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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the process in which statistical analysis is performed on the data collected from NACHO studies.

POLICY

All NACHO clinical trials must retain a qualified statistician to develop a statistical plan and to perform analyses of data at designated time points from protocol development phase through final publication.

PROCEDURES

I. Study Development Phase

A. A statistician must be designated during the development of a protocol (after the concept has been approved) to provide input on the study design, including stopping rules, monitoring rules, and rules related to toxicity.
B. A statistician must sign off on the protocol final version prior to submission to the IRB.

II. Study Conduct Phase

A. During the conduct of the study, data will be entered into the electronic clinical research database by participating NACHO sites.
B. The designated statistician(s) will query data as requested by the Study Chair (SC) as needed to review stopping rules, toxicity rates, or other questions related to safe study conduct.
C. The designated statistician will be responsible for extracting data that is used for regular study progress reports and/or submitted to the Data Safety Monitoring Committee.

III. Study Completion

A. At study completion, the designated statistician will analyze the clinical study data and the correlative biology data in relation to the study's primary and secondary endpoints. All analyses will be reviewed by the SC, the Scientific Committee, and the Executive Committee prior to publication.
B. Once all planned manuscripts from a trial have been accepted for publication, all relevant data files used to produce the manuscript(s) will be archived at the NACHO Operations Center as described in the SOP "Archiving Data from Complete Studies"

SUPPLEMENTAL DOCUMENTS

See also NACHO SOP "Changes in 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.