NeuroNEXT Network

Standard Operating Procedure (SOP)

Site Invoicing and Payments

Version 2.0

SOP NN PM 506

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date: DocuSigned by Christopher Coffey Christopher Coffey | I approve this document 15-Feb-2023 | 8:17:09 AM PST C68AC8DD80334CF982AED1200765F147 15-Feb-2023
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)
Signature and Date: DocuSigned by Merit Cudkowicz Merit Cudkowicz | I approve this document 17-Feb-2023 | 9:38:02 AM EST 9F8FE4180E504C6AB0A67B835E80C644 17-Feb-2023
Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)
Signature and Date: DocuSigned by Marianne Chase Marianne Chase | I approve this document 15-Feb-2023 | 8:42:31 PM EST 58FE690F6BCA4F2390E3DA15BCE3F578 15-Feb-2023
Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)

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15-Feb-2023

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

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22-Feb-2023

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

Signature and Date:

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15-Feb-2023

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

NN PM 506

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SITE INVOICING AND PAYMENTS

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 11th 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

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 Conference on 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 11th 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.		
8.	DCC, CCC and CSS	Resolve outstanding discrepancies.		
9.	CCC	Initiate processing of invoices for payment to CSS once outstanding discrepancies are resolved.		

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DIXIE ECKLUND dixie-ecklund@uiowa.edu Security Level: Email, Account Authentication (Required), Login with SSO	 Signature Adoption: Drawn on Device Signature ID: 7006AF62-2EFC-40B6-A067-A08EC02591B6 Using IP Address: 128.255.112.230 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/15/2023 8:35:48 AM Viewed: 2/15/2023 2:51:58 PM Signed: 2/15/2023 2:52:58 PM
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Joan Ohayon ohayonj@ninds.nih.gov Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 72C6AAFD-8CC4-4855-82AC-A0700072901A Using IP Address: 156.40.137.188 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/15/2023 8:35:51 AM Viewed: 2/15/2023 12:00:44 PM Signed: 2/15/2023 12:01:07 PM
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Marianne Chase MCHASE@mgh.harvard.edu Sr Director, Clinical Trial Operations Insight OBO The Massachusetts General Hospital Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 58FE690F-6BCA-4F23-90E3-DA15BCE3F578 Using IP Address: 73.114.253.109 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/15/2023 8:35:49 AM Viewed: 2/15/2023 8:41:57 PM Signed: 2/15/2023 8:42:35 PM
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Merit Cudkowicz cudkowicz.merit@mgh.harvard.edu Chief of Neurology Security Level: Email, Account Authentication (Required), Logged in	 DocuSigned by Merit Cudkowicz I approve this document 17-Feb-2023 | 9:38:02 AM EST 9F8FE4180E504C6AB0A67B835E80C644 Signature Adoption: Pre-selected Style Signature ID: 9F8FE418-0E50-4C6A-B0A6-7B835E80C644 Using IP Address: 68.239.56.73 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/15/2023 8:35:50 AM Viewed: 2/17/2023 9:37:53 AM Signed: 2/17/2023 9:38:04 AM
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Stacey Grabert sgrabert@mgh.harvard.edu Director QA Stacey Grabert Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 60CC52B0-747A-44E6-B220-8D8D880698C0 Using IP Address: 132.183.56.49 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/15/2023 8:35:50 AM Viewed: 2/22/2023 11:21:24 AM Signed: 2/22/2023 11:21:36 AM
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Envelope Summary Events	Status	Timestamps
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Signing Complete	Security Checked	2/22/2023 11:21:36 AM
Completed	Security Checked	2/22/2023 11:21:36 AM

Payment Events	Status	Timestamps

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