support, and training (when applicable) for NACHO sponsored studies.

MAINTENANCE RESPONSIBILITY

The NACHO SOP Ad Hoc Committee is responsible for the 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
06/25/2015	V 1.0	Original documentation/publication; reviewed/approved by Full Member Institution representatives acting as the Executive Committee (EC), as EC not officially formed as of 06/25/2015.
11/11/2015	V 2.0	Reference to location of operating center removed (policy section); vote needed to approve affiliate members adjusted from two-thirds to majority (VIII.B.1).
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; move meeting metric to appropriate performance standards sections; group meetings changed to Executive Committee meetings; additional membership benefit added.
5/25/2022	V 4.0	Applied same membership standards to both full and associate members, added clarification for review of new member applications, added information for sites who will join but will not participate in clinical trials, streamlined the process for member termination