NeuroNEXT Network

Standard Operating Procedure (SOP)

Dissemination of Final Study Results

Version 1.0

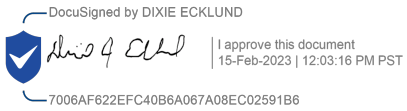
SOP NN PM 508

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 | 8:16:03 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 | 9:36:36 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 | 8:39:11 PM EST 58FE690F6BCA4F2390E3DA15BCE3F578 15-Feb-2023
Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)

Signature and Date:



15-Feb-2023

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

Signature and Date:

22-Feb-2023

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

Signature and Date:

15-Feb-2023

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

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NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR DISSEMINATION OF FINAL STUDY RESULTS

1. POLICY

This SOP describes procedures for disseminating final study results for clinical trials supported by the NeuroNEXT Network. After the last participant's last visit for a study, the Data Coordinating Center (DCC) and the Clinical Coordinating Center (CCC) collaborate to ensure that study data are as complete and accurate as possible before the clinical database is locked from further changes. For most NeuroNEXT studies, the DCC will perform any ongoing statistical analyses (including baseline analyses) and the primary statistical analyses of the final study data. Final study results are disseminated according to the procedures described below.

Sharing Final Study Results with the Protocol Principal Investigator (PPI)

The DCC shares the final study results with the PPI only after all data from outside sources have been received and all primary and key secondary analyses outlined in the study Statistical Analysis Plan are complete. The PPI receives the final study results in the form of a final study report and a slide presentation by the DCC PI during an in-person or virtual meeting.

Final, un-blinded study data are shared with the PPI in the form of data sets and data tables. Outcome data will not be shared until the clinical database is locked. For additional information regarding data sharing, please refer to SOPs NN GA 107 *Data Sharing* and NN GA 109 *Sharing Data with Industry Collaborators*.

Sharing Final Study Results with the Protocol Steering Committee (PSC)

The PPI shares the final study results with the Protocol Steering Committee (PSC) via a virtual meeting or teleconference.

Sharing Final Study Results with the Clinical Study Site Principal Investigators (CSSPIs) and NeuroNEXT Network Principal Investigators (NNPIs)

The PPI shares final study results and summaries of study data with participating CSSPIs, CSS Study Coordinators (CSSSCs), NNPIs, and NN Study Coordinators (NNSCs) during a virtual study close-out meeting.

Final un-blinded study data may be shared with eligible CSSPIs in accordance with the NeuroNEXT Data Sharing Policy and procedures described in SOPs NN GA 107 or NN GA 109.

Sharing Final Study Results with Study Participants

Depending on the study participant population and as outlined in the informed consent form or at the discretion of the PPI, the PPI may share final study results with study participants t

After the manuscript that describes the final study results has been accepted for publication by a professional journal, the DCC and CCC collaborate with the PPI to provide a list to each participating CSS that describes the study allocation (randomization group assignment) for each of the study participants at that CSS. The CSS may then inform interested study participants of their assignments via phone call or Single IRB (SIRB) approved letter.

Sharing Final Study Results with the NeuroNEXT Data and Safety Monitoring Board (DSMB)

At least one (1) week prior to a public presentation of final study results, the study results and the slide presentation are circulated to all members of the NeuroNEXT DSMB for review.

Sharing Final Study Results through Publications and Presentations

Final study results may be disseminated to the public and the scientific community through publications in professional journals, presentations at professional conferences, and via ClinicalTrials.gov. In accordance with the NeuroNEXT Publication Policy and SOP NN GA 106 *Publication Policy Development*, the DCC and CCC collaborate with the PPI to generate manuscripts and abstracts, as well as the primary manuscript that describes the final study results.

If sufficient resources are available, the DCC and CCC may also assist the PPI with preparing presentations for the purpose of sharing study results at professional conferences.

Sharing Final Study Results through ClinicalTrials.gov

The DCC will provide the data needed for the clinicaltrial.gov posting. The investigators and the study Sponsor to prepare and submit final study results to the ClinicalTrials.gov online registry and the associated results database at the completion of an NIH-sponsored clinical trial.

