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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. (see figure attached).
B. The NACHO OC will review staffing and resource requirements for the management of the protocol with the study chair during the initial phase of protocol 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. Protocol funding plan
   A. The study chair is expected to secure funding for the protocol.
   B. The NACHO OC will provide input and NACHO Consortium phrasing for funding applications as needed.
D. The CSC provides guidance and feedback to the protocol team as needed throughout the protocol design process.
E. Statistical design will be developed in collaboration with a designated statistician (See SOP "Statistical Analysis of NACHO Studies"
F. 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)".
G. The SC will review the final draft of the protocol for scientific rigor and alignment with the original approved concept.

III. IND studies

A. If a NACHO treatment protocol requires an IND, the study chair will proceed with the application as described in SOP "IND Sponsor Investigator Instructions"

IV. 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.

V. 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 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	Updated Timelines and added clarification

SUPPORTING DOCUMENTS

Attachment 1: NACHO Protocol Development Process

- Process Flow Chart for Protocol Development

Attachment 1: NACHO Protocol Development Process