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## PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the distribution and management of NACHO approved research protocols and protocol related documents to NACHO member sites.

## POLICY

Final NACHO approved research protocols and related documents are distributed via the NACHO website.

## PROCEDURES

Each research protocol will have its own page on the NACHO website where all protocol documents will be posted for access by NACHO members and site study staff. The most current protocol documents will be posted to the NACHO website by the Study Manager or NACHO Operations Center (NACHO OC). It is the responsibility of the research protocol Study Chair to ensure the Study Manager has the most current documents. The posting will be accompanied by an emailed notice to participating NACHO members. (see NACHO SOP "Notification of New NACHO Research Protocols"). The IRB approved protocol and accompanying IRB approved documents will be posted in a non-editable PDF format for download.

NACHO members and study staff will need to obtain a valid username and password from the Study Manager or the NACHO OC in order to access the protocol webpage on the NACHO website.

Documents posted for each protocol will include, but are not limited to, the following:

### I. New Site Startup

- A. New Site Instruction Letter
- B. Site Information Form
- C. Essential Documents Checklist
- D. Delegation of Responsibility Form (DOR)
- E. Financial Disclosure Form
- F. Monitoring Plan

### II. Current Protocol Documents

- A. Currently approved protocol document in PDF format.
- B. Currently approved model informed consents
- C. Protocol appendices
- D. Eligibility checklists

### III. Data Collection

- A. Link to Database
- B. Database User Manual

C. Case Report Forms (paper backup only)

**IV. Study Memos and Meetings**

- A. Amendment notices
- B. Numbered memos related to the study.
- C. DSMC Reports
- D. Study Group Monthly Teleconference minutes

**V. Supporting Documents**

- A. Therapy Roadmaps
- B. Transmittal forms for any samples to be collected
- C. Screening/Enrollment logs (if applicable)
- D. Manual of Procedures

**VI. Archived Study Documents**

- A. Superseded versions will remain available to members in the archives section.

**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
12/11/2017	V 1.0	Original documentation/publication.
02/23/2022	V 2.0	Clarified role of NACHO Ops and expanded the list of documents provided to sites