TABLE OF CONTENTS

PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to define the requirements for managing records related to clinical studies for the North American Consortium for Histiocytosis (NACHO) and to ensure compliance with applicable regulations, laws and policies.

POLICY

The Principal Investigator (PI) at the NACHO member institution is responsible for overseeing the maintenance of clinical research records associated with Consortium clinical studies according to the procedures below.

PROCEDURES

I. Ownership of Clinical Research Records

A. Clinical research records are the property of the institution where the records originated.
B. Records include, but are not limited to, those listed below.
   1. Local institutional review board (IRB) submissions and approvals.
   2. Delegation of Authority Log.
   3. US Food and Drug Administration (FDA) Form 1572 or national equivalent.
   4. Financial and conflict of interest disclosures.
   5. Signed and dated Informed Consent Documents (ICD).
   6. Source documents including, but not limited to, hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, and radiology films/CDs.

II. Storage and Retention of Clinical Research Records

A. Clinical research records will be stored in a manner that ensures privacy, confidentiality, security, and accessibility during the conduct of the study and after the study is completed.
   1. Records may be kept in hardcopy, electronic or other media form.
   2. Transfer of documents from paper records to electronic formats and/or archiving this information on available media is permissible.
   3. The NACHO Operations Center will store clinical research records in the same manner as stated above.
B. Retention of study clinical research records must comply with:
   1. The policies and procedures of the NACHO PI's own institution,
   2. FDA or Health Canada requirements,
   3. Health Insurance Portability and Accountability Act (HIPAA) or Personal Health Information Protection Act (PHIPA), and
   4. Pharmaceutical sponsor's requirements, if applicable.
C. NACHO member institutions are responsible for making alternate arrangements if they are unable to store or retain clinical research records according to the requirements of this SOP and for each NACHO clinical study in which they have patients enrolled.

1. Plans for alternate storage and retention must be reported to and approved in advance by the NACHO Operations Center.

III. Access to Clinical Research Records

A. Clinical research records will be made available to the parties identified in ICD for each NACHO study protocol.
   1. Parties may include, but are not limited to, independent auditors, study sponsors, and the FDA or Health Canada.

B. The NACHO EC, or their designee, reserves the right to conduct an on-site inspection at any NACHO member institution of the records associated with NACHO clinical studies.
   1. Reasonable advance notification of on-site visit will be provided.
   2. Audits will be conducted on a weekday during regular business hours.

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 Executive Committee (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
08-06-2015	V 1.0	Original documentation/publication.

TABLE OF CONTENTS

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.

TABLE OF CONTENTS

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) 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. The institution wherein NACHO's Operations Center is located is responsible for developing and executing contracts on behalf of NACHO. The institutions participating in the consortium funding application made to and funded by St. Baldrick's Foundation (SBF) defined NACHO's original members. Other parties interested in opening a NACHO study must apply for Associate 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 in the funding application to SBF that outlined the design and 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 Memorandum of Agreement executed between the Operations Center institution and NACHO site institutions regarding SBF funding.
    a) Additional Full level 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 VIII of this SOP.
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 are relieved from meeting the same performance standards as Full Member Institutions.
8. 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 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 clinical trials audits at least once every three (3) years.
   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. Membership Requirements

NACHO institutions agree to the stipulations and activity listed below.

A. Execute the NACHO Master Consortium Agreement within six (6) months of receipt, if applicable.
B. Comply with all provisions outlined in the written NACHO Master Consortium Agreement for the duration of membership in NACHO, including the confidentiality clause.
C. Execute individual Clinical Study Protocol Riders, as applicable, for each NACHO study within nine (9) months of receipt.
D. 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.
E. Comply with NACHO clinical trials audits at least once every three (3) years.
F. Comply with FDA requirements and/or other local, regional, state, and national government regulations, as applicable, for conduct of clinical trials.
G. Adhere to NACHO regulatory requirements and SOPs.

H. Participate in NACHO teleconferences and in-person meetings.

IV. Executive Committee Meetings

A. Monthly Executive Committee teleconferences and one in-person meeting (hereafter referred to collectively as "meetings") are held to provide updates on NACHO clinical studies and activities and to address other consortium related business.
   1. Meeting dates, times and location, if applicable, will be communicated at least 14 days in advance of the event.

B. Attendance at meetings is open to NACHO Full Member institution PIs and/or Alternate PIs. Other participants may be invited at the discretion of the NACHO EC.