For an applicable clinical trial (ACT), the responsible party must report summary results no later than 12 months after the completion date of the study (unless a certification for delayed submission of results or a request for extension of the deadline has been submitted).

Refer to the *Food and Drug Administration Amendments Act of 2007* (FDAAA 801) for definitions of an ACT to determine if a clinical trial meets the requirements under the regulation.

If required, the DCC submits study data, results, and associated materials to data repositories that are designated by the Sponsor. For additional information, please refer to SOPs NN GA 107 and NN GA 109.

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 DCC is responsible for sharing final study data with the PPI, CSSPIs, and other authorized NeuroNEXT personnel or entities (e.g. PSC, DSMB) according to procedures described in this SOP.

The DCC and CCC are responsible for working with the PPI to generate and submit manuscripts for publication of final study results in a timely fashion, and according to Sponsor directives.

The Sponsor is responsible for adhering to all deadlines that are required for submission of final study results to ClinicalTrials.gov, and for providing all required data and materials.

The Sponsor or designee is responsible for submitting clinical study results to NIH though the ClinicalTrials.gov online registry and results database within 12 months of the primary completion date, or for submitting a certification for delayed submission of results or a request for an extension of the deadline (if applicable).

The Study Team may be responsible for assisting the Sponsor (or other responsible party under FDAAA 801) with preparing final study results for submission to ClinicalTrials.gov within the required time period.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50	Protection of Human Subjects
21 CFR 312	Investigational New Drug Application

21 CFR 812	Investigational Device Exemptions
21 CFR 312.50	General Responsibilities of Sponsors
45 CFR 46	Protection of Human Subjects
ICH E6	Good Clinical Practice: Consolidated Guidance
ICH E6, 2.7	The Principles of ICH GCP
ICH E6, 5.1	Quality Assurance and Quality Control
ICH E6, 5.5	Trial Management, Data Handling and Record Keeping
ICH E6, 5.22	Clinical Trial/Study Reports
ICH E6, 5.23	Multicenter Trials
ICH E8	General Considerations for Clinical Trials
FDA	Food and Drug Administration Amendments Act, Section 801 (FDAAA 801) - 121 Stat. 906 Public Law 110–85—September 27, 2007
FDA	Guidance for Sponsors, Investigators, and Institutional Review Boards: Questions and Answers on Informed Consent Elements, 21 CFR 50.25(c) (Small Entity Compliance Guide), February 2012

ClinicalTrials.gov

Elaboration of Definitions of Responsible Party and Applicable Clinical Trial (March 2009)

Reporting “Basic Results” in ClinicalTrials.gov. Tse, T.; Williams, R.J.; Zarin, D.A. *CHEST, 136:295-300, July 2009.*

Update on Registration of Clinical Trials in ClinicalTrials.gov. Tse, T; Williams, R.J.; Zarin, D.A. *CHEST, 136:304-305, July 2009.*

5. REFERENCES TO OTHER APPLICABLE SOPS

NN GA 103	Document Development and Change Control
NN GA 107	Data Sharing
NN GA 109	Sharing Data with Industry Collaborators
NN RA 202	Trial Master File Maintenance
NN RA 203	Site Regulatory File Maintenance
NN PM 501	Communications
NN SS 403	Routine Monitoring Visits
NN SS 405	Study Closeout Visit
NN SM 602	Central Institutional Review Board Reporting
NN CS 706	Retention and Protection of Electronic Records
NN BIO 902	Statistical Analysis Plan Development
NN BIO 904	Generation and Validation of Analysis Data Sets
NN BIO 905	Validating Statistical Programs and Deliverables
NN BIO 906	Presenting Statistical Results for a Final Study Report
NN DM 1001	Clinical Data Management
NN DM 1005	Data Collection and Data Handling

