NeuroNEXT Network

Standard Operating Procedure (SOP)

Sharing Data with Industry Collaborators

Version 2.0

SOP NN GA 109

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

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NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SHARING DATA WITH INDUSTRY COLLABORATORS

SOP: NN GA 109 Version No: 2.0 Issue Date:01Mar2024 Effective Date: 15Apr2024	SHARING DATA WITH INDUSTRY COLLABORATORS	Supersedes Document: 1.0 Effective Date: 21Oct2016

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04-Mar-2024

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1. POLICY

The purpose of this SOP is to describe NeuroNEXT Data Coordinating Center (DCC) and Clinical Coordinating Center (CCC) roles, responsibilities, policies, and procedures associated with sharing study data with industry Collaborators under terms of a Cooperative Research & Development Agreement (CRADA). Additional data sharing processes and procedures for NeuroNEXT Network studies are described in SOP NN GA 107 *Data Sharing*.

Sharing Data with Protocol Principal Investigators

The Protocol PI will receive a copy of the final, un-blinded results, tables, and datasets from the DCC within sixty (60) days after conclusion of the study, or according to the provisions set forth in the executed CRADA for the study. The Protocol PI may receive his or her site-specific data from the DCC at any time during or after the study.

The DCC will perform ongoing and final statistical analyses for NeuroNEXT and will collaborate with the PPI to generate manuscripts and abstracts as well as the primary manuscript that describes the final study results. The Collaborator may perform its own statistical analysis of the final, un-blinded study data, either with in-house or contract statisticians.

All publications resulting from NeuroNEXT clinical trials will be reviewed by the NeuroNEXT Publication and Data Sharing Committees according to NN SOP GA 106 Publication Policy.

Sharing Data with Clinical Study Site Principal Investigators

As described in the Notice of Grant Award, each CSS will generally be considered to own the data that have been generated at its respective site during the study. All study data must be transmitted to the DCC. A CSS may receive its site-specific data from the DCC at any time during or after the study but will not receive subject-level data from other CSS. Except for the Protocol PI's CSS, no CSS will receive the final, un-blinded results until at least three (3) years after conclusion of the study, or according to the provisions set forth in the executed CRADA for the study.

Sharing Data with the Scientific Community

Individuals or groups who are not participants in the NeuroNEXT CRADA study will not be given access to any study-related data from the DCC or CSS. They may access only de-identified datasets and associated documentation archived for public access.

Sharing De-Identified Data Sets for Public Use

The DCC will submit de-identified data sets and associated documentation to NINDS or another designated repository for archiving and public access at the request and direction of NINDS and as consistent with the current NINDS Data Management and Sharing Policy. The DCC will provide documentation with each final data set to ensure that other users can efficiently and accurately use the data set, and to prevent misinterpretation or misuse. This documentation may include information about how the data were collected, provide details about the code used to generate the dataset, and define variables and variable field locations.

To protect the rights and privacy of human subjects who participate in NeuroNEXT trials, study data will be redacted prior to sharing for public use to remove any personally identifying information. Any direct identifiers (e.g., name, contact information, Social Security Numbers) that may be present in study data will be removed prior to creation of the dataset. Indirect identifiers that could lead to

deductive disclosure of participant identities (e.g., birth date) will be removed or otherwise de-identified.

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 E (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 researchers, 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 serves as the primary Statistical Analysis group for the NeuroNEXT Network, and performs ongoing and interim statistical analyses for all NeuroNEXT protocols. For most NeuroNEXT protocols, the DCC performs the ongoing statistical analyses and the primary statistical analysis of the final study data, and assists with secondary analyses as appropriate. The DCC also collaborates with Protocol and CSS Principal Investigators to generate manuscripts that describe study design and final study results.

The NeuroNEXT DCC is responsible for developing and validating database systems, collecting and storing data, and sharing study data according to the procedures described in this and other applicable NeuroNEXT Network SOPs.

4. APPLICABLE POLICIES AND GUIDELINES

NIH	Final NIH Statement on Sharing Research Data, February 26, 2003.http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html
NIH	NIH Data Sharing Policy and Implementation Guidance March 5, 2003.http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm
NIH	NIH Scientific Data Sharing: New Policy effective January 25, 2023 https://sharing.nih.gov/
NINDS	NINDS Archived Clinical Research Datasets https://www.ninds.nih.gov/current-research/research-funded-ninds/clinical-research/archived-clinical-research-datasets

5. REFERENCES TO OTHER APPLICABLE SOPS

NN GA 106	Publication Policy Development
NN GA 107	Data Sharing
NN CS 704	System Security Measures and Website Access
NN CS 706	Retention and Protection of Electronic Records
NN BIO 901	Working with an External Biostatistician
NN BIO 902	Statistical Analysis Plan Development
NN BIO 904	Generation and Validation of Analysis Data Sets
NN BIO 906	Presenting Statistical Results for a Final Study Report

