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.