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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to summarize the responsibilities and conduct for Study Chairs and to inform Study Chairs of the NACHO procedures related to their role.

POLICY

All NACHO studies must have leadership by a Study Chair (SC), beginning from project concept development, continuing through study conduct until completion of the project and any related publications.

PROCEDURES

I. Project Concept Phase

A. The SC is, in most cases, the NACHO Member who is identified as the leader of a new protocol concept. The SC will follow the process outlined in the SOP "NACHO Protocol Concept Proposal Submission" and will recruit additional members to the study team.

II. Protocol Design Phase

A. The SC is responsible for the timely development of protocol drafts with input from the collaborators according to the SOP "NACHO Protocol Development". In addition to the activities outlined there, the SC is expected to oversee logistical activities for the project, including but not limited to:
   1. Study drug management (including IND application, if required)
   2. Schedule of research activities
   3. Funding applications

B. The SC must approve the final versions of all study forms and the study database.

C. The SC acts as the primary contact for communications with the Scientific Committee, Clinical Studies Committee, the Executive Committee, and NACHO Operations Center as needed during the development of the protocol.

III. Regulatory review

A. Initial protocol submission
   1. The SC is expected to open the protocol at his/her institution, which will act as the coordinating center for the multi-center project
   2. Upon IRB review at the coordinating center, the protocol will be distributed to participating sites according to SOP "Protocol Document Distribution and Management".

B. Protocol Amendments / revisions
   1. Any amendments/revisions to the protocol must be approved by the SC and Clinical Studies Committee prior to IRB submission and distribution to participating sites. Major

changes to the design of the protocol may require additional review and approval by the Scientific Committee or the Executive Committee, as determined by the Clinical Studies Committee.

IV. Study Conduct / Trial oversight

A. The SC is responsible for the following activities while the trial is ongoing:
   1. Review of data at end of a dose level
   2. Writing study progress reports for DSMB review and CTC toxicity review
   3. Review of SAE reports
   4. Access to study data
   5. Approving amendments/revisions

B. If the SC is not available for a period of time, the SC must designate a qualified member of the study team to act on his/her behalf during the absence.

V. Study closure

A. The SC is responsible for verifying the details for study closure and notifying the NACHO Operations Center immediately. The Operations Center will notify the participating sites of the change in status with a memo.

B. Studies will remain open for follow-up at all sites that enrolled a patient until the primary manuscript has been accepted for publication.

VI. Abstracts and Publications

A. Please refer to NACHO SOP “Publication Policy”

VII. NACHO Administrative Support of Study Chair

A. At all phases listed above, the NACHO Operations Center will assist the SC with the administration and coordination of the duties described above.

SUPPORTING DOCUMENTS

See also the NACHO SOP “Changes to Study Staff”

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
12/11/2017	V 1.0	Original documentation/publication.