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## PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to define the requirements for managing records related to clinical studies for the North American Consortium for Histiocytosis (NACHO) and to ensure compliance with applicable regulations, laws and policies.

## POLICY

The Principal Investigator (PI) at the NACHO member institution is responsible for overseeing the maintenance of clinical research records associated with Consortium clinical studies according to the procedures below.

## PROCEDURES

### I. Ownership of Clinical Research Records

A. Clinical research records are the property of the institution where the records originated.
B. Records include, but are not limited to, those listed below.
   1. Local institutional review board (IRB) submissions and approvals.
   2. Delegation of Authority Log.
   3. US Food and Drug Administration (FDA) Form 1572 or national equivalent.
   4. Financial and conflict of interest disclosures.
   5. Signed and dated Informed Consent Documents (ICD).
   6. Source documents including, but not limited to, hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, and radiology films/CDs.

### II. Storage and Retention of Clinical Research Records

A. Clinical research records will be stored in a manner that ensures privacy, confidentiality, security, and accessibility during the conduct of the study and after the study is completed.
   1. Records may be kept in hardcopy, electronic or other media form.
   2. Transfer of documents from paper records to electronic formats and/or archiving this information on available media is permissible.
   3. The NACHO Operations Center will store clinical research records in the same manner as stated above.
B. Retention of study clinical research records must comply with:
   1. The policies and procedures of the NACHO PI's own institution,
   2. FDA or Health Canada requirements,
   3. Health Insurance Portability and Accountability Act (HIPAA) or Personal Health Information Protection Act (PHIPA), and
   4. Pharmaceutical sponsor's requirements, if applicable.
C. NACHO member institutions are responsible for making alternate arrangements if they are unable to store or retain clinical research records according to the requirements of this SOP and for each NACHO clinical study in which they have patients enrolled.

1. Plans for alternate storage and retention must be reported to and approved in advance by the NACHO Operations Center.

## III. Access to Clinical Research Records

A. Clinical research records will be made available to the parties identified in ICD for each NACHO study protocol.
   1. Parties may include, but are not limited to, independent auditors, study sponsors, and the FDA or Health Canada.

B. The NACHO EC, or their designee, reserves the right to conduct an on-site inspection at any NACHO member institution of the records associated with NACHO clinical studies.
   1. Reasonable advance notification of on-site visit will be provided.
   2. Audits will be conducted on a weekday during regular business hours.

## 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 (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 |
|---|---|---|
| 08-06-2015 | V 1.0 | Original documentation/publication. |
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