

NeuroNEXT Network

Standard Operating Procedure (SOP)

Document Translation

Version 3.0

SOP RA 208

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date: <i>Christopher S. Coffey</i> <small>Electronically signed by: Christopher S. Coffey Reason: I approve this document Date: Mar 8, 2024 08:13 CST</small>	08-Mar-2024
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: Feb 22, 2024 12:18 CST</small>	22-Feb-2024
Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)	
Signature and Date: <i>Marianne Chase</i> <small>Electronically signed by: Marianne Chase Reason: I approve this document Date: Feb 22, 2024 14:55 EST</small>	22-Feb-2024
Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)	


NN RA 208

**NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR
DOCUMENT TRANSLATION**

SOP: RA 208 Version No.: 3.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	DOCUMENT TRANSLATION	Supersedes Document : Version 2.0 Effective Date : 08Apr2023
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Signature and Date: <i>Dixie Ecklund</i> <small>Electronically signed by: Dixie Ecklund Reason: I approve this document Date: Feb 24, 2024 17:18 CST</small>	24-Feb-2024
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Name and Title: Dixie J. Ecklund, RN MSN MBA (DCC Associate Director)

Signature and Date:  <small>Electronically signed by: Stacey Grabert Reason: I approve this document Date: Feb 22, 2024 13:54 EST</small>	22-Feb-2024
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Name and Title: Stacey Grabert, Pharm.D, MS, (CCC Director of Quality Assurance)

Signature and Date: <i>Joan Ohayon</i> <small>Electronically signed by: Joan Ohayon Reason: I approve this document Date: Mar 11, 2024 11:19 EDT</small>	11-Mar-2024
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Name and Title: Joan Ohayon, RN, MSN, CRNP, MSCN (NINDS, NeuroNEXT Program Official)

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1. POLICY

It is the policy of the NeuroNEXT Network that study documents may require translation from English into non-English languages, or from non-English languages into English, to support specific site or study participant populations. Translation services may be contracted for translating NeuroNEXT Network essential document templates, or for Clinical Study Site (CSS)-specific documents. The Protocol Principal Investigator (PPI), Data Coordinating Center (DCC), Clinical Coordinating Center (CCC), the Single Institutional Review Board (SIRB), or a CSS may serve as the party contracting with the translation service vendor, depending on the protocol and type of document requiring translation. Documents that may require translation may include model or site-specific Informed Consent Forms, study drug or study procedure instructions, study drug container labels, recruitment and marketing materials, or other documents as appropriate to the study.

Translation of any study document will be completed by qualified translation vendors that have been vetted and approved by the PPI, DCC, CCC, SIRB and/or the National Institute of Neurological Disorders and Stroke (NINDS) as necessary.

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 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

It is the responsibility of the PPI, in collaboration with the CCC, DCC, and/or SIRB as necessary, to identify the need for translation of template or study-wide documents and to include estimated costs for this service in the clinical trial budget.

It is the responsibility of the CSS Principal Site Investigator to identify documents that may require translation due to local participant population needs, and to communicate this need to the PPI, CCC, and/or DCC.

The PPI is responsible for selecting, in consultation with CCC, DCC, and/or SIRB, a qualified vendor to perform translations and back-translations, if needed. The following criteria may be used in completing vendor selection:

1. The vendor has achieved certification in quality management through ISO 9001:2000.
2. The vendor provides translators who are fluent in the native language requested for translation.
3. The vendor provides translators fluent in numerous languages.
4. The vendor provides translators experienced in medical terminology.
5. The vendor provides independent back translations.
6. The vendor provides translations in an acceptable timeframe and at an acceptable fee.
7. The vendor will provide a certificate of authenticity for all translations.

