SOP Number: ADM 22
SOP NAME: NIH StrokeNet Ancillary Study Approval Process
Effective Date: 12-Aug-2016 (rev 30-May-2023)

1. POLICY

The purpose of the Standard Operating Procedure (SOP) is to define the standard procedures for proposing, reviewing, and approving ancillary studies conducted within the NIH StrokeNet Network.

2. DEFINITIONS AND ABBREVIATIONS

Abbreviations:

CIRB	Central Institutional Review Board at University of Cincinnati or Advarra IRB
ICD	Informed Consent Document
NCC	National Coordinating Center at University of Cincinnati
NDMC	National Data Management Center at Medical University of South Carolina
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke
NINDS ESC	NINDS Extramural Science Committee
NIH SN-EC	NIH StrokeNet Executive Committee
NIH SN-SC	NIH StrokeNet Steering Committee
AS-PPI	Ancillary Study Protocol Principal Investigator
PP-DSMB	Prime Awardee Protocol Data and Safety Monitoring Board
PP-PPI	Prime Awardee Protocol Principal Investigator
RCC	Regional Coordinating Center
SOP	Standard Operating Procedure

DEFINITIONS:

Ancillary study (or sub-study): A research activity undertaken to address a scientific question that requires access to data or records from a NIH StrokeNet Prime Awardee study and/or involves collection of additional data, specimens, or records from patients enrolled in a Prime study.
Prime Awardee study: The primary study funded through a grant mechanism or other form of support.

3. SCOPE

This policy applies to all investigators, small businesses, or industry sponsor requesting to work collaboratively with the NIH StrokeNet infrastructure resources. This procedure also applies to any unfunded investigator sponsored proposal to add to an existing funded NIH StrokeNet Trial.

4. PROCEDURES

A. Concept synopsis should be submitted to the PP-SC at least 9 months before a funding application is submitted.

B. To obtain approval from the PP-PPI and study team for an ancillary study, the Prime study ancillary study policy and procedures must be followed. These will include consideration of the following criteria:
   1. The proposed study addresses a question of scientific or clinical importance.
   2. The proposed study does not compete with any previously approved ancillary study.
   3. Conduct of the study does not adversely affect the Prime study.
   4. Funding for the study, if required, will be obtained by the AS-PPI and will be independent of the Prime study funding.
   5. Procedures for accessing necessary data and records from the Prime study during and after the study completion are explicit and acceptable.
   6. The AS-PPI has the appropriate team with expertise and facilities to conduct the study.
   7. Plans for publication and authorship of the ancillary study results are appropriate, including review and approval of manuscripts per the NIH StrokeNet and Prime study publication policies.
   8. PP-PPI and study team members are given adequate time to review the proposal before approval.

C. If approved by the Prime Protocol Study Team (NINDS representation included):
   1. The AS-PPI is advised to submit the NIH StrokeNet Clinical Study Concept Synopsis form and the budget to NINDS as early as possible but must be submitted no later than 2 months before the planned submission date in order to get approval from the NINDS to submit the application.
   2. Ancillary study team will present to the appropriate working group for feedback.
   3. NINDS ESC approval will be requested.
   4. If ESC approved, AS-PPI will work with the working group chair for assistance with the epidemiologic (epi) and feasibility assessments.
   5. Ancillary study team will present their concept synopsis proposal to the SN-Steering Committee.
   6. Feasibility survey will be distributed to StrokeNet RCCs allowing 2-3 weeks for responses.
   7. A survey summary will be sent to the working group for analysis after the NDMC collates the data.
   8. A summary of the epidemiological and feasibility assessments will be presented to the SN-Executive Committee by the AS-PPI and a working group representative.
      i. If approved by the SN-EC and additional funding is required, the AS-PPI may proceed to seek funding. funding is to be through an application to NINDS, the AS-PPI should consult with NINDS program staff to determine the appropriate funding mechanism for the application and necessary steps for requesting NINDS approval to submit the application.

ii. If approved by the SN-EC and **no** additional funding is required or additional funding is awarded, the AS-PPI will be notified by the SN-EC to submit a complete protocol and ICD or necessary ICD modifications to the SN University of Cincinnati CIRB or to the Advarra IRB.

D. A list of all proposed and approved ancillary proposals and/or synopses will be maintained by the NIH StrokeNet NCC.

5. APPLICABLE REGULATIONS AND GUIDELINES

https://nexus.od.nih.gov/all/tag/ancillary-study/

6. REFERENCES TO OTHER APPLICABLE SOPS

SOP ADM 3 StrokeNet Publications Committee and Policy, Parts A & B

8. Document History

Version	Description of Modification	Completion Date	Issue Date	Effective Date
0.1	DRAFT	1-Dec-2015 JF		**Upon date of last signature**
0.2	DRAFT	27-Jul-2016 JAS		
0.3	Penultimate	2-Aug-2016		
1.0	Final	12-Aug-2016	12-Aug-2016	12-Aug-2016
2.0	Update to reflect current process	30-May-2023	30-May-2023	30-May-2023

NIH StrokeNet Network

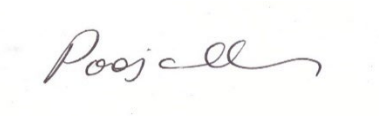
Standard Operating Procedure (SOP)

NIH StrokeNet Ancillary Study Approval Process

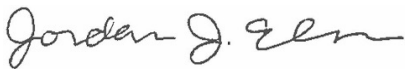
Version 2.0

ADM #22

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)