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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the process of NACHO protocol development and the corresponding responsibilities of the NACHO Operations Center (NACHO OC) and the study team.

POLICY

Following concept approval, NACHO clinical research projects will be evaluated by the Scientific Committee (SC), the Clinical Studies Committee (CSC), and the Executive Committee (EC) at specified time points during protocol development, prior to implementation of the study.

PROCEDURES

I. Protocol Concept Approval

A. All NACHO protocols must be reviewed and approved as outlined in the SOP "NACHO Protocol Concept Proposal" prior to development.

II. Protocol Design Process

A. The protocol team, led by the Study Chair, will develop drafts of the protocol and other protocol-related documents. The first draft of the protocol is expected to be submitted to the CSC within 90 days of the approval of the protocol concept, or the project may be tabled.

B. The recommended protocol sections include:

1. Title page with title, date, version, study team, IND number
2. Protocol summary
3. Table of Contents
4. Objectives
5. Background and Rationale
6. Eligibility Criteria and Study Enrollment
   a) Inclusion and Exclusion criteria
   b) Process for study enrollment
   c) Randomization plan (if applicable)
7. Treatment Plan
8. Drug/Device/Agent information
9. Required evaluations, tests, observations
   a) Pre-study activities (screening and/or baseline)
   b) Evaluations during therapy
   c) Response/ off study evaluations
   d) Long term follow up activities
10. Evaluation Criteria
    a) Disease response criteria
    b) Toxicity evaluation criteria

11. Removal from protocol and off-study criteria
12. Safety and Adverse Event Reporting
13. Data Collection, Monitoring, and Confidentiality
14. Statistical plan
15. Informed Consent Process
16. References
17. Model consent(s) and assent statements which adhere to 45 CFR 46.116 “General requirements for informed consent”

C. The CSC provides guidance and feedback to the protocol team as needed throughout the protocol design process.
D. Statistical design will be developed in collaboration with a designated statistician (See SOP “Statistical Analysis of NACHO Studies”)
E. The NACHO OC will assist the study team in the design of the study database and electronic case report forms to meet the objectives of the protocol (See SOP “Management of the Clinical Research Database(s)”.
F. The SC will review the final draft of the protocol for scientific rigor and alignment with the original approved concept before the Study Chair may begin applications for funding.

III. IND studies

A. If a NACHO therapeutic protocol requires an IND, the Study Chair will proceed with the application as described in SOP “IND Sponsor Investigator Instructions”

IV. Protocol Funding Plan

A. The Study Chair is expected to secure funding for the protocol in collaboration with the NACHO OC.
B. The NACHO OC will provide the study chair with NACHO Consortium information for funding applications as needed.

V. Final Protocol Approval

A. The EC must review and approve the final protocol and funding plan before the study may enter the regulatory process at the initiating site.

VI. Regulatory Review Process

A. The lead institution will submit the final approved protocol for regulatory review and manage additional requirements, with the assistance from the NACHO Operations Center and the study team as described in SOP “Regulatory Requirements for Sites and Investigators”

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

Step 1 — SOP: NACHO Protocol Concept Proposal

Research Question	• Clinical Studies Committee generates an idea for study, or • NACHO Member has an idea for a study
Protocol Concept Form	• Project lead / Study chair completes Protocol Concept Form (See SOP "Study Concept Submission Guidelines") • Include: Proposed study team, scientific aim, funding ideas, feasibility, conflicts with NACHO projects
Scientific Committee	• SC reviews concept, requests clarifications or changes • SC informs study chair within 45 days: Proceed, tabled (may reapply), declined
Executive Committee	• Reviews decision of SC and confirms alignment with NACHO priorities

Step 2 — SOP: NACHO Protocol Development

Protocol Development Phase	• Study chair and team write protocol (see SOP "NACHO Protocol Development") • Study chair submits protocol draft and related documents to CSC
Clinical Studies Committee	• CSC provides guidance and feedback throughout protocol development process
Scientific Committee	• Reviews final protocol and related documents for rigor and alignment with original concept
Funding Plan	• Study chair develops funding plan and secures funding
Executive Committee	• Final review of all protocol documents • Review/approve funding plan • Approval to begin regulatory process

Step 3 — Regulatory Review

IRB	• Study chair submits protocol to local IRB • Study chair must consult with SC for any major modifications required by IRB

Participants:

Study Chair | Scientific Committee | Clinical Studies Committee | Executive Committee