SOP Number GCP 06
SOP NAME StrokeNet Central Pharmacy Guidelines for Handling Investigational Product
Effective Date: 21-Jun-2016 (revised 13 FEB 2023)

1. Policy: Investigational study product will be managed in accordance with FDA guidelines by appropriate personnel.

2. Definitions and Abbreviations

CPS	Clinical Practice Site
FDA	Food and Drug Administration
GCP	Good Clinical Practice
NCC	NIH StrokeNet National Coordinating Center located at the University of Cincinnati
NDMC	NIH StrokeNet National Data Management Center located at the Medical University of South Carolina
StrokeNet	NIH StrokeNet
SNCP	NIH StrokeNet Central Pharmacy
SOP	Standard Operating Procedure

Investigational study product refers to any drug, medicinal food, device or other material used for the treatment or prevention of a disease or medical condition that is provided by the NCC or a Network affiliated trial sponsor for use in an investigational study.

3. Scope: This SOP is a guideline outlining general standards that the SNCP, and CPSs should abide for handling investigational study drug that are not otherwise listed in StrokeNet SOPs

4. Procedures

I. Licensure: CPSs and CPS staff must continuously maintain all applicable local, state, and Federal licenses needed to handle investigational study product to participate in NIH StrokeNet trials.
II. Investigational study product supplied by the SNCP to CPSs will be limited to investigational use only
    a. The SNCP will obtain protocol specific investigational study product.
    b. The SNCP will ship investigational study product to approved CPSs after the associated CPSs completes site authorization to enroll subjects into a protocol. CPSs can be at or affiliated with a NIH StrokeNet regional coordinating center or an approved non-NIH StrokeNet site. Additionally, CPS pharmacies must submit the names and credentials of pharmacy personnel responsible for study product.

c. Procedures must be in place at the CPS to ensure that study product is only dispensed to or used for subjects enrolled in the protocol for which they have been provided. Study product must be separated from commercial supply and access should be limited to study personnel.
d. Investigational study product may only be dispensed for enrolled subjects; an SOP detailing the mechanism by which the dispensing pharmacist will know a patient is enrolled in a study protocol must be in place.
e. Records must be kept at the CPS, that reflect the dispensation of investigational study product to enrolled subjects. When appropriate, records must also reflect bottle numbers and appropriate study arm dispensation. The WebDCU™ system at the National Data Management Center (NDMC) must be used for all NIH StrokeNet studies unless stated otherwise in the study protocol. CPSs may keep additional records as required by institutional or local protocols in addition to the WebDCU™.
f. All local, state, and federal laws must be followed by CPSs.

III. Training
a. Investigational pharmacy staff must have current GCP training and other research related training per FDA, state, local, and institutional regulations.
b. Investigational pharmacy staff must undertake protocol specific training and/or review protocol specific training materials prior to dispensing an investigational study product for a particular protocol.
c. Regional Coordinating Centers are responsible for SOPs regarding training, and in conjunction with a trial's sponsor, for maintaining this information.

IV. Investigational study product accountability
a. Shipping documents of investigational study product from the SNCP to CPSs must bear the date and the signature of a responsible, appropriately licensed, SNCP Pharmacist.
b. Relevant document records of shipping, receiving, destruction, or destruction on site of investigational study product must be kept by the SNCP and CPS. See StrokeNet SOP GCP14 Study Drug Shipping and Distribution.
c. Investigational study product receipts must be acknowledged in a timely manner by the SNCP and CPS.

V. Labeling: Investigational study product must be labeled in accordance with state, local, and federal guidelines. See StrokeNet SOP GCP14 Study Drug Shipping and Distribution. At a minimum the product label must contain:
a. Investigational study product name
b. Protocol number or other study specific identifier
c. The following statement "Limited by Federal (or United States) Law to Investigational Use Only."

VI. Investigational study product may not be destroyed at a CPS without approval by a NIH StrokeNet Representative. See StrokeNet SOP GCP15 Distribution and Protecting Study Drug Integrity.

VII. Monitoring: Study records and physical inventory of study product must be available for inspection by NIH StrokeNet monitors and FDA.

5. Applicable Regulations and Guidelines

21 CFR 312.40 General Requirements for Use of an Investigational New Drug in a Clinical Investigation

21 CFR 312.61 Control of Investigational Drug

21 CFR 312.69 Handling of Controlled Substances

ICH E6, 2.12 The Principles of ICH GCP

ICH E6, 4.6 Investigational Products

ICH E6, 5.13 Manufacturing, Packaging, Labeling and Coding Investigational Product(s)

6. References to Other Applicable SOPs

StrokeNet SOP GCP14 Study Drug Shipping and Distribution

StrokeNet SOP GCP15 Distribution and Protecting Study Drug Integrity

7. Attachments and References

8. Document History

Version	Description of Modification	Justification for Modification	Completion Date	Issue Date	Effective Date
0.1	Draft		25-Mar-2014		
1.0	Final		21-Jun-2016	21-Jun-2016	21-Jun-2016
2.0	**General updates**		**13-Feb-2023**	**16-Feb-2023**	**16-Feb-2023**