NIH StrokeNet Network
Standard Operating Procedure

SOP Number: GCP 11
SOP NAME: Management of the Per Patient Payment
Effective Date: 4-Jan-2016 (rev 30-Jun-2023)

1. **POLICY**

All payment for subject enrollment in an NIH StrokeNet trial will be made by the NIH StrokeNet National Coordinating Center (NCC) as electronic funds transfers as described in the Clinical Trial Agreement. Payments will be initiated when participant data entry for the interval of payment are completed and confirmed without errors or queries in the trial database in the WebDCU™ clinical trial management system (CTMS), located at the NIH StrokeNet National Data Management Center (NDMC). The WebDCU™ trial database will automatically trigger payment to be made by the NCC.

2. **DEFINITIONS AND ABBREVIATIONS**

CTMS	Clinical trial management system
F & A	Facilities and administration fee
GCP	Good clinical practice
NCC	National Coordinating Center at the University of Cincinnati
NDMC	National Data Management Center at Medical University of South Carolina
SOP	Standard operating procedure
WebDCU™	Clinical trial management system developed and maintained at the NDMC

3. **SCOPE**

This standard operating procedure (SOP) has been developed to be in alignment with federal regulations and Good Clinical Practices (GCP) as set forth in the 1996 ICH E6 Consolidated Guidance. The policies and procedures described in this SOP apply to the NIH StrokeNet NCC and NDMC within the context of their oversight and advisory roles for the NIH StrokeNet Network, and to all investigators, staff, subcontractors, or other entities associated with the NIH StrokeNet Network who manage, oversee, and conduct clinical trial research regulated by FDA and/or applicable review committees.

4. **PROCEDURES**

The following information is to be used as a guide for per subject payment. Payment intervals will depend on trial requirements and pre-determined milestones set on a per trial bases. The following represents an *example* of payment intervals.

a. **<u>Payment One</u>**: Baseline - $XXX.XX at randomization

- Eligible participant is enrolled and completes screening and baseline study visit
- All data for screening and baseline study visit is entered into WebDCU™
- All queries are resolved for the visit
- Participant visit reads “Ready” in WebDCU™

b. **Payment Two**: Post-Treatment – $XXX.XX at completion of subject visits

- Completes all requirements for ALL visits. Proration of the second interval payment will be based on the number of completed visits over XX minutes in length.
- Participant is not lost to follow up
- All data for study visits are entered into WebDCU™
- All queries are resolved for the visit
- Participant Post-Therapy visits reads "Ready" in WebDCU™

c. **Payment Three**: End of Study - $XXX.XX at end of study

- Participant is not lost to follow up
- Completes all requirements for Post-Treatment, 30 Day Follow-Up, and End of Study Form
- All data for study visits are entered into WebDCU™
- All queries are resolved for the visits
- Participant visits reads "Ready" in WebDCU™

5. APPLICABLE REGULATIONS AND GUIDELINES

ICH E6, 5.8	Compensation to Subjects and Investigators
ICH E6, 5.9	Financing
42 CFR 50, Subpart F	Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought
45 CFR 92	Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local, and Tribal Governments
Federal Demonstration Partnership	(FDP) http://sites.nationalacademies.org/PGA/fdp/index.htm

6. REFERENCES TO OTHER APPLICABLE SOPS

StrokeNet ADM SOP 7	Regulatory and Clinical Data Maintenance Storage

7. ATTACHMENTS AND REFERENCES

NIH StrokeNet Trial Performance Site Clinical Trial Agreement (CTA) per FDA template

8. DOCUMENT HISTORY

Version	Description of Modification	Completion Date	Issue Date	Effective Date
1.0	Final	18-Dec-2015	21-Dec-2015	4-Jan-2016
2.0	Administrative changes	30-Jun-2023	30-Jun-2023	30-Jun-2023