SOP Number: ADM 07
SOP NAME: Per Subject Payments and Development of Clinical Trial Budgets
Effective Date: 3-Jun-2014 (rev 31-May-2023)

1. POLICY

For all grant applications reviewed through NIH StrokeNet, the National Coordinating Center (NCC), National Data Management Center (NDMC) and StrokeNet Working Groups will assist the Protocol Principal Investigator (PPI) in the development of the clinical trial budget, including the determination of the Per Subject Reimbursement (PSR), identification of subject research related costs, and additional study related budgets for the NCC and NDMC.

2. DEFINITIONS AND ABBREVIATIONS

CRF	Case Report Form
ESC	Extramural Scientific Committee
ICH	International Conference on Harmonization
IND	Investigation New Drug
IDE	Investigational Device Exemption
NCC	National Coordinating Center at the University of Cincinnati
NDMC	National Data Management Center at the University of South Carolina
NIHSS	National Institutes of Health Stroke Scale
NINDS	National Institute of Neurological Disorders and Stroke
PHS	Public Health Service
PPI	Protocol Principal Investigator
PSR	Per Subject Reimbursement
SOE	Schedule of Events
StrokeNet	NIH StrokeNet Network

3. SCOPE

This policy applies to any subcontractors, staff, investigators and other entities associated with the StrokeNet who manage, oversee and conduct research or related activities within the network.

4. PROCEDURES

A. PPI Responsibilities:

1. Develop the trial Schedule of Events (SOE) that includes the anticipated total number of visits for each subject and a description of the procedures to be conducted at each study visit.
2. Develop the final study Case Report Forms (CRFs) in collaboration with NDMC and NCC.
3. In collaboration with the NCC Trial Budget and Operations Planning Liaison, determine what is standard of care versus what is a research procedure based on published best practice guidelines with guidance from the appropriate StrokeNet Working Group.
4. Obtain quotes from appropriate vendors (e.g., drug or device companies) with assistance provided by the NCC.
5. Develop a budget for all PPI's study-related costs including, but not limited to, those related to PPI's personnel, Investigation New Drug/ Investigational Device Exemption (IND/IDE) related costs, translations not covered by the NCC, vendors and study-related travel costs for PPI's personnel.
6. Make budget modifications based upon comments from the ESC and NINDS representatives as needed in collaboration with the NCC and NDMC.
7. Develop the final study budget and accompanying justification document in collaboration with the NCC and NDMC

B. National Coordinating Center Services:

1. Assist the PPI with calculating projected costs for each procedure and evaluation and with developing the anticipated PSR based on the SOE and published practice guidelines.
2. Assist with determining trial-related costs including:
   a. NCC personnel Costs (including F&A)
   b. Start-up and annual maintenance fees
   c. External Central Institutional Review Board costs
   d. Study meetings/travel (e.g., Kick-off, close-out meetings)
   e. Trial specific communication costs (conference call services, webinars, website etc.)
   f. Document translation (e.g., informed consent (short or long forms)
   g. Site pharmacy fees
   h. Appropriate shipping fees/ supplies (e.g., dry ice, IATA approved shipping containers)
   i. Study related travel for NCC personnel
   j. Study related Central Pharmacy Services
   k. Study related materials
   l. Study related required certifications/training costs (e.g., NIHSS, modified Rankin)
   m. Imaging management

3. Assist in making budget modifications based upon comments from the ESC and NINDS representative as needed in collaboration with the PPI and NDMC.
4. Assist in the development of the final study budget and accompanying justification document in collaboration with the PPI and NDMC.
5. Identify additional costs related to trial management services to be supported by payments to the NCC from individual trial budgets.
6. Collaborate with the trial PPI and NDMC in the development of the final study CRFs and patient payment modules.

C. National Data Management Center Services:

1. Assist the PPI with the development of a budget for all WebDCU^{tm} study-related costs including, but not limited to personnel costs for statistical work, costs related to the study specific clinical database development and data management, CRF development, study monitoring and study related travel for the NDMC personnel.
2. In collaboration with NCC and the trial PPI, develop the final study CRFs and patient payment modules.
3. In collaboration with the NCC and PPI, assist in making budget modifications based upon comments from the ESC and NINDS representative as needed.
4. In collaboration with the NCC and PPI, assist in the development of the final study budget and accompanying justification document.

D. Timeline

The PPI is responsible for developing a preliminary budget with input from NCC and NDMC for submission to ESC with their initial trial proposal. Once ESC approved, the PPI will work with NCC and NDMC to develop a final budget for grant submission, not to exceed a pre-specified amount approved by ESC. The final budget is created during the proposal development stage which is anticipated to take 3-6 months. The near-final Specific Aims and the Research Plan sections including the budget assumptions should be sent to NCC and NDMC a minimum of four weeks prior to the grant submission deadline.

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 Requirement for Grants and Cooperative Agreements to State, Local and Tribal Governments

2 CFR, Part 220 Cost Principles for Educational Institutions

6. REFERENCES TO OTHER APPLICABLE SOPS

ADM#2 Network Process for Reporting Financial Conflict of Interest

7. ATTACHMENTS AND REFERENCES

8. DOCUMENT HISTORY

Version	Description of Modification Justification for Modification	Completion Date	Issue Date	Effective Date
1.0	Final	3-Jun-2014	3-Jun-2014	3-Jun-2014
1.1	Biannual review with minor administrative changes	15-Sep-2016		
2.0	Final	15-Sep-2016	15-Sep-2016	15-Sep-2016
3.0	Renewal review with minor administrative changes	31-May-2023	02-Jun-2023	02-Jun-2023

NIH StrokeNet Network

Standard Operating Procedure (SOP)

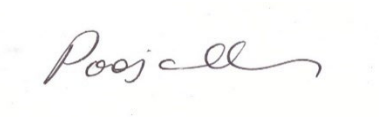
Per Subject Payments and Development of Clinical Trial Budgets

Standard Operation Procedures

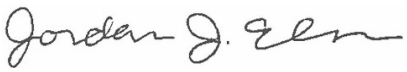
Version 3.0

ADM #7

Reviewed and Approved by:



Pooja Khatri, MD, (StrokeNet NCC Principal Investigator)



Jordan Elm, PhD, (StrokeNet NDMC Principal Investigator)

Scott Janis, PhD, (NIH/NINDS Program Director)