

NIH StrokeNet Standard Operating Procedure

SOP Number: ADM 04
SOP NAME: Network Data Sharing Policy
Effective Date: 30-Sep-2014

1. PURPOSE

To define guidelines for sharing the data from clinical trials conducted in the NIH StrokeNet.

2. DEFINITIONS AND ACRONYMS

DHHS	Department of Health and Human Services
FDA	U. S. Food and Drug Administration
eCRF	Electronic Case Report Form
GUID	Globally Unique Identifier
HIPAA	Health Insurance Portability and Accountability Act of 1996
NCC	National Coordinating Center at the University of Cincinnati
NDMC	National Data Management Center at Medical University of South Carolina
NIH	National Institutes of Health
NIHSS	NIH Stroke Scale
NINDS	National Institute of Neurological Disorders and Stroke
PHI	Protected Health Information
PHS	Public Health Service
PUDS	Public Use Data Sets
RCC	Regional Coordinating Centers
SOP	Standard Operating Procedure
StrokeNet	NIH Stroke Trials Network

3. SCOPE

This SOP applies to all personnel involved with the StrokeNet. This SOP is applicable to the NCC, the NDMC, the RCC and all StrokeNet investigators, staff, subcontractors, consultants or other entities associated with the StrokeNet who manage, oversee, and conduct research within the network regulated by the Public Health Service (PHS) and/or the FDA.

4. GOALS OF DATA SHARING

To make available final data from StrokeNet clinical trials to the research community, while safeguarding the privacy of trial participants and protecting confidential and proprietary data.

5. PROCEDURES

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For each clinical trial conducted within StrokeNet and for which the NDMC is responsible for the clinical database and data management, the following procedure will be implemented. Upon database lock, the NDMC statisticians will generate data files from each data table (corresponding to each eCRF) in the database. In compliance with the HIPAA regulations, each data table will be stripped of any and all personal identifiers and will undergo a de-identification process (see **Table 1**). Furthermore, the NDMC statisticians will create a minimum number of derived variables that would be necessary to ensure reproducibility of the primary analysis.

Table 1. De-identification for PUDS
• delete subject ID numbers and assign a random number to each subject
• delete site ID numbers and assign a random number to each
• delete investigator or assessor names/IDs
• delete the randomization date but keep the month and year and add the order in which patients enrolled
• convert all dates and times (e.g., birth date, death date, end of study date) to the number of days/minutes from the date and time of randomization
• as appropriate, include GUID for each subject

Within one year from the acceptance of the primary manuscript for publication OR no-later than two years from the database lock the PUDS will be submitted to the NINDS data repository, along with the final version of the study protocol, the data dictionary, and a user guide (or a “Readme” file) regarding the data files, including an explanation of derived variables such as the total NIHSS scores.

Once the PUDS are available, any researcher (study investigator or otherwise) wishing to receive them can contact the NINDS (CRLiaison@ninds.nih.gov). All manuscripts, abstracts and press releases using the study data must acknowledge the StrokeNet investigators and the NINDS as the study sponsor with the relevant grant numbers.

6. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 155.260 – Privacy and security of personally identifiable information
45 CFR 164.501 – DHHS Definitions
45 CFR 164.508 – Uses and disclosures for which an authorization is required
45 CFR 164.512(I) – Uses and disclosures for which an authorization or opportunity to agree or object is not required

Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (November 12,

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2012) - http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/hhs_deid_guidance.pdf

NIH Data Sharing Policy and Implementation Guidance (March 5, 2003)

7. REFERENCES TO OTHER APPLICABLE SOPS

Adm 3 Network Publication Policy SOP

8. ATTACHMENTS AND REFERENCES

9. DOCUMENT HISTORY

Version	Description of Modification	Completion Date	Issue Date	Effective Date
1.0	Final	30-Sep-2014	30-Sep-2014	30-Sep-2014
1.1	Biannual Review with minor administrative changes	24-Aug-2016		
2.0	Final	15-Sep-2016	15-Sep-2016	15-Sep-2016



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Standard Operating Procedure (SOP)

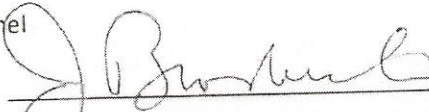
Network Data Sharing Policy

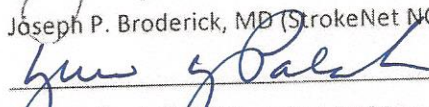
Version 1

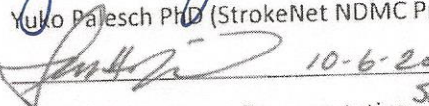
ADM #4

Originators: NIH StrokeNet NCC Personnel

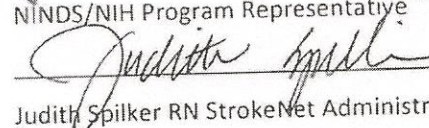
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