

**NIH StrokeNet Network
Standard Operating Procedure**

SOP Number: ADM 07

SOP NAME: Per Subject Payments and Development of Clinical Trial Budgets

Effective Date: 3-Jun-2014

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 Fee (PSF), identification of subject research related costs, and additional study related budgets for the NCC and NDMC.

2. DEFINITIONS AND ABBREVIATIONS

CRF	Case Report Form
DHHS	Department of Health and Human Services
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
PSF	Per Subject Fee
SOA	Schedule of Assessments
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:

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1. Develop the trial Schedule of Assessments (SOA) 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 NDMS and NCC.
3. 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, 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 developing the anticipated Per Subject Fee (PSF) based on the SOA and published practice guidelines.
2. Assist with determining trial-related costs including:
 - a. NCC personnel Costs (including F&A)
 - b. Study meetings/travel (e.g. Kick-off, close-out meetings)
 - c. Trial specific communication costs (conference call services, webinars, website etc.)
 - d. Document translation (e.g., informed consent (short or long forms) or protocols)
 - e. Site pharmacy fees
 - f. Appropriate shipping fees/ supplies (e.g. dry ice, IATA approved shipping containers)
 - g. Study related travel for NCC personnel
 - h. Study related Central Pharmacy Services
 - i. Study related materials
 - j. Study related required certifications/training costs (e.g. NIHSS, modified Rankin)
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.

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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 Case Report Forms (CRFs) and patient payment modules.

C. National Data Management Center Services:

1. Assist the PPI with the development of a budget for all WebDCU™ 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 is responsible for developing the final study Case report forms (CRFs) and patient payment modules.
3. In collaboration with the NCC and PPI will assist in making budget modifications based upon comments from the ESC and NINDS representative as needed.
4. In collaboration with the NCC and PPI will assist in the development of the final study budget and accompanying justification document.

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



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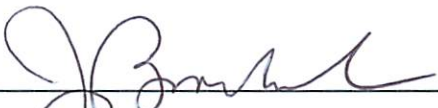
Standard Operating Procedure (SOP) Per Subject Payment and Development of Clinical Trial Budgets

Version 1

ADM #7

Originators: NIH StrokeNet NCC Personnel


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 6/3/14

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 3 June 2014

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