

NeuroNEXT Network

Standard Operating Procedure (SOP) Data Management Plan Development Version 4.0 SOP NN DM 1002




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: Feb 23, 2024 13:41 CST</small>	23-Feb-2024
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)	
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**NN DM 1002
NEURONEXT NETWORK STANDARD OPERATING
PROCEDURE FOR DATA MANAGEMENT PLAN
DEVELOPMENT**

SOP: DM 1002 Version No.: 4.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	Data Management Plan Development	Supersedes Document Version : 3.0 Effective Date : 08Apr2023
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Signature and Date: <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="text-align: center;">  <small>Electronically signed by: Dixie Ecklund Reason: I approve this document Date: Feb 23, 2024 17:16 CST</small> </div> <div style="text-align: right; padding-top: 10px;"> 23-Feb-2024 </div> </div>
Name and Title: Dixie J. Ecklund, RN MSN MBA (DCC Associate Director)
Signature and Date: <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="text-align: center;">  <small>Electronically signed by: Stacey Grabert Reason: I approve this document Date: Feb 22, 2024 15:11 EST</small> </div> <div style="text-align: right; padding-top: 10px;"> 22-Feb-2024 </div> </div>
Name and Title: Stacey Grabert, Pharm.D, MS, (CCC Director of Quality Assurance)
Signature and Date: <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="text-align: center;">  <small>Electronically signed by: Joan Ohayon Reason: I approve this document Date: Mar 11, 2024 09:06 EDT</small> </div> <div style="text-align: right; padding-top: 10px;"> 11-Mar-2024 </div> </div>
Name and Title: Joan Ohayon, RN, MSN, CRNP, MSCN (NINDS, NeuroNEXT Program Official)

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1. POLICY

A comprehensive Data Management Plan will be created for the NeuroNEXT Network that describes areas of Data Management (DM) oversight and activities that will be conducted for the Network. The NeuroNEXT Network comprehensive Data Management Plan may include, but is not limited to, the following components:

- Overview
- Website development
- Database model
- Database and website environments
- Electronic CRF (eCRF) development and testing
- Save-audit testing
- Subject identification system
- Clinical data entry procedures
- Reports
- Data backup and archiving
- Data sharing
- Electronic data transfer
- Adverse event tracking and management
- MedDRA coding system
- Data quality assurance
- Glossary
- Appendices, including all study-specific Data Management Plans

The NeuroNEXT Data Coordinating Center (DCC) DM Team will collaborate with the NeuroNEXT Clinical Coordinating Center (CCC) to develop the comprehensive Data Management Plan. The Plan will be maintained by the DCC DM Team, and may be updated (as needed) in collaboration with the CCC.

Study-specific Data Management Plans

A study-specific Data Management Plan will be developed by the DCC DM team for each study protocol, in collaboration with the CCC, the Protocol Principal Investigator (PPI) and study team, and others as needed. The study-specific Plan will be included as an appendix to the NeuroNEXT comprehensive Data Management Plan. The study-specific Plan is established at the beginning of the study, and will be maintained as a living document.

The primary purpose of the study-specific Data Management Plan is to convey website details, protocol information, and data entry application details to the IT application developers at the DCC. While the Plan may contain informational materials related to the project, certain information provided in the Plan may be considered to be written specifications. Components that may be included in the study-specific Data Management Plan are described in section 8.C.

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 DM Team is responsible for creating a comprehensive Data Management Plan for the NeuroNEXT

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Network with an appendix for each study protocol, in consultation with the CCC and NeuroNEXT Leadership (CCC PI and DCC PI).

The DCC DM Team will maintain the comprehensive Data Management Plan, and will update the Plan as needed in collaboration with the NeuroNEXT CCC.

Individual Study-Specific Data Management Plans will be created and maintained by the DCC Data Management Team as appendices to the main Data Management Plan in collaboration with, but not limited to, the NeuroNEXT CCC, the Protocol Principal Investigator (PPI) and study team, and others as needed.

The responsibility to conduct any or all of these activities may be delegated at the discretion of the Sponsor to the DCC. 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

ICH E6, 2.10 The Principles of ICH GCP

ICH E6, 6.0 Clinical Trial Protocol and Protocol Amendment(s)

ICH E8 General Considerations for Clinical Trials (December 1997)

5. REFERENCES TO OTHER APPLICABLE SOPS

NN GA 103	Document Development and Change Control
NN GA 107	Data Sharing
NN CS 702	Application Development and Validation
NN CS 703	IT Environments
NN CS 704	System Security Measures and Website Access
NN CS 705	Data Backup, Recovery, and Contingency Plans
NN QA 801	Quality Assurance Audits
NN QA 802	Quality Management
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 1003	Case Report Form Development
NN DM 1004	Specifications Development, Testing Plans, and Validation Documentation
NN DM 1005	Data Collection and Data Handling
NN DM 1006	Adverse Event Coding

