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**PURPOSE**

This SOP is established to provide structure for development, approval, implementation, review, revision, and archival of all NACHO SOPs. This SOP will also address document control in order to maintain a system to control all critical documents.

**PROCEDURES**

***I. Standard Operating Procedure (SOP) Development***

A. Any member of NACHO may identify processes and/or procedures routinely used that would require the use of an SOP. This member will notify the NACHO Operations Center (OC) with recommendations of the need for the SOP.
   1. This process is also the same for changes to existing SOPs

B. The NACHO OC will assess the need for the SOP
   1. If the need for a new SOP is confirmed, NACHO OC will gather appropriate people to assist in the creation of the SOP
   2. NACHO OC can request a meeting of the NACHO SOP Ad Hoc Committee to review the progress of the SOP or request more assistance

C. After the first draft of the new SOP is completed, the SOP is sent to the SOP Ad Hoc Committee. After review, they may request the following:
   1. Changes requested of the SOP
   2. Meeting via teleconference to discuss the SOP and any potential changes
   3. Approval

D. Once an SOP has been reviewed by the NACHO SOP Committee, and any requested changes made, the SOP will be presented to the NACHO Executive Committee (EC) for a vote.
   1. The SOP should be sent to the EC before the next EC meeting for review
   2. The SOP will be presented to the EC for discussion
   3. After discussion, the EC will vote on the approval of the SOP

E. The SOP becomes effective on the date that it was approved by the NACHO Executive Committee
   1. After approval, the SOP will be uploaded to the NACHO Website

***II. Numbering and Organization of the SOP***

A. Each SOP will be numbered in three sections in a uniform manner according to their content by sections and version number
   1. The first number of the SOP indicates the section that the SOP belongs to
      - Section 10: Structure/Administration
      - Section 20: Membership
      - Section 30: Protocol Development
      - Section 40: Study Conduct
      - Section 50: Regulatory Affairs
      - Section 60: Monitoring/Auditing
      - Section 70: Document Control

- Section 80: Analysis and Publication

2. The second number of the SOP is the chronological number assigned within the section that the SOP belongs
3. The third number of the SOP is the version number of that particular SOP.
4. Example: 50.04.02 – This SOP belongs to the Regulatory Affairs Section, is the fourth SOP in that section, and is on its second version

B. The format of the SOPs would include the following uniform elements, where applicable. If any of the elements are not used in the SOP, the category will be deleted. Elements to be considered and included as below:

1. Purpose
   - Identify the goal of the SOP
2. Policy
   - NACHO policies that supersede this SOP
   - Leave blank if there are none
3. Procedures
   - The listed procedures for this SOP
4. Maintenance Responsibility
   - Statement of who is responsible for review and updates related to this SOP
5. Authorization
   - Statement of who approved the SOP
6. Version/Revision History
   - Table logging the revisions to the SOP and their history
7. Supporting Documents
   - List of any attachments to the SOP
   - Leave blank if there are none

### *III. Review and Revisions to the SOP*

A. NACHO SOPs will be reviewed by the NACHO OC at least every three years.
B. Any necessary revisions will be identified and corrected during this process. Any member can propose new language or propose a revision.
C. Revisions to an SOP may occur when the need arises
D. The steps required to revise an SOP will mirror the steps required to create an SOP
E. After revisions have been made, an entry will be added to the Version/Revision History table with information about the revision and when it took place

### *IV. SOP Storage*

A. Approved and Final SOPs will be stored on the NACHO website for access to any NACHO member and stored by NACHO OC
B. Archived SOPs are kept by NACHO OC and are available upon request

**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 |
|---|---|---|
| 02/23/2022 | V 1.0 | Original documentation/publication. |