6. ATTACHMENTS AND REFERENCES

NN PM 508 - A Document History

7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

DCC	Data Coordinating Center at The University of Iowa
CCC	Clinical Coordinating Center at Massachusetts General Hospital
Clinical Study Site (CSS)	Clinical site that conducts research for a NeuroNEXT protocol
DSMB	Data Safety Monitoring Board
Protocol Principal Investigator (PPI)	Principal Investigator of a NeuroNEXT protocol
PSC	Protocol Steering Committee
Clinical Study Site Principal Investigator (CSSPI)	Investigator who is responsible for the implementing and conducting a specific NeuroNEXT protocol at a Clinical Study Site
NeuroNEXT Network Principal Investigator (NNPI)	Principal Investigator who is awarded the NeuroNEXT site grant and oversees NeuroNEXT projects at a Clinical Study Site
SIRB	Single Institutional Review Board

8. SPECIFIC PROCEDURES

A. Sharing Final Study Results with the Protocol Principal Investigator (PPI)

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	DCC Biostatisticians	Ensure that all data from outside sources have been received and that primary and key secondary analyses outlined in the SAP are complete.		
2.	DCC PI	Present the final study results to the PPI at an in-person or virtual meeting.		
3.	DCC Biostatisticians and Study Team	Work with the PPI to resolve any questions regarding the study data or results.		
4.	DCC Directors	Provide the PPI with the final, un-blinded study data in accordance with SOPs NN GA 107 or NN GA 109.		NN GA 107 NN GA 109

B. Sharing Final Study Results with the Protocol Steering Committee (PSC)

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	DCC or CCC	Assist the PPI with scheduling a webinar or other teleconferencing method with the PSC.		
2.	PPI	Share the final study results with the PSC during the webinar or teleconference.		

C. Sharing Final Study Results with the Clinical Study Site Principal Investigators (CSSPIs) and NeuroNEXT Network Principal Investigators (NNPIs)

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC or CCC	Assist the PPI with scheduling a webinar or other teleconferencing method with participating CSSPIs, CSSCs, NNPIs, and NNSCs.		
2.	PPI	Share the final study results and summaries of study data during the webinar or teleconference.		
3.	DCC	Share study data according to GA 107 and GA 109		NN GA 107 NN GA 109

D. Sharing Final Study Results with Study Participants

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC and CCC	After the manuscript that describes the final study results is in press, and if applicable to a study, collaborate with the PPI to provide a letter or other means of communication to participating CSS that describes the study allocation for each of the study participants at that CSS. If the primary manuscript is not published within 12 months after database lock, study allocation correspondence may be sent to each participating CSS and communicated to participants.		
2.	CSS	Inform interested study participants of their assignments.		

E. Sharing Final Study Results with the NeuroNEXT Data and Safety Monitoring Board (DSMB)

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC	At least one (1) week prior to a public presentation of final study results, circulate the slide presentation to all members of the NeuroNEXT DSMB for review.		

F. Sharing Final Study Results through Publications and Presentations

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC and CCC	Collaborate with the PPI to generate manuscripts and abstracts, in accordance with the NeuroNEXT Publication Policy and SOP NN GA 106.		NN GA 106

G. Sharing Final Study Results through ClinicalTrials.gov

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.				
2.	PPI / Sponsor or designee	Review all data tables for clarity and completeness.		
3.	PPI/ Sponsor or designee	Submit the results.		
4.	PPI/ Sponsor or designee	If requested by ClinicalTrials.gov personnel, provide clarification or corrections to the protocol or results section of the study record.		
5.	PPI/ Sponsor or designee	After the initial posting of the study results, make updates or edits as needed.		

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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 8:40:55 AM Viewed: 2/15/2023 11:59:24 AM Signed: 2/15/2023 11:59:47 AM
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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 8:40:54 AM Viewed: 2/15/2023 8:38:38 PM Signed: 2/15/2023 8:39:20 PM
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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 8:40:55 AM Viewed: 2/22/2023 11:20:16 AM Signed: 2/22/2023 11:20:29 AM
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