

# NeuroNEXT Network

## Standard Operating Procedure (SOP)




### Site Invoicing and Payments

Version 3.0

SOP NN PM 506

Originators: NeuroNEXT CCC and DCC Personnel



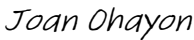
Reviewed and Approved by:

<b>Signature and Date:</b>  <small>Electronically signed by: Christopher S. Coffey Reason: I approve this document Date: Mar 7, 2024 14:56 CST</small>	07-Mar-2024
<b>Name and Title:</b> Christopher S. Coffey, PhD (DCC Principal Investigator)	
<b>Signature and Date:</b>  <small>Electronically signed by: Merit Cudkowicz Reason: I approve this document Date: Feb 22, 2024 17:49 CST</small>	22-Feb-2024
<b>Name and Title:</b> Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)	
<b>Signature and Date:</b>  <small>Electronically signed by: Marianne Chase Reason: I approve this document Date: Feb 22, 2024 14:56 EST</small>	22-Feb-2024
<b>Name and Title:</b> Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)	

NN PM 506

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR  
SITE INVOICING AND PAYMENTS

SOP: NN PM 506 Version No.: 3.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	SITE INVOICING AND PAYMENTS	Supersedes Document Version : 2.0 Effective Date : 08Apr2023
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<b>Signature and Date:</b>  <i>Electronically signed by: Dixie Ecklund Reason: I approve this document Date: Feb 24, 2024 17:10 CST</i>	24-Feb-2024
<b>Name and Title:</b> Dixie J. Ecklund, RN MSN MBA (DCC Associate Director)	
<b>Signature and Date:</b>  <i>Electronically signed by: Stacey Grabert Reason: I approve this document Date: Feb 22, 2024 13:53 EST</i>	22-Feb-2024
<b>Name and Title:</b> Stacey Grabert, Pharm.D, MS, (CCC Director of Quality Assurance)	
<b>Signature and Date:</b>  <i>Electronically signed by: Joan Ohayon Reason: I approve this document Date: Mar 11, 2024 09:47 EDT</i>	11-Mar-2024
<b>Name and Title:</b> Joan Ohayon, RN, MSN, CRNP, MSCN (NINDS, NeuroNEXT Program Official)	

## NN PM 506

# NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SITE INVOICING AND PAYMENTS

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## 1. POLICY

For all NeuroNEXT Network funded studies, the Clinical Coordinating Center (CCC) will work with Data Coordinating Center (DCC) to generate site invoices based on study data entered via the Electronic Data Capture (EDC) system. The CCC will ensure that site invoices for work performed are submitted to each participating Clinical Study Site (CSS) on a quarterly basis unless another schedule is determined to be more appropriate for a particular study. The CCC will ensure that invoices are processed for payment after review by each CSS.

## 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 CCC is responsible for communicating the cost per procedure, developed in collaboration with the PPI and funded by the NINDS, to the DCC for each NeuroNEXT study.

The DCC is responsible for programming the Electronic Data Capture (EDC) system to generate invoices based on data entered into the system, using the study-specific costs communicated by the CCC.

The DCC will run invoices for each NeuroNEXT study every 2 – 3 months, or as needed. Once generated, the DCC will send invoices to the CCC for review. After the invoices have been reviewed for accuracy, the CCC will send the invoices to each CSS to confirm anticipated payment.

Each CSS is responsible for reviewing the invoice and communicating questions to the CCC within 10 business days of receipt of the preliminary invoice.

The CCC is responsible for commencing the processing of payments to each CSS on or after the 11<sup>th</sup> business day following receipt of the preliminary invoice at the CSS, unless there is an unresolved discrepancy that is still under review.

The CCC, DCC, and CSS are responsible for resolving any discrepancies that are noted on invoices.

The CCC is responsible for processing payments to each CSS once outstanding discrepancies are resolved.

## 4. 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 Requirements for Grants and Cooperative Agreements to State, Local, and Tribal Governments

## 5. REFERENCES TO OTHER APPLICABLE SOPS

None

## NN PM 506

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## 6. ATTACHMENTS AND REFERENCES

NN PM 506 – A Document History

## 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
EDC	Electronic Data Capture
FDA	U.S. Food and Drug Administration
ICH	International Council for Harmonisation
PPI	Protocol Principal Investigator

## 8. SPECIFIC PROCEDURES

### A. Invoice Generation, Review and Processing

#	Who	Task	Attachment / References	Related SOP
1.	CCC	Communicate the cost per procedure for all NeuroNEXT studies to the DCC.		
2.	DCC	Program the EDC system to generate invoices, using information on costs provided by CCC.		
3.	DCC	Generate invoices for each NeuroNEXT study every 2 – 3 months, or as needed for a given study, and submit to the CCC for review.		
4.	CCC	Review invoices provided by DCC prior to distributing to CSS for review.		
5.	CSS	Review invoices provided by the CCC, and submit questions or provide feedback regarding discrepancies to the CCC within 10 business days of receipt of the preliminary invoice.		
6.	CCC	Initiate the processing of invoices for payment to the CSS on or after the 11 <sup>th</sup> business day following receipt of the invoice at the CSS, unless there is an unresolved discrepancy that is under review.		
7.	CCC	Bring any discrepancies noted by the CCC or CSS to the attention of the DCC.		