6. ATTACHMENTS AND REFERENCES

NN DM 1002 - A Document History

7. TERMS AND ABBREVIATIONS

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The following terms and abbreviations are used in this

document: AE Adverse Events

- CCC Clinical Coordinating Center at Massachusetts General Hospital
- CFR Code of Federal Regulations
- DCC Data Coordinating Center at The University of Iowa
- DM Data Management
- FDA Food and Drug Administration
- GCP Good Clinical Practices
- ICH International Conference on Harmonisation
- PPI Protocol Principal Investigator
- QA Quality Assurance
- SAE Serious Adverse Events

8. SPECIFIC PROCEDURES

A. Maintaining the NeuroNEXT Network Comprehensive Data Management Plan

The DCC DM Team will create the NeuroNEXT Network comprehensive Data Management Plan as described in the Policy section, and will maintain the Plan as described below:

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC DM Team Lead	Determine who is responsible for reviewing and modifying the comprehensive Data Management Plan.		NN DM 1001
2.	DCC DM Team	As needed, update the Data Management Plan to reflect changes in DM procedures.		
3.	DCC DM Team	After all revisions are complete, update the version date and increment the version number to the next whole number (1.x to 2.0).		NN GA 103

B. Creating and Maintaining a Study-Specific Data Management Plan

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC DM Lead	Assign a Data Management Team member to create and maintain the study-specific Data Management Plan.		
2.	Assigned DCC Team Member	Create the study-specific Data Management Plan, and include applicable components described in section 8.C.		
3.	DCC DM Lead	Review the study-specific Data Management Plan and offer feedback, if necessary.		

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4.	DCC DM Team Lead	Include the final study-specific Data Management Plan as an appendix in the NeuroNEXT Network comprehensive Data Management Plan.		
5.	DCC DM Team Leader	Periodically review the study-specific Data Management Plan, and track any major changes on a document change log.		

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Attachment NN DM 1002 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Data Management Plan Development SOP NN DM 1002					
Version	Description of Modification	Reason or Justification for Modification	Issue Date	Effective Date	Reviewer(s)
1.0	New	N/A	13Apr2012	13May2012	N/A
2.0	Removed references to the Protocol Steering Committee and the approval process for study-specific Data Management Plans. Simplified the development, review, and revision processes. Modified or removed several components of study-specific plans. Other minor edits.	Updates for v2.0	21Sep2016	21Oct2016	N/A
3.0	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 for version 3.0	22Feb2023	08Apr2023	Catherine Gladden

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4.0	Minor edits for clarity	Periodic review	01Mar2024	15Apr2024	Preeti Paul
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NN DM 1002 Data Management Plan Development v4.0 clean

Final Audit Report

2024-03-11

Created:	2024-02-22
By:	Tania Leeder (tleeder@mgb.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAAom4Mo5kDgw9OmImR2jc3CI2A-DGGb58e
Number of Documents:	1
Document page count:	8
Number of supporting files:	0
Supporting files page count:	0

"NN DM 1002 Data Management Plan Development v4.0 clean" History

-  Document created by Tania Leeder (tleeder@mgb.org)
2024-02-22 - 8:01:37 PM GMT
-  Document emailed to christopher-coffey@uiowa.edu for signature
2024-02-22 - 8:04:34 PM GMT
-  Document emailed to cudkowicz.merit@mgh.harvard.edu for signature
2024-02-22 - 8:04:34 PM GMT
-  Document emailed to Marianne Chase (mchase@mgh.harvard.edu) for signature
2024-02-22 - 8:04:34 PM GMT
-  Document emailed to dixie-ecklund@uiowa.edu for signature
2024-02-22 - 8:04:34 PM GMT
-  Document emailed to Stacey Grabert (SGrabert@mgh.harvard.edu) for signature
2024-02-22 - 8:04:34 PM GMT
-  Document emailed to ohayonj@ninds.nih.gov for signature
2024-02-22 - 8:04:35 PM GMT

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

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2024-02-22 - 8:10:51 PM GMT

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2024-02-22 - 10:45:29 PM GMT

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📄 Tania Leeder (tleeder@mgb.org) added alternate signer cscoffey@iowa.uiowa.edu. The original signer christopher-coffey@uiowa.edu can still sign.

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

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

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Signature Date: 2024-02-23 - 7:41:01 PM GMT - Time Source: server

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2024-02-23 - 11:16:34 PM GMT


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Signature Date: 2024-02-23 - 11:16:52 PM GMT - Time Source: server

 Email viewed by ohayonj@ninds.nih.gov

2024-03-11 - 1:05:25 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 - 1:05:48 PM GMT

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2024-03-11 - 1:06:04 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 - 1:06:06 PM GMT - Time Source: server- IP address: 72.83.187.43

 Agreement completed.

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