NeuroNEXT Network

Standard Operating Procedure (SOP)

Communication

Version 3.0

SOP NN PM 501

Originators: NeuroNEXT CCC and DCC Personnel

Signature and Date: Christopher S. Coffey *Electronically signed by: Christopher S. Coffey Reason: I approve this document Date: Mar 7. 2024 14:52 CST* 07-Mar-2024
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)
Signature and Date: MVS *Electronically signed by: Merit Cudkowicz Reason: I approve this document Date: Feb 22, 2024 12:44 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 15:09 EST* 22-Feb-2024
Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)

NN PM 501

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR COMMUNICATION

SOP: NN PM 501 Version No.: 3.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	COMMUNICATION	Supersedes Document Version : 2.0 Effective Date : 08Apr2023

Signature and Date:

Dixie Ecklund

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24-Feb-2024

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Electronically signed by: Stacey Grabert
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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
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Date: Mar 11, 2024 11:24 EDT

11-Mar-2024

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

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR COMMUNICATION

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1. POLICY

Ongoing communications within the NeuroNEXT Network, including those between the National Institute of Neurological Diseases and Stroke (NINDS), the Clinical Coordinating Center (CCC), the Data Coordinating Center (DCC), the Clinical Study Sites (CSS), Protocol Principal Investigators (PPI), and all other relevant parties, is crucial to ensure the quality of all Network activities. By keeping all affected parties fully apprised of Network and study specific activities, accurate records of activities can be maintained and deviations from accepted procedures can be prevented. All communications should be appropriately detailed, documented on the appropriate forms or as meeting minutes, and distributed and/or filed as required by policy and/or regulation.

All pertinent Network and Study specific communications will be documented. Pertinent communications include, but may not be limited to, the following: scheduled teleconferences, face-to-face meetings, and one-to-one telephone calls or e-mail exchanges that impact Network and/or Study-specific functions. These records will be maintained by a designated party to document the content and frequency of communications, and to assess the effectiveness of communications.

To ensure completeness and continuity, action items from prior meetings should be reviewed at the start of each subsequent meeting and their status (i.e., ongoing, pending, completed) should be noted.

A study-specific Communication Plan that describes how each party involved with the management of a study (i.e., NINDS, CCC, DCC, PPI) will communicate, including details of membership for each study specific committee, frequency of meetings, and a detailed work scope of activities, will be developed for each NeuroNEXT study. Details for this plan will be captured in the study-specific manual of procedures (MOP) for each study.

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

Each interested party (CCC, DCC, PPI, NINDS or other relevant group) is responsible for documenting any pertinent communication that it is responsible for managing (e.g. NeuroNEXT Executive Committee [NEC] meetings, Coordinator teleconferences, protocol working group [PWG] teleconferences, study team teleconferences), and for distributing this documentation to attendees for review.

Where applicable, it is the responsibility of the interested party sending written communication to confirm all parties have received, read and appropriately distributed the communication.

Each party in NeuroNEXT is responsible for ensuring appropriate other parties are apprised of changes or new relevant information to facilitate optimal functioning of the Network and study-specific activities.

The CCC, DCC, PPI and NINDS are responsible for developing a study specific Communication Plan for all NeuroNEXT studies.

Many of the other SOPs detail communication between interested parties for specific Network and project activities, such as study, medical and safety monitoring, protocol development, site and study start-up, etc.

4. APPLICABLE REGULATIONS AND GUIDELINES

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21 CFR 312.50	General Responsibilities of Sponsors
ICH E6, 2.7	The Principles of ICH GCP
ICH E6, 5.1	Quality Assurance and Quality Control

5. REFERENCES TO OTHER APPLICABLE SOPS

NN RA 206	Medical Monitoring and Safety Monitoring
NN PD 304	Clinical Protocol Finalization and Maintenance
NN SS 403	Routine Monitoring Visits

6. ATTACHMENTS AND REFERENCES

NN PM 501 – 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
DCC	Data Coordinating Center at The University of Iowa
FDA	U.S. Food and Drug Administration
GCP	Good Clinical Practices
ICH	International Council for Harmonisation
NINDS	National Institute of Neurological Disorders and Stroke
PPI	Protocol Principal Investigator

8. SPECIFIC PROCEDURES

A. Network Communication between NINDS, CCC and DCC

#	*Who*	*Task*	*Attachment / References*	*Related SOP*
1.	CCC PI / DCC PI	Communicate any desired changes or new relevant information to NINDS Program Directors in a timely fashion. Where applicable, this communication should be documented in writing (may include via email correspondence).		
2.	NINDS Program Directors	Communicate any Network changes or new relevant information to CCC PI and DCC PI in a timely fashion. Where applicable, this communication should be documented in writing.		

B. Network Communication between CCC/ DCC and CSS

#	*Who*	*Task*	*Attachment / References*	*Related SOP*
1	CCC	Email all CSSs monthly, or as needed throughout the duration of the Network, with reminders and new information.		
2	CCC / DCC	Inform all appropriate parties of upcoming Network webinars, meetings and/or deadlines for requested information.		
3.	CCC / DCC	Provide meeting minutes and/or other appropriate documentation from applicable Network meetings and webinars to all CSSs.		

C. Study Specific Communication between CCC/ DCC and PPI

#	*Who*	*Task*	*Attachment / References*	*Related SOP*
1	CCC / DCC	Provide meeting minutes and/or other appropriate documentation from applicable study-specific meetings and webinars to PPI.		
2	CCC / DCC / PPI / NINDS	Develop study specific Communication Plan, to ensure all parties understand and accept their roles and responsibilities in management of the study.		

D. Study Specific Communication between CCC / DCC and CSS

#	*Who*	*Task*	*Attachment / References*	*Related SOP*
1	CCC / DCC	Provide meeting minutes and/or other appropriate documentation from applicable study-specific meetings and webinars to all CSSs.		

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Attachment NN PM 501 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Communication SOP NN PM 501					
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)”. Updated signature block to accommodate for electronic signatures. Additional minor updates throughout	Updated to version 2.0			Catharine Gladden
3.0	Minor edits for clarity	Periodic review	01Mar2024	15Apr2024	Preeti Paul

NN PM 501 Communication v3.0 clean

Final Audit Report 2024-03-11

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Number of Documents:	1
Document page count:	6
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Document emailed to christopher-coffey@uiowa.edu for signature
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cudkowicz.merit@mgh.harvard.edu authenticated with Adobe Acrobat Sign.
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2024-03-07 - 8:52:12 PM GMT

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

Challenge: The user opened the agreement.

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

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Signature Date: 2024-03-11 - 3:24:36 PM GMT - Time Source: server- IP address: 72.83.187.43

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