

NeuroNEXT Network

Standard Operating Procedure (SOP)




Clinical Trial Budget Development

Version 2.0

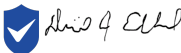
SOP NN PM 502

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date:   I approve this document 15-Feb-2023 8:19:14 AM PST 15-Feb-2023 <small>C68AC8DD80334CF982AED1200765F147</small>
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NN PM 502

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR CLINICAL TRIAL BUDGET DEVELOPMENT

1. POLICY

For all NeuroNEXT Network grant applications, the Clinical Coordinating Center (CCC) and Data Coordinating Center (DCC) will assist the Protocol Principal Investigator (PPI) in the development of the clinical trial budget, including determination of the Per Participant Fee (PPF) to be paid to Clinical Study Sites (CSS) and additional study-related budgets for the CCC and DCC.

2. SCOPE

This SOP has been developed to be in alignment with federal regulations and Good Clinical Practices (GCP) as set forth in the 2016 Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). The policies and procedures described in this SOP apply to the NeuroNEXT CCC and DCC within the context of their oversight and advisory roles for the NeuroNEXT Network, and to all NeuroNEXT investigators, staff, subcontractors, or other entities associated with the NeuroNEXT Network who manage, oversee, and conduct research regulated by FDA and/or applicable review committees.

3. ROLES AND RESPONSIBILITIES

The PPI is responsible for obtaining quotes from appropriate vendors, with assistance provided by the DCC and CCC.

The PPI is responsible for developing Schedule of Assessments (SOA) that includes the anticipated total number of visits for each participant and a description of the procedures to be conducted at each study visit.

The PPI is responsible for developing a budget for all PPI study-related costs including, but not limited to, those related to PPI personnel, vendors, and study-related travel costs for PPI personnel.

The CCC is responsible for assisting the PPI with calculating projected costs for each procedure and developing the anticipated cost per participant, assessing the appropriate Per Participant Fee (PPF) based on the SOA, and for advising the PPI on NeuroNEXT CSS indirect cost rates.

The CCC is responsible for developing a budget for all CCC study-related costs including, but not limited to, those related to required CCC personnel, vendors, as appropriate, and the following additional items:

- CCC personnel costs
- Study supplies, as appropriate
- Study initiation (Kick-off) meeting
- Study close-out meeting
- Conference call services
- Document translation
- Site pharmacy fees
- Appropriate shipping fees
- Study-related travel for CCC personnel
- Site long-term document storage fees

The DCC is responsible for developing a budget for all DCC study-related costs including, but not limited to, DCC personnel, costs related to study monitoring and study-related travel for DCC personnel.

The PPI, CCC, and DCC are responsible for making budget modifications based upon comments from the ESC and the NINDS representative, as needed. They are also responsible for developing the final study budget and the accompanying justification document.

4. APPLICABLE REGULATIONS AND GUIDELINES

ICH E6, 5.8	Compensation to Participants 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

5. REFERENCES TO OTHER APPLICABLE SOPS

NN GA 105	Vendor Selection and Agreements
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6. ATTACHMENTS AND REFERENCES

NN PM 502 – A	Document History
NN PM 502 – B	Template SOA

7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

CCC	Clinical Coordinating Center at Massachusetts General Hospital
CSS	Clinical Study Site(s)
DCC	Data Coordinating Center at The University of Iowa
ESC	Extramural Scientific Committee
FDA	U.S. Food and Drug Administration
ICH	International Conference on Harmonisation
PPF	Per Participant Fee
PPI	Protocol Principal Investigator
SOA	Schedule of Assessments
SUNY	State University of New York
URMC	University of Rochester Medical Center

8. SPECIFIC PROCEDURES

A. Budget Development and Justification

#	Who	Task	Attachment / References	Related SOP
1.	PPI, with assistance from CCC and DCC	Obtain quotes from study-required vendors, as appropriate.		NN GA 105
2.	PPI	Develop the SOA for the study.	NN PM 502-B	

3.	PPI	Develop an estimated budget for PPI-related study costs.		
4.	CCC	Assist the PPI in developing the PPF based on the SOA.		
5.	CCC	Develop an estimated budget for all CCC-related study costs.		
6.	DCC	Develop an estimated budget for all DCC-related study costs.		
7	PPI, CCC and DCC	Prepare a final budget document to justify all study costs included in the final budget.		
8	PPI	Submit budget projection with any additional project requirements to NINDS for review by the Extramural Science Committee (ESC)		
9	PPI	If project is approved by ESC, work with CCC, DCC and appropriate vendors to finalize and submit the final budget documents along with the full grant submission.		

Attachment NN PM 502 - B. Per Participant Fee (PPF) Template

INSERT template see: NeuroNEXT PPF Template_v3.4_20Jan2022 saved at \\Cifs2\neurnext\$\Proposals Pre-Grant Submission\Budget Information to send to new PPI\draft PPF for SOP

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