NeuroNEXT Network

Standard Operating Procedure (SOP)

Clinical Trial Budget Development

Version 3.0

SOP NN PM 502

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date: Christopher S. Coffey *Electronically signed by: Christopher S. Coffey Reason: I approve this document Date: Mar 7, 2024 14:53 CST* 07-Mar-2024
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)
Signature and Date: *Electronically signed by: Merit Cudkowicz Reason: I approve this document Date: Feb 22, 2024 12:46 CST* 22-Feb-2024
Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)
Signature and Date: Marianne Chase *Electronically signed by: Marianne Chase Reason: I approve this document Date: Feb 22. 2024 15:12 EST* 22-Feb-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.: 3.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	CLINICAL TRIAL BUDGET DEVELOPMENT	Supersedes Document Version : 2.0 Effective Date : 08Apr2023

Signature and Date:

Dixie Ecklund

Electronically signed by: Dixie Ecklund
Reason: I approve this document
Date: Feb 24, 2024 17:07 CST

24-Feb-2024

Name and Title: Dixie J. Ecklund, RN MSN MBA (DCC Associate Director)

Signature and Date:

Electronically signed by: Stacey Grabert
Reason: I approve this document
Date: Feb 22, 2024 13:45 EST

22-Feb-2024

Name and Title: Stacey Grabert, Pharm.D, MS, (CCC Director of Quality Assurance)

Signature and Date:

Joan Ohayon

Electronically signed by: Joan Ohayon
Reason: I approve this document
Date: Mar 11, 2024 09:45 EDT

11-Mar-2024

Name and Title: Joan Ohayon, RN, MSN, CRNP, MSCN (NINDS, NeuroNEXT Program Official)

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR CLINICAL TRIAL BUDGET DEVELOPMENT

SOP: NN PM 502 Version No.: 3.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	CLINICAL TRIAL BUDGET DEVELOPMENT	Supersedes Document Version : 2.0 Effective Date : 08Apr2023

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

SOP: NN PM 502 Version No.: 3.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	CLINICAL TRIAL BUDGET DEVELOPMENT	Supersedes Document Version : 2.0 Effective Date : 08Apr2023

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

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
PPF	Per Participant Fee
PPI	Protocol Principal Investigator
SOA	Schedule of Assessments
SUNY	State University of New York
URMC	University of Rochester Medical Center

SOP: NN PM 502 Version No.: 3.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	CLINICAL TRIAL BUDGET DEVELOPMENT	Supersedes Document Version : 2.0 Effective Date : 08Apr2023

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 - 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

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 v3.0 clean

Final Audit Report 2024-03-11

Created:	2024-02-22
By:	Tania Leeder (tleeder@mgb.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAAVl8_wksTouGzOJLsAJcWnzQFbloL9hPG
Number of Documents:	1
Document page count:	7
Number of supporting files:	0
Supporting files page count:	0

"NN PM 502 Clinical Trial Budget Development v3.0 clean" History

Document created by Tania Leeder (tleeder@mgb.org)
2024-02-22 - 6:42:51 PM GMT

Document emailed to christopher-coffey@uiowa.edu for signature
2024-02-22 - 6:44:41 PM GMT

Document emailed to cudkowicz.merit@mgh.harvard.edu for signature
2024-02-22 - 6:44:41 PM GMT

Document emailed to Marianne Chase (mchase@mgh.harvard.edu) for signature
2024-02-22 - 6:44:41 PM GMT

Document emailed to dixie-ecklund@uiowa.edu for signature
2024-02-22 - 6:44:41 PM GMT

Document emailed to Stacey Grabert (SGrabert@mgh.harvard.edu) for signature
2024-02-22 - 6:44:42 PM GMT

Document emailed to ohayonj@ninds.nih.gov for signature
2024-02-22 - 6:44:42 PM GMT

Email viewed by cudkowicz.merit@mgh.harvard.edu
2024-02-22 - 6:44:53 PM GMT

cudkowicz.merit@mgh.harvard.edu authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-22 - 6:45:33 PM GMT