The PPI, in collaboration with the CCC, DCC and/or SIRB, is responsible for providing the final versions of any English-language documents that require translation. The appropriate party (PPI, DCC, CCC or CSS) will contact the vendor and initiate a contract for translation and back-translation, as needed. Back-translation allows for QA of the translated documents. If back-translation is completed, the following steps may be taken:

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1. If there are unresolved discrepancies, the CCC requests that the contracted vendor have an independent translator review the documents and clarify each discrepancy.
2. When all discrepancies are resolved, all translated and back-translated documents are finalized (closed to further translations), submitted to the CRIB for review and approval, provided to the necessary study personnel, and stored in the Trial Master Files with the original English-language documents.

The CCC is responsible for providing the translated documents to the CSS, and for filing translated versions of essential study documents in the Trial Master File along with the English-language versions of the documents.

The responsibility to conduct any or all of these activities may be delegated at the discretion of the Sponsor to the NeuroNEXT DCC, CCC, SIRB, or CSS staff. Those individuals and entities also take on responsibility for meeting regulatory requirements on behalf of the Sponsor, but the Sponsor has the ultimate responsibility, and must therefore supervise those delegated activities effectively.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50	General Responsibility of Sponsors
ICH E6, 2.7	The Principles of ICH GCP

5. REFERENCES TO OTHER APPLICABLE SOPS

NN GA 103	Document Development and Change Control
NN GA 105	Vendor Selection and Agreements
NN RA 202	Trial Master File Maintenance
NN RA 204	Model Informed Consent Form Preparation
NN PM 502	Clinical Trial Budget Development
NN PM 503	Study Materials Development

6. ATTACHMENTS AND REFERENCES

NN RA 208-A	Document History
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7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

CCC	Clinical Coordinating Center at Massachusetts General Hospital
CFR	Code of Federal Regulations
CSS	Clinical Study Site
DCC	Data Coordinating Center at The University of Iowa
FDA	Food and Drug Administration
ICH	International Council for Harmonisation
NINDS	National Institute of Neurological Disorders and Stroke
PPI	Protocol Principal Investigator

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SIRB Single Institutional Review Board (Mass General Brigham)

8. SPECIFIC PROCEDURES

A. Study-Wide Document Translation

#	Who	Task	Attachment/ References	Related SOP
1.	PPI / CCC or DCC designee	Identify need for document translation.		NN GA 103 NN RA 204 NN PM 503
2.	PPI or designee	Include estimated cost for document translation in clinical trial budget.		NN PM 502
3.	PPI / CCC or DCC designee	Evaluate and secure an appropriate translation vendor.		NN GA 105
4.	PPI / CCC or DCC designee	Determine the need for back-translation and complete review of back-translated documents, if necessary.		
5.	CCC	Distribute translated documents to CSS staff, SIRB, DCC and/or other parties as required.		

B. Site-Level Document Translation

#	Who	Task	Attachment/ References	Related SOP
1.	CSS Principal Investigator or designee	Identify need for document translation and communicate this need to CCC.		NN GA 103 NN RA 204 NN PM 503
2.	PPI or designee	Include estimated cost for document translation in clinical trial budget		NN PM 502
3.	CSS / PPI / CCC or DCC designee	Evaluate and secure an appropriate translation vendor.		NN GA 105
4.	CSS / PPI / CCC or DCC designee	Determine the need for back-translation and complete review of back-translated documents, if necessary.		
5.	CCC	Ensure that the final version of the translated site- specific document is distributed to the DCC, SIRB and/or other parties as required.		

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#	Who	Task	Attachment/ References	Related SOP
6.	CCC	File translated, back-translated, and original versions of essential study documents in the Trial Master File.		NN RA 202

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Attachment NN RA 208 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP)					
Document Translation					
SOP NN RA 208					
Version	Description of Modification	Reason or Justification for Modification	Issue Date	Effective Date	Reviewer(s)
1.0	New	N/A	06Apr2012	06May2012	N/A
1.0	Reviewed – no changes (2016)	N/A	06Apr2012	06May2012	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 CIRB to SIRB. Updated signature block to accommodate for electronic signatures. Additional minor updates throughout	Updates for v2.0	22Feb2023	08Apr2023	Catherine Gladden
3.0	Minor edits for clarity	Periodic Review	01Mar2024	15Apr2024	Preeti Paul

