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PURPOSE

This Standard Operating Procedure (SOP) is intended to summarize standard expectations and procedures related to the Sponsor Investigator's role and responsibilities for use of Investigational New Drugs (IND) in NACHO clinical trials.

POLICY

NACHO protocols will comply with all regulations for the submission of the Investigational New Drug (IND) application if the study meets the requirement as stated in 21 CFR 312, Sec 312.20, Requirement for an IND.

DEFINITIONS:

Sponsor Investigator - an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The sponsor investigator is the signatory on the FDA 1571 form.

NACHO Study Chair – the investigator who is responsible for the initiation, conduct, close-out, and publication of a NACHO clinical trial. Please see NACHO SOP "Protocol Study Chair Instructions" for more information.

PROCEDURES

I. Sponsor Investigator Selection

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. In most cases, the NACHO Study Chair also serves as the Sponsor Investigator. Changes to this practice can be made with approval from the Clinical Studies Committee and NACHO Executive Committee.

II. Sponsor Investigator Role

A. The Sponsor Investigator is responsible for the submission of the IND application, the IND safety reporting, the annual report, and the withdrawal of the IND. The NACHO Operations Center (NACHO OC) will provide required documentation to the Sponsor Investigator as needed.
B. The Sponsor Investigator also has the option to transfer part of his/her obligation to the NACHO OC. Per 21 CFR 312, Sec 312.52, the transfer of obligation must be in writing and the document must be signed by the Sponsor Investigator and the NACHO OC / St. Jude Children's Research Hospital.
C. The following obligations are required to be transferred to the NACHO OC unless approval for other arrangements have been granted.
    1. The development and conduct of monitoring/audit of the study activities
    2. Data management including case report form creation, overall data management and statistical analysis

III. Sponsor Investigator Responsibilities

The Sponsor Investigator will be responsible for the items below unless the obligations for the items have been transferred to the NACHO Operations Center:

A. IND Application

1. The Sponsor Investigator is responsible for the submission of the Investigator New Drug (IND) application if the study meets the requirement as stated in 21 CFR 312, Sec 312.20, Requirement for an IND.

B. Protocol Amendments

1. Once an IND is in effect, the Sponsor Investigator is responsible for amending the IND as needed to ensure that the study is being conducted according to the protocol included in the IND application.
2. An amendment for the IND is required when a change is proposed in the study that "significantly affects the safety of subjects, the scope of the investigation, or the scientific quality of the study." [21CFR 312, Sec. 312.30]. Some examples of when an IND Amendment is required are:
   a. Change is proposed in the protocol that affects the safety of the research subjects
   b. Additions of new research procedures in the protocol
   c. Change in the design of the protocol
   d. Change of Principal Investigator at a NACHO site
   e. Addition of a new NACHO site
3. Instructions for IND amendment submissions can be found in 21 CFR 312, Sec. 312.30.

C. IND Safety Reporting

1. The Sponsor Investigator is expected to follow the guidelines in the NACHO SOP, "IND Safety Reporting Procedures" and comply with the safety reporting requirements in in 21 CFR 312, Sec. 312.32.

D. Annual Report

1. The Sponsor Investigator is responsible for the submission of annual reports within 60 days of the anniversary date that the IND went into effect. The NACHO OC will provide any needed documentation to the Sponsor Investigator with the annual report. Annual report requirements can be found in 21 CFR 312, Sec. 312.33.

E. Withdrawal of an IND

1. The Sponsor Investigator is responsible for notifying the FDA if an IND is to be withdrawn [21 CFR 312, Sec. 312.38]. The NACHO Operations Center will be responsible for notifying the NACHO Consortium Members of the withdrawal.

IV. NACHO Responsibilities to IND Sponsor Investigator

The NACHO OC will provide administrative support to the Sponsor Investigator with the following tasks for IND Submissions:

A. Access to study data for use in interim data analyses and safety analyses
B. Providing monitoring reports

V. Maintenance of Records

A. Copies of all submissions and correspondences pertaining to the IND for NACHO studies should be maintained by the Sponsor Investigator and shall be made available for routine monitoring as requested.

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 documentation/publication.
04/28/2021	V 2.0	Updated definitions and provided minor clarifications to roles.