SOP: NN GA 109 Version No: 2.0 Issue Date:01Mar2024 Effective Date: 15Apr2024	SHARING DATA WITH INDUSTRY COLLABORATORS	Supersedes Document: 1.0 Effective Date: 21Oct2016

6. ATTACHMENTS

NN GA 109 – 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
Protocol Principal Investigator (PPI)	Principal Investigator of a NeuroNEXT protocol
Clinical Study Site Principal Investigator	Investigator who is responsible for the implementation and conduct of a specific NeuroNEXT protocol at a Clinical Study Site
DCC Biostatistician	Any Biostatistician who is a member of the DCC Biostatistics team
Lead Biostatistician	DCC Biostatistician who has primary statistical oversight for a NeuroNEXT protocol
Study Biostatistician	DCC Biostatistician assigned to a NeuroNEXT protocol. At least one Study Biostatistician will be assigned to each protocol, but only one Biostatistician will be assigned to prepare the randomization.
External Biostatistician	A Biostatistician who is not a member of the DCC Biostatistics Team. The External Biostatistician may be employed directly by a NeuroNEXT site, or engaged as a subcontractor.

8. SPECIFIC PROCEDURES

A. Sharing Data with Protocol Principal Investigators

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	DCC Biostatisticians	During the course of the study, perform requested analyses and communicate the results to the PPI in the form of tables or data sets.		NN BIO 902 NN BIO 904
2.	DCC Biostatisticians	Provide a copy of the final, un-blinded results, tables, and data sets to the PPI and Industry Collaborator within sixty (60) days after conclusion of the study, or according to the provisions set forth in the executed CRADA for the study. The Protocol PI may receive his or her site-specific data from the DCC at any time during or after the study.		
3.	DCC Biostatisticians and PPI	For most studies, DCC Biostatisticians will: • perform the primary statistical analysis of the final study data;		NN GA 106 NN BIO 906

#	Who	Task	Attachment	Related SOP
		• communicate the results to the PPI in the form of tables or data sets; and • collaborate with the PPI to generate the primary manuscript that describes the final study results for review by the NeuroNEXT Publication and Data Sharing Committees.		
4.	DCC Biostatisticians, PPI, External Biostatistician	If applicable to the protocol, and approved by NINDS, the PPI may engage a Biostatistician who is external to the DCC to perform the primary statistical analysis. In this case, the DCC will: • transmit the final data set to the external Biostatistician in an agreed-upon format using a secure, encrypted method; and • offer to collaborate during the analysis phase; and • collaborate with the external Biostatistician to generate the primary manuscript that describes the final study results for review by the NeuroNEXT Publication and Data Sharing Committee.		NN GA 106 NN BIO 901 NN BIO 906

B. Sharing Data with Clinical Study Site Principal Investigators

#	Who	Task	Attachment	Related SOP
1.	CSS	A CSS may submit written requests for transfers of their own site-specific data from the DCC during or after a study, but they will not receive subject-level data from other CSS.		
2.	DCC	Transfer site-specific data only to the requesting CSS upon written request.		
3.	DCC Biostatisticians	Except for the Protocol PI's CSS, the final, un-blinded results will not be shared with other CSS until at least three (3) years after conclusion of the study, or according to the provisions set forth in the executed CRADA for the study.		

C. Sharing De-Identified Data Sets for Public Use

#	Who	Task	Attachment	Related SOP
1.	DCC	Redact data sets to remove all personally identifying information prior to sharing for public use. • Prior to creating the data set, remove all direct identifiers (e.g. name, contact information, SSN) that may be present in study data. • Remove or otherwise de-identify any indirect identifiers (e.g. birth date, procedure dates)		

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#	Who	Task	Attachment	Related SOP
		that could lead to a deductive disclosure of participant identity.		
2.	DCC	At the request and direction of NINDS, submit de-identified data sets and associated documentation to NINDS or other designated repository for archiving and public access, consistent with the current NINDS Data Management and Sharing Policy.		
3.	DCC Biostatisticians	Provide documentation with each final data set. Documentation may include, but is not limited to, the following information: • how the data were collected; • details of the code used to generate the data set; • definitions of variables and variable field locations		

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Attachment NN GA 109 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Sharing Data with Industry Collaborators SOP NN GA 109				
Version	**Description of Modification**	**Reason or Justification for Modification**	**Issue Date**	**Effective Date**
1.0	New	N/A	21Sep2016	21Oct2016
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.	Updates for v2.0	01Mar2024	15Apr2024

NN GA 109 Sharing Data with Industry Collaborators v2.0

Final Audit Report 2024-03-07

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Agreement completed.

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