C. The PI or Alternate PI for all NACHO Full Member institutions is expected to attend and participate in no fewer than 50% of meetings during a six (6) month period of time.

D. The presence of a majority of NACHO EC members constitutes a quorum.
   1. If a PI and Alternate PI from the same institution both participate in a meeting, only the PI will have the right to vote.

E. Unless otherwise stated, the monthly group teleconference will take place at the same time each month.

F. The NACHO Operations Center staff is responsible for organizing meetings that support the business of NACHO.

V. Performance Standards for Full Member Institutions

The guidelines below define participation levels needed from Full Member Institutions to maintain membership in good standing with NACHO. Refer to Section VI of this SOP for Associate Member Institution performance standards.

A. Reporting Period
   1. The annual accrual period will be based on the start date of June 1.
   2. Institution Activity Reports summarizing IRB approvals, Patient Screening Logs, patient accrual, and meeting attendance will be generated by the NACHO Operations Center quarterly on June 1, September 1, December 1 and March 1 of each year.

B. Study Activation
   1. An active study is defined as one that has been open within NACHO for three (3) months.
   2. Full Member Institutions are expected to have 50% or more of all active NACHO studies approved by their local IRB and to do so within nine (9) months of executing Clinical Study Protocol Riders.
      a) Studies on hold for nine (9) months or more, either for drug supply or other reasons as determined by the NACHO EC, will not be considered in this evaluation.

C. Patient Screening Logs
   1. All member institutions will maintain monthly Patient Screening Logs (PSL).
   2. The NACHO Operations Center will provide members with a PSL template following membership approval or at an otherwise designated time.
   3. Institutions will be responsible for completing and submitting PSLs to the NACHO Operations Center on a monthly basis.
      a) The PSL template will include a choice to demonstrate that no patients were screened during a particular month.

D. Patient Accrual
   1. Full Member Institutions are expected to enroll eligible patients on active NACHO studies for which Clinical Study Protocol Riders have been executed and that have received local IRB approval.
   2. The measures below are calculated based on active NACHO studies collectively of those that have received local IRB approval.
      a) A minimum of one (1) patient should be enrolled in the first twelve (12) months following local IRB approval.

b) At least two (2) patients should be enrolled in each subsequent twelve (12) months.

3. Accrual expectations may be adjusted based on the total number of and/or specific, active NACHO clinical studies.

E. Membership Probation and Termination (for Full Member Institutions)

1. A warning notice will be issued to institutions that do not meet the standards below, as demonstrated in quarterly activity reports.
   a) No patients have been accrued in the first twelve (12) months after a NACHO study is approved by a local IRB, and/or
   b) Less than 50% of active NACHO studies have local IRB approval, based on studies that have been active with NACHO for at least six (6) months at the time of the report, and/or
   c) Fewer than ten (10) PSLs have been submitted during a twelve (12) month period.
2. An initial probation period of six (6) months will be applied to institutions that received a warning notice if the subsequent quarterly activity report demonstrates that the standards cited in the warning notice has still not been met. During the initial probation, institutions must meet the standards below or membership will be terminated.
   a) Accrue at least one (1) patient on an active NACHO study, and/or
   b) Obtain local IRB approval for at least 50% of active NACHO studies, and/or
   c) Submit at least ten (10) of the twelve (12) delinquent PSLs, and/or
   d) Attend at least 50% of group meetings (PI or Alternate PI).
3. Institutions meeting the criteria during initial probation may be granted a second six (6) month probation period during which the standards below must be met or membership will be terminated.
   a) Accrue at least one (1) additional patient on a NACHO study, and/or
   b) Obtain local IRB approval for at least 50% of NACHO studies, and/or
   c) Submit at least 80% of delinquent PSLs and maintain monthly submission thereafter, and/or
   d) Attend at least 50% of group meetings (PI or Alternate PI).
4. Institutions meeting the criteria to be placed on probation for a third time, after having resolved probation successfully on two prior occasions, will have membership terminated.
5. Membership in NACHO can also be terminated for:
   a) Failure to execute the NACHO Master Consortium Agreement within six (6) months of receipt.
   b) The NACHO PI or Alternate PI has attended fewer than three (3) group meetings in a six (6) month period.
   c) Failure to comply with the confidentiality clause in the NACHO Master Consortium Agreement.
   d) Failure to comply with federal and/or other local, regional, state, and national government regulations, as applicable, for conduct of clinical trials.
   e) Failure to disclose conflicts of interest that affects NACHO research and/or goals.
   f) An audit that identifies serious problems in clinical trials conduct as determined by the NACHO EC.
6. The NACHO EC will review membership terminations prior to notices being issued.

