

NeuroNEXT Network

Standard Operating Procedure (SOP)

Clinical Trial Budget Development

Version 4.0

SOP NN PM 502

Originators: NeuroNEXT CCC and DCC Personnel

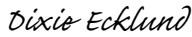

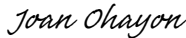
Reviewed and Approved by:

Signature and Date: <i>Christopher Coffey</i> <small>Electronically signed by: Christopher Coffey Reason: I approve this document Date: Jan 24, 2025 07:38 CST</small> 24-Jan-2025
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)
Signature and Date: <i>Merit Cudkowicz</i> <small>Electronically signed by: Merit Cudkowicz Reason: I approve this document Date: Dec 17, 2024 18:16 GMT-3</small> 17-Dec-2024
Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator) or Aleks Videnovic, MD (CCC Principal Investigator)
Signature and Date: <i>Marianne Chase</i> <small>Electronically signed by: Marianne Chase Reason: I approve this document Date: Dec 19, 2024 10:53 EST</small> 19-Dec-2024
Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)

NN PM 502

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR
CLINICAL TRIAL BUDGET DEVELOPMENT

SOP: NN PM 502 Version No.: 4.0 Issue Date: 15 Nov 2024 Effective Date: 15 Dec 2024	CLINICAL TRIAL BUDGET DEVELOPMENT	Supersedes Document Version : 3.0 Effective Date : 15Apr2024
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Signature and Date:  <i>Electronically signed by: Dixie Ecklund Reason: I approve this document Date: Dec 17, 2024 11:23 CST</i>		17-Dec-2024
Name and Title: Dixie J. Ecklund, RN MSN MBA (DCC Associate Director)		
Signature and Date:  <i>Electronically signed by: Stacey Grabert Reason: I approve this document Date: Dec 17, 2024 12:51 EST</i>		17-Dec-2024
Name and Title: Stacey Grabert, Pharm.D, MS, (CCC Director of Quality Assurance)		
Signature and Date:  <i>Electronically signed by: Joan Ohayon Reason: I approve this document Date: Jan 14, 2025 09:26 EST</i>		14-Jan-2025
Name and Title: Joan Ohayon, RN, MSN, CRNP, MSCN (NINDS, NeuroNEXT Program Official)		

**NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR
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1. POLICY

For OT: For all NeuroNEXT Network Stage 2 OT applications, the Clinical Coordinating Center (CCC) and Data Coordinating Center (DCC) will assist the Protocol Principal Investigator (PPI) by managing 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 PPI, CCC, and DCC.

For U44 (SBIR) Grants: For all NeuroNEXT Network grant applications, the Clinical Coordinating Center (CCC) and Data Coordinating Center (DCC) will assist the Protocol Principal Investigator (PPI) and associated company 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

For OT At the instruction of the CCC, the PPI is responsible for obtaining quotes from appropriate vendors, with assistance provided by the DCC and CCC as needed.

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 adding 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

NN PM 502

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- Site pharmacy fees
- Appropriate shipping fees
- Study-related travel for CCC personnel
- Site long-term document storage fees
- Lab collection and processing fees

The CCC is also responsible for submitting the final full study budget and justification to the ESC for review and final Stage 2 submission.

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

For U44 (SBIR) Grants: The PPI and associated company are 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 and associated company are responsible for developing a budget for all PPI study-related costs including, but not limited to, those related to company personnel, vendors, and study-related travel costs for the PPI and company personnel.

The CCC is responsible for assisting the PPI's associated company 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

NN PM 502

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- 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, sponsor company, 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 Council for Harmonisation
OT	Other Transactions
PPF	Per Participant Fee
PPI	Protocol Principal Investigator
SOA	Schedule of Assessments

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SUNY State University of New York
 URM University of Rochester Medical Center

8. SPECIFIC PROCEDURES

A. Budget Development and Justification for OTA Grants

#	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	CCC	Submit budget projection with any additional project requirements to NINDS for review by the Extramural Science Committee (ESC)		
9	CCC	If project is approved by ESC, work with PPI, DCC, and appropriate vendors to finalize and submit the final budget documents along with the full grant submission.		

NN PM 502

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B. Budget Development and Justification for U44 (SBIR) Grants

#	Who	Task	Attachment / References	Related SOP
1.	PPI and Sponsor Company, with assistance from CCC and DCC	Obtain quotes from study-required vendors, as appropriate.		NN GA 105
2.	PPI and Sponsor Company	Develop the SOA for the study.	NN PM 502-B	
3.	PPI and Sponsor Company	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, Sponsor Company, CCC, and DCC	Prepare a final budget document to justify all study costs included in the final budget.		
8.	PPI and Sponsor Company	Submit budget projection with any additional project requirements to NINDS for review by the Extramural Science Committee (ESC)		
9.	PPI and Sponsor Company	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.		

NN PM 502
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Attachment NN PM 502 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Clinical Trial Budget Development SOP NN PM 502					
Version	Description of Modification	Reason or Justification for Modification	Issue Date	Effective Date	Reviewer(s)
1.0	New	N/A	13Apr2012	13May2012	N/A
1.0	Reviewed – no changes (2016)	N/A	13Apr2012	13May2012	N/A
2.0	Updated “1996 ICH E6 Consolidated Guidance” to “2016 Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)”. Changed “subject” to “participant” throughout. Updated signature block to accommodate for electronic signatures. Additional minor updates throughout.	Updated for version 2.0	22Feb2023	08Apr2023	Catherine Gladden
3.0	Minor edits for clarity	Periodic review	01Mar2024	15Apr2024	Preeti Paul
4.0	Made updates to reflect the OTA grant mechanism and separate process for U44 (SBIR) grants.	Updates for OTA grants	15 Nov 2024	15 Dec 2024	Tania Leeder

NN PM 502
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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









NN PM 502 Clinical Trial Budget Development v4.0 07Nov2024

Final Audit Report

2025-01-24

Created:	2024-12-17
By:	Tania Leeder (tleeder@mgb.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAAtR0IYoGDs1nu_h42ZgOJfoYBNawAjTy-
Number of Documents:	1
Document page count:	9
Number of supporting files:	0
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2024-12-17 - 4:34:28 PM GMT
-  Document emailed to cudkowicz.merit@mgh.harvard.edu for signature
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-  Document emailed to Marianne Chase (mchase@mgh.harvard.edu) for signature
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-  Document emailed to ecklundd@uiowa.edu for signature
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-  Document emailed to Stacey Grabert (SGrabert@mgh.harvard.edu) for signature
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 Tania Leeder (tleeder@mgb.org) added alternate signer christopher-coffey@uiowa.edu. The original signer cscoffey@iowa.uiowa.edu can still sign.
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