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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to outline the regulatory responsibilities of the NACHO Operations Center (NACHO OC), the Study Coordinating Center and the participating NACHO sites throughout the development and conduct of NACHO research protocols.

POLICY

All NACHO institutions must fulfill the local and federal regulatory requirements for human subject investigations as well as NACHO study activation requirements prior to enrolling any patient on a NACHO research protocol.

PROCEDURES

I. New Participating Sites

A. Institutions that request to participate in NACHO research protocols must adhere to being a member of the consortium in good standing. The NACHO OC will verify a site's eligibility to participate in any NACHO research protocol.

B. All sites which intend to open NACHO research protocols will be required to submit the properly executed specific rider (Rider) to the NACHO OC for each research protocol that will be activated at the site (refer to NACHO SOP "Membership Categories, Criteria and Standards, section III).

II. All Participating Sites

A. All sites which intend to open NACHO research protocols will be required to submit the following study-specific documents to the Study Coordinating Center (SCC)0 prior to activation of the study at that site:

1. Conflict of Interest and Confidentiality Disclosure Form (PI and sub investigators)
2. Institutional laboratory licensure and normal ranges for laboratory results
3. Signed and dated CV and medical license for all named investigators at the site
4. Office of Human Research Protection approved Federalwide Assurance (FWA) number and the contact information of the local Institutional Review Board (IRB)
5. Completed Delegation of Responsibility (DOR) log
6. Documentation of current training in Good Clinical Practice and Human Subjects Protection for all study staff listed on the DOR log, according to the site's institutional policy
7. FDA form 1572 (when applicable)
8. IRB approval memo with expiration date, including locally-approved informed consent forms and other study related documents specific to the site
9. Attendance logs for the Site Initiation Visit and Database Training
10. Additional forms may be required per each Coordinating Center's policies.

B. It is the responsibility of the NACHO member institution to notify the SCC and/or the NACHO OC of any updates, changes, or revisions to the submitted documents throughout the conduct of NACHO research protocols. The SCC is responsible for monitoring expiration dates of any of the submitted documents.

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.