VI. Performance Standards for Associate Member Institutions

The guidelines below define the participation needed from Associate Member Institutions to maintain membership in good standing with NACHO. Refer to Section V of this SOP for Full Member Institution performance standards.

A. Reporting Period

1. The annual accrual period will be based on the start date of June 1.

2. Institution Activity Reports summarizing IRB approvals, Patient Screening Logs, patient accrual, and meeting attendance will be generated by the NACHO Operations Center quarterly on June 1, September 1, December 1 and March 1 of each year.

B. Study Activation
   1. An active study is defined as one that has been open within NACHO for three (3) months.
   2. Associate Member Institutions are expected to activate all NACHO studies for which they have executed a Clinical Study Protocol Rider within nine (9) months of signing said Rider.
      a) Studies on hold for nine (9) months or more, either for drug supply or other reasons as determined by the NACHO Executive Committee, will not be considered in this evaluation.

C. Patient Screening Logs
   1. All member institutions will maintain monthly Patient Screening Logs (PSL).
   2. The NACHO Operations Center will provide members with a PSL template following membership approval or at an otherwise designated time.
   3. Institutions will be responsible for completing and submitting PSLs to the NACHO Operations Center on a monthly basis.
      a) The PSL template will include a choice to demonstrate that no patients were screened during a particular month.

D. Patient Accrual
   1. Associate Members are expected to enroll eligible patients on active NACHO studies for which Clinical Study Protocol Riders have been executed and that have received local IRB approval.
   2. The measures below are calculated based on active NACHO studies collectively of those that have received local IRB approval.
      a) A minimum of one (1) patient should be enrolled in the first twelve (12) months following local IRB approval.
      b) At least two (2) patients should be enrolled in each subsequent twelve (12) months.
   3. Accrual expectations may be adjusted based on the total number of and/or specific, active NACHO clinical studies.

E. Membership Probation and Termination (for Associate Member Institutions)
   1. A warning notice will be issued to institutions that do not meet the standards below, as demonstrated in quarterly activity reports.
      a) No patients have been accrued in the first twelve (12) months after a NACHO study is approved by a local IRB, and/or
      b) Fewer than ten (10) PSLs have been submitted during a twelve (12) month period, and/or
   2. An initial probation period of six (6) months will be applied to institutions that received a warning notice if the subsequent quarterly report demonstrates the criteria noted in the warning notice has still not been met. During the initial probation, institutions must meet the criteria below or membership will be terminated.
      a) Accrue at least one (1) patient on an active NACHO study, and/or
      b) Submit at least ten (10) of the twelve (12) delinquent PSLs, and/or
      c) Attend at least 50% of group meetings (PI or Alternate PI).
   3. Institutions meeting the criteria during initial probation may be granted a second six (6) month probation period during which the criteria below must be met or membership will be terminated.
      a) Accrue at least one (1) additional patient on a NACHO study, and/or
      b) Submit at least 80% of delinquent PSLs and maintain monthly submission thereafter, and/or
      c) Attend at least 50% of group meetings (PI or Alternate PI).
   4. Institutions meeting the criteria to be placed on probation for a third time, after having resolved probation successfully on two prior occasions, will have membership terminated.

5. Membership in NACHO can also be terminated for:
    a) The NACHO PI or Alternate PI has attended fewer than three (3) group meetings in a six (6) month period.
    b) Failure to comply with the confidentiality clause in the NACHO Master Consortium Agreement.
    c) Failure to comply with federal and/or other local, regional, state, and national government regulations, as applicable, for conduct of clinical trials.
    d) Failure to disclose conflicts of interest that affects NACHO research and/or goals.
    e) An audit that identifies serious problems in clinical trials conduct as determined by the NACHO EC.
6. The NACHO EC will review membership terminations prior to notices being issued.

VII. Benefits of Membership

Full and Associate 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.

VIII. Associate 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 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. Applicants will be notified via email of their acceptance status within six (6) to eight (8) weeks of submitting an application.
D. Provisional membership approval may be granted in order to expedite the process of initiating a NACHO clinical study.

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
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.

TABLE OF CONTENTS

PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to identify criteria for authorship and define the expectations and procedures for submitting publications for the North American Consortium for Histiocytosis (NACHO) and its studies.