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2feb2024 clean

Final Audit Report

2024-03-11

Created:	2024-02-22
By:	Tania Leeder (tleeder@mgb.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAAor9VLRGhf_YaauNCxiCQxs8w0NQporFD
Number of Documents:	1
Document page count:	7
Number of supporting files:	0
Supporting files page count:	0

"NN RA 208 Document Translation v3.0 2feb2024 clean" History

-  Document created by Tania Leeder (tleeder@mgb.org)
2024-02-22 - 6:14:47 PM GMT
-  Document emailed to christopher-coffey@uiowa.edu for signature
2024-02-22 - 6:16:21 PM GMT
-  Document emailed to cudkowicz.merit@mgh.harvard.edu for signature
2024-02-22 - 6:16:21 PM GMT
-  Document emailed to Marianne Chase (mchase@mgh.harvard.edu) for signature
2024-02-22 - 6:16:21 PM GMT
-  Document emailed to dixie-ecklund@uiowa.edu for signature
2024-02-22 - 6:16:22 PM GMT
-  Document emailed to Stacey Grabert (SGrabert@mgh.harvard.edu) for signature
2024-02-22 - 6:16:22 PM GMT
-  Document emailed to ohayonj@ninds.nih.gov for signature
2024-02-22 - 6:16:22 PM GMT
-  Email viewed by cudkowicz.merit@mgh.harvard.edu
2024-02-22 - 6:17:01 PM GMT

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

Challenge: The user opened the agreement.

2024-02-22 - 6:17:26 PM GMT

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

2024-02-22 - 6:18:29 PM GMT

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

Signing reason: I approve this document

Signature Date: 2024-02-22 - 6:18:31 PM GMT - Time Source: server

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

Challenge: The user opened the agreement.

2024-02-22 - 6:53:57 PM GMT

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

Signing reason: I approve this document

Signature Date: 2024-02-22 - 6:54:07 PM GMT - Time Source: server

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

Challenge: The user opened the agreement.

2024-02-22 - 7:55:31 PM GMT

📄 Email viewed by christopher-coffey@uiowa.edu

2024-02-22 - 7:55:46 PM GMT

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

Signing reason: I approve this document

Signature Date: 2024-02-22 - 7:55:48 PM GMT - Time Source: server

📄 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 - 6:53:45 PM GMT

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

2024-02-23 - 6:53:46 PM GMT

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


2024-02-23 - 6:53:56 PM GMT

✉ Document emailed to ecklundd@uiowa.edu for signature

2024-02-23 - 6:53:56 PM GMT

📄 Email viewed by cscoffey@iowa.uiowa.edu

2024-02-23 - 7:14:11 PM GMT

 Email viewed by ecklundd@uiowa.edu

2024-02-24 - 11:18:20 PM GMT

 ecklundd@uiowa.edu authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-24 - 11:18:36 PM GMT

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

2024-02-24 - 11:18:50 PM GMT

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

Signing reason: I approve this document

Signature Date: 2024-02-24 - 11:18:52 PM GMT - Time Source: server

 Email viewed by cscoffey@iowa.uiowa.edu

2024-03-08 - 9:19:54 AM GMT- IP address: 172.226.137.0


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

Challenge: The user opened the agreement.

2024-03-08 - 2:13:14 PM GMT


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

2024-03-08 - 2:13:29 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: 2024-03-08 - 2:13:32 PM GMT - Time Source: server- IP address: 128.255.113.139

 Email viewed by ohayonj@ninds.nih.gov

2024-03-11 - 3:19:25 PM GMT- IP address: 104.47.65.254


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

Challenge: The user opened the agreement.

2024-03-11 - 3:19:34 PM GMT

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

2024-03-11 - 3:19:46 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 - 3:19:48 PM GMT - Time Source: server- IP address: 72.83.187.43

 Agreement completed.

2024-03-11 - 3:19:48 PM GMT