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## PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to establish guidelines for NACHO members to initiate a NACHO-supported research project or initiative with the goal of:

- Encouraging constructive collaboration from the earliest stages of project development
- Supporting research projects which are aligned with the priorities of NACHO while eliminating overlap

## POLICY

All new research concepts will be submitted as a proposal to NACHO leadership for review and approval prior to development of a full protocol that is supported by NACHO.


## PROCEDURES

### I. Protocol Concept Proposal

- A. A protocol concept may be generated by the Clinical Studies Committee or by an individual NACHO member
- B. A protocol concept leader (likely the eventual Study Chair) will complete the NACHO Protocol Concept Form (attached)
  - 1. The protocol concept leader must be a member of NACHO in good standing
  - 2. Refer to NACHO SOP "Protocol Study Chair Responsibilities" for additional guidance on the role of the Study Chair
  - 3. The designation of the Study Chair and/or the Sponsor Investigator will be approved by the NACHO Scientific Committee at the time of concept approval.
- C. The completed Project Concept Form should be submitted to the Scientific Committee (SC)

### II. Protocol Concept Review

- A. The SC will review the proposal within 45 days of receipt, during which time the Committee may request clarifications or suggest changes to the protocol concept leader
  - 1. The protocol concept leader will have 10 days to respond to requests or suggested changes to the original proposal
  - 2. The SC will have an additional 15 days to present the final recommendation to the EC
- B. Not more than 70 days after receipt, the SC will make one of the following recommendations to the EC:
  - 1. Protocol development may proceed,
  - 2. Proposal has been tabled (the concept may be reconsidered by NACHO in the future with a new Protocol Concept Proposal Form), or
  - 3. Proposal is declined by NACHO
- C. The Executive Committee (EC) reviews the decision of the SC at the next scheduled EC meeting, or sooner if appropriate
  - 1. The EC reviews the protocol concept proposal to evaluate alignment with NACHO scientific priorities and other factors
  - 2. The EC may overrule the decision of the SC
  - 3. The EC will communicate the final decision to the SC within 5 days of meeting
- D. The SC communicates the final decision to the protocol concept leader
  - 1. The chair of the SC will send official notification of the decision to the concept leader via memo

	<b>NACHO STANDARD OPERATING PROCEDURES</b>	
	<b>Protocol Concept Proposal Submission</b>	
	Effective Date: 12/18/2018	Approved by: NACHO Executive Committee
	Revised Date: 10/22/2020	Page: 2 of 4

2. The SC retains minutes of the concept review for documentation of the process
- E. Protocol development may begin as outlined in the NACHO SOP “NACHO Protocol Development”

**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 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
12/18/2018	V 1.0	Original Version
10/22/2020	V 2.0	Version updated with new timelines and clarification


**SUPPORTING DOCUMENTS**

Attachment 1: Protocol Concept Form


- Example of the Protocol Concept Form to be filled out

Attachment 2: NACHO Protocol Development Process

- Process Flow Chart of the Protocol Development Process

 North American Consortium for Histiocytosis	<b>NACHO STANDARD OPERATING PROCEDURES</b>	
	<b>Protocol Concept Proposal Submission</b>	
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### Attachment 1: Protocol Concept Form

 North American Consortium for Histiocytosis	<b>NACHO Protocol Concept Proposal Form</b>	
	Effective Date: xx/xx/xxxx	Approved by: NACHO Executive Committee
	Revised Date: NA	Page: 1 of 1

*NOTE: Please refer to NACHO SOP "Protocol Concept Proposal Submission" for more information.*

**Concept Leader / Institution:**

**Concept Title:**

**Email address:**

**NACHO Collaborators:**

**Proposal date:**

**Other Collaborators:**

**1. Project Type**

- |  |   |
|--|---|
| <input type="checkbox"/> Therapeutic prospective protocol, Phase _____ | <input type="checkbox"/> Retrospective data analysis              |
| <input type="checkbox"/> Non-therapeutic prospective protocol          | <input type="checkbox"/> Biology study (human samples)            |
|  | <input type="checkbox"/> Laboratory study (pre-clinical research) |

**2. Protocol Summary**

Please attach a summary (not more than 5 pages) of the study concept which includes background, hypothesis, objectives, design/methods, intervention (if applicable), and references.

**3. What conflicts exist between this proposed study and current NACHO protocols or approved protocols in development, and what is the plan to mitigate the conflicts?**

**4. Project Funding**

Have funding sources been identified for this project? **Yes / No**

If yes, describe:

If no, what are the plans to secure funding?

If study drug is required, has the pharmaceutical company been contacted?

If no, what are the plans to secure study drug?

**5. Submission**

Please submit the completed form and attachments along with a completed Conflict of Interest Form for each Chair and co-Chair to: [NACHO.OperationsCenter@stjude.org](mailto:NACHO.OperationsCenter@stjude.org) The completed Concept Form will be forwarded to the current chair of the Scientific Committee (SC). Clarifications and changes may be requested by the SC during the 45-day review period. The SC will notify the EC of their recommendation within 70 days. The submitting NACHO member will be notified by the SC when the EC has finalized the decision.

**Attachment 2: NACHO Protocol Development Process**

**NACHO Protocol Development Process**