POLICY

I. Timely publication of results is paramount to NACHO's mission and is a means by which to measure accomplishments.
II. Publications are defined as manuscripts, abstracts and presentations that report clinical and laboratory findings and conclusions of NACHO clinical studies including linked correlative biology aims and pharmacology studies.
III. Each study is expected to produce at least one (1) published, peer-reviewed manuscript and is expected to present findings at national and/or international meetings.
IV. Publication policies and requirements of individual protocols supersede this NACHO Publications SOP.

PROCEDURES

I. Publication Proposals

A. The protocol coordinator or data safety monitoring board for each clinical study will be responsible for providing notification via email that study accrual is complete and when development of publications may commence.
    1. Parties to be notified include but are not limited to the study's chair(s), statistician, and investigators, and the NACHO Executive Committee (EC) and Operations Center.
B. Suggestions for development of a publication will be submitted to the NACHO EC for review and approval and may be proposed by protocol study chairs and/or the NACHO EC, Scientific and/or Clinical Studies Committee.

II. Publication Development

A. The NACHO EC will identify a writing committee that will be charged with reporting study findings, at the suggestion of the study chair, or the Clinical Studies and Scientific Committees.
B. Publications will acknowledge funding from current and future Consortium sponsors and recognize any protocol specific contributions and/or in-kind support.
C. The choice of journal or meeting for submission will be reviewed and approved by the NACHO EC prior to submission.

III. Authorship

A. Authors will include individuals who have had significant scientific input and/or made substantial intellectual contribution to the design, conduct and/or data analysis of the protocol on which a publication will focus.
    1. The International Committee of Medical Journal Editors' guidelines and recommendations (www.icmje.org) regarding authorship will be consulted where questions reside.

B. The primary author(s) will be the designated by the writing committee and approved by the NACHO EC.
C. The statement "For the North American Consortium for Histiocytosis (NACHO)" will follow the final list of authors.
D. All NACHO member institutions participating in a study will be listed in the appendix of participants of each publication associated with that study.
E. The writing committee will submit the final author list to the NACHO EC for review and approval.

IV. Publication Circulation, Review and Timetable

A. The writing committee will develop an initial draft within nine (9) months after completion of study enrollment and after receiving notification from the protocol coordinator or data safety monitoring board that development of publications can commence.
    1. All publications will be reviewed and approved by the study and/or NACHO statistician.
    2. All co-authors will review and approve the initial draft.
    3. The NACHO EC will review and provide feedback to the writing committee within one (1) month of receiving the initial draft.
B. The writing committee will submit a final draft to the NACHO EC within one (1) month after receiving their initial feedback.
    1. The NACHO EC will provide feedback to the writing committee within one (1) month of receiving the final draft.
    2. All co-authors will review and approve the final draft.
C. The NACHO EC reserves the right to:
    1. Identify and allow for special circumstances in which the above noted circulation and timetable may be adjusted and/or waived.
    2. Monitor progress of publication development and request updates during meetings and/or via written report.
    3. Replace an author or co-author if that investigator does not fulfill their responsibilities to allow for completion of a publication.
    4. Delegate its publications-related responsibilities to a working group or other designee.

V. Abstracts for Presentation

A. Data regarding current patient accrual, toxicities and preliminary laboratory results that do not include clinical outcomes or data that could potentially influence enrollment may be presented as an abstract at meetings prior to the completion of patient accrual and study aims.
    1. The primary author will submit the abstract for review to the NACHO EC at least three (3) weeks prior to the meeting submission deadline.
    2. Abstracts will be reviewed and approved by all co-authors and the study and/or NACHO statistician prior to submission.
B. Information regarding response data may not be presented prior to study completion unless the NACHO EC grants special permission.
C. Authorship on abstracts is not binding for authorship on subsequent publications.
D. The primary author will provide the NACHO Operations Center with a copy of the abstract that will be included in the list of publications on the NACHO website and submitted to all sponsors when appropriate and/or required.

VI. Submission

A. The primary author will be responsible for submitting the final publication to the journal or meeting of choice as previously reviewed and approved by the NACHO EC.
B. The primary author will provide the NACHO Operations Center with a copy of the publication for its records and so that it may coordinate submission of the publication to Consortium sponsors when appropriate and/or required. Publication citations will also be listed on the NACHO website.

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 Executive Committee.

AUTHORIZATION

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

VERSION/REVISION HISTORY

Approval Date	Version	Version/Revision Summary
08/21/2015	V 1.0	Original documentation/publication.