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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to establish guidelines for NACHO members to initiate or sponsor a 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 inadvertent overlap
- Improving the quality of NACHO research projects by following a consistent process of development and internal review

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. Experienced investigators should encourage newer members to serve as the protocol concept leader when appropriate, and act as mentors for new protocol leaders
 - 3. Refer to NACHO SOP "Protocol Study Chair Responsibilities" for additional guidance on the role of the Study Chair
- 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 forty-five (45) days, during which time the SC may request clarifications or suggest changes to the protocol concept leader
- B. No longer than forty-five (45) days after receipt, the SC will make a recommendation to the Executive Committee (EC):
 - 1. Proposal is approved and protocol development may proceed, or
 - 2. Proposal has been tabled (the concept may be reconsidered by NACHO in the future with a revised Protocol Concept Proposal Form), or
 - 3. Proposal is disapproved.
- C. The EC reviews the decision of the SC at the next scheduled 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 communicates the final decision to the SC as promptly as feasible
- D. The SC communicates the final decision to the protocol concept leader
 - 1. The chair of the SC will send notification of the decision to the concept leader via memo
 - 2. The SC retains minutes of the concept review for documentation of the process

	NACHO STANDARD OPERATING PROCEDURES	
	Protocol Concept Proposal Submission	
	Effective Date: 12/18/2018	Approved by: NACHO Executive Committee
	Revised Date: NA	Page: 2 of 3

- 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 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
12/18/2018	V 1.0	Original documentation/publication.

Attachment

NACHO Protocol Development Process



Participants:

■ Study Chair
 ■ Scientific Committee
 ■ Clinical Studies Committee
 ■ Executive Committee