## NN PM 506

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#	Who	Task	Attachment / References	Related SOP
8.	DCC, CCC and CSS	Resolve outstanding discrepancies.		
9.	CCC	Initiate processing of invoices for payment to CSS once outstanding discrepancies are resolved.		

## NN PM 506

### NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SITE INVOICING AND PAYMENTS

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#### Attachment NN PM 506 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Site Invoicing and Payments SOP NN PM 506					
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)”. Updated signature block to accommodate for electronic signatures.	Updates to version 2.0	22Feb2023	08Apr2023	Catherine Gladden
3.0	Minor edits for clarity	Periodic review	01Mar2024	15Apr2024	Preeti Paul









# NN PM 506 Site Invoicing and Payments v3.0 clean

Final Audit Report

2024-03-11

Created:	2024-02-22
By:	Tania Leeder (tleeder@mgb.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAAD-oKKRyyU_-aihJC2pJ-u1mjRMrr3OMR
Number of Documents:	1
Document page count:	6
Number of supporting files:	0
Supporting files page count:	0

## "NN PM 506 Site Invoicing and Payments v3.0 clean" History

-  Document created by Tania Leeder (tleeder@mgb.org)  
2024-02-22 - 6:51:30 PM GMT
-  Document emailed to christopher-coffey@uiowa.edu for signature  
2024-02-22 - 6:52:51 PM GMT
-  Document emailed to cudkowicz.merit@mgh.harvard.edu for signature  
2024-02-22 - 6:52:51 PM GMT
-  Document emailed to Marianne Chase (mchase@mgh.harvard.edu) for signature  
2024-02-22 - 6:52:51 PM GMT
-  Document emailed to dixie-ecklund@uiowa.edu for signature  
2024-02-22 - 6:52:51 PM GMT
-  Document emailed to Stacey Grabert (SGrabert@mgh.harvard.edu) for signature  
2024-02-22 - 6:52:51 PM GMT
-  Document emailed to ohayonj@ninds.nih.gov for signature  
2024-02-22 - 6:52:51 PM GMT
-  Stacey Grabert (SGrabert@mgh.harvard.edu) authenticated with Adobe Acrobat Sign.  
Challenge: The user opened the agreement.  
2024-02-22 - 6:53:30 PM GMT

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

Signing reason: I approve this document

Signature Date: 2024-02-22 - 6:53:40 PM GMT - Time Source: server


 Email viewed by christopher-coffey@uiowa.edu

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

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Challenge: The user opened the agreement.

2024-02-22 - 7:56:14 PM GMT


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Signing reason: I approve this document

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2024-02-22 - 11:48:59 PM GMT

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2024-02-22 - 11:49:14 PM GMT


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2024-02-22 - 11:49:25 PM GMT

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

Signing reason: I approve this document


Signature Date: 2024-02-22 - 11:49:27 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 - 6:59:55 PM GMT

 Document emailed to ecklundd@uiowa.edu for signature

2024-02-23 - 6:59:55 PM GMT

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2024-02-23 - 7:00:04 PM GMT


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2024-02-23 - 7:00:04 PM GMT

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2024-02-23 - 7:14:12 PM GMT



 Email viewed by ecklundd@uiowa.edu

2024-02-24 - 11:10:09 PM GMT

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2024-02-24 - 11:10:21 PM GMT

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2024-02-24 - 11:10:38 PM GMT

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

Signing reason: I approve this document

Signature Date: 2024-02-24 - 11:10:41 PM GMT - Time Source: server

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2024-03-07 - 8:56:00 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 - 8:56:14 PM GMT


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2024-03-07 - 8:56:28 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 - 8:56:31 PM GMT - Time Source: server- IP address: 128.255.113.139

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2024-03-11 - 1:47:14 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 - 1:47:23 PM GMT

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2024-03-11 - 1:47:37 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 - 1:47:39 PM GMT - Time Source: server- IP address: 72.83.187.43

 Agreement completed.

2024-03-11 - 1:47:39 PM GMT