Stacey Grabert (SGrabert@mgh.harvard.edu) authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-22 - 6:45:42 PM GMT

Document e-signed by Stacey Grabert (SGrabert@mgh.harvard.edu)

Signing reason: I approve this document

Signature Date: 2024-02-22 - 6:45:51 PM GMT - Time Source: server

cudkowicz.merit@mgh.harvard.edu authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-22 - 6:46:23 PM GMT

Signer cudkowicz.merit@mgh.harvard.edu entered name at signing as Merit Cudkowicz

2024-02-22 - 6:46:43 PM GMT

Document e-signed by Merit Cudkowicz (cudkowicz.merit@mgh.harvard.edu)

Signing reason: I approve this document

Signature Date: 2024-02-22 - 6:46:45 PM GMT - Time Source: server

Email viewed by christopher-coffey@uiowa.edu

2024-02-22 - 7:55:47 PM GMT

Marianne Chase (mchase@mgh.harvard.edu) authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-22 - 8:12:37 PM GMT

Document e-signed by Marianne Chase (mchase@mgh.harvard.edu)

Signing reason: I approve this document

Signature Date: 2024-02-22 - 8:12:54 PM GMT - Time Source: server

Tania Leeder (tleeder@mgb.org) added alternate signer ecklundd@uiowa.edu. The original signer dixie-ecklund@uiowa.edu can still sign.

2024-02-23 - 7:01:28 PM GMT

Document emailed to ecklundd@uiowa.edu for signature

2024-02-23 - 7:01:28 PM GMT

Tania Leeder (tleeder@mgb.org) added alternate signer cscoffey@iowa.uiowa.edu. The original signer christopher-coffey@uiowa.edu can still sign.

2024-02-23 - 7:01:34 PM GMT

Document emailed to cscoffey@iowa.uiowa.edu for signature

2024-02-23 - 7:01:35 PM GMT

Email viewed by cscoffey@iowa.uiowa.edu

2024-02-23 - 7:14:13 PM GMT

Email viewed by ecklundd@uiowa.edu

2024-02-24 - 11:07:09 PM GMT

ecklundd@uiowa.edu authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-24 - 11:07:21 PM GMT

Signer ecklundd@uiowa.edu entered name at signing as Dixie Ecklund

2024-02-24 - 11:07:41 PM GMT

Document e-signed by Dixie Ecklund (ecklundd@uiowa.edu)

Signing reason: I approve this document

Signature Date: 2024-02-24 - 11:07:43 PM GMT - Time Source: server

Email viewed by cscoffey@iowa.uiowa.edu

2024-03-07 - 8:52:37 PM GMT- IP address: 128.255.113.139

cscoffey@iowa.uiowa.edu authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-03-07 - 8:52:57 PM GMT

Signer cscoffey@iowa.uiowa.edu entered name at signing as Christopher S. Coffey

2024-03-07 - 8:53:12 PM GMT- IP address: 128.255.113.139

Document e-signed by Christopher S. Coffey (cscoffey@iowa.uiowa.edu)

Signing reason: I approve this document

Signature Date: 2024-03-07 - 8:53:15 PM GMT - Time Source: server- IP address: 128.255.113.139

Email viewed by ohayonj@ninds.nih.gov

2024-03-11 - 1:44:35 PM GMT- IP address: 104.47.64.254

ohayonj@ninds.nih.gov authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-03-11 - 1:44:47 PM GMT

Signer ohayonj@ninds.nih.gov entered name at signing as Joan Ohayon

2024-03-11 - 1:45:04 PM GMT- IP address: 72.83.187.43

Document e-signed by Joan Ohayon (ohayonj@ninds.nih.gov)

Signing reason: I approve this document

Signature Date: 2024-03-11 - 1:45:06 PM GMT - Time Source: server- IP address: 72.83.187.43

Agreement completed.

2024-03-11 - 1:45:06 PM GMT