NeuroNEXT Network

Standard Operating Procedure (SOP)

Data Sharing

Version 3.0

SOP NN GA 107

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

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NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR DATA SHARING

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 generated during the course of a NeuroNEXT clinical trial. For additional information regarding data sharing under grants funded by the NIH Resource Action Program (X01) or under SBIR Cooperative Agreements (U44), see SOP NN GA 109 *Sharing Data with Industry Collaborators*.

Developing Data Management and Sharing Plans

NeuroNEXT trials generate scientific data and will be expected to comply with the new NIH Data Management and Sharing Policy effective January 2023. The Data Coordinating Center (DCC) and Clinical Coordinating Center (CCC) will work with all Protocol Principal Investigators (PPIs) during the pre-award phase to develop appropriate Data Management and Sharing (DMS) Plans. The DMS Plans will include the following elements: data types, tools and software needed to access and manipulate the data, standards applied to data and metadata, designated repository and requirements to access and distribute the data, as well as oversight for compliance with the policy.

Sharing Data with Protocol Principal Investigators

For most NeuroNEXT trials, the DCC will perform any ongoing statistical analyses (including baseline analysis) and the primary statistical analysis of the final study data. The PPI will have access to these data in the form of results and tables or datasets through the DCC, and the DCC will collaborate with the PPI to generate manuscripts and abstracts as well as the primary manuscript that describes the final study results. Baseline datasets may be available during ongoing NN trials. No datasets that include the primary and key secondary outcomes that are specified in the Statistical Analysis Plan (SAP) are shared prior to database lock.

If applicable to the protocol, and approved by NINDS, a NeuroNEXT 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 dataset to the external Biostatistician in an agreed-upon format using a secure, encrypted method, and will offer to collaborate during the analysis phase. The DCC will work with the PPI and the external Biostatistician to generate the primary manuscript that describes the study results. The PPI may also request assistance from the DCC concerning questions or additional analyses related to the final study data. The PPI will submit a statistical analysis request that describes the type of analysis to be performed. If agreed and there is sufficient funding available to support the DCC effort, the DCC statistical implementation team will collaborate with the PPI to generate subsequent manuscripts for peer review and subject to approval from the Publication and Data Sharing Committees. The full study data sets will be shared with the PPI at the time of submission of the primary manuscript

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, NeuroNEXT Clinical Study Site (CSS) awardees may generally be considered to own the data that have been generated at their site during the course of participation in a NeuroNEXT clinical trial. However, all data collected during NeuroNEXT studies must be transmitted to the DCC. Upon request to the DCC, CSS awardees may have access to the data generated at their own site in the form of datasets during or after the study, but will not receive subject-level data from other CSS. If there are baseline datasets available during ongoing NN trials, interested NN CSS that participated in the study protocol may request access to the baseline datasets. These requests require review and approval by the PPI and the Publication and Data Sharing Committees.

At the time that the primary manuscript that describes the final study results is published, the DCC may make datasets available to interested CSS in accordance with the approved DMS plan and in compliance with the NIH Data Management and Sharing Policy. The CSS may also request assistance from the DCC concerning questions or proposed secondary analyses related to the final study data. To facilitate this process, the CSS may be asked to submit a statistical analysis request to the DCC that describes the type of analysis to be performed, and any questions that are hoped to be resolved through a secondary analysis. If agreed upon and sufficient funding is available to support the DCC effort, the DCC statistical implementation team may assist the CSS with secondary analyses, and will collaborate with the CSS to generate subsequent manuscripts for peer review, subject to approval by the PPI as well as the Publication and Data Sharing Committees. NN Investigators who are covered entities under the Health Insurance Portability and Accountability Act (HIPAA) must also consider issues related to the Privacy Rule. The DCC and CCC, in collaboration with the single Institutional Review Board (sIRB), will implement strategies to minimize the risk of unauthorized disclosure of personal identifiers.

Sharing Data during Ongoing Protocol

During the course of trials conducted within the Network, situations often arise where protocol-specific data needs to be transmitted to external cores involved with a particular aspect of the study protocol. Similarly, data may need to be received from these external cores for merging with data collected through the main study database (e.g., external imaging data, external laboratory data, etc.). In all instances, a formal Data Transfer Agreement (DTA) will be prepared and executed through the appropriate institutional offices (e.g. Sponsored Programs). The DTA will augment the contractual agreements with clarity of the general structure of each transferred data set, the mechanism through which files will be transferred, how the data will be used, and responsibility for the conduct of any electronic checks or queries to verify the accuracy of the transferred data sets. All data that are shared with external sources will be compliant with the Health Insurance Portability and Accountability Act (HIPAA) and/or subject to IRB approval. All data files will be distributed using secure file transfer. The data files can be supplied via an agreed upon format including SAS datasets or Excel files. Because the SAS statistical package is widely available, this format has proven to be an acceptable method for sharing data. To facilitate this process, datasets may be sent with supporting documentation such as the protocol, a data dictionary describing the contents of each dataset, and case report forms.

Sharing De-Identified Datasets for Public Use

At the conclusion of each clinical study, the DCC will submit de-identified datasets and associated documentation to the NINDS data repository or another data repository if an alternative repository is more relevant for the study, for archiving and public access consistent with the NIH Data Management and Sharing Policy. The datasets are de-identified under the HIPAA Safe Harbor provision and following current best practices regarding data safety and participant privacy. Adhering to the FAIR principles, data are made interoperable by the use of Common Data Elements and other applicable data standards. Ensuring reusability, supporting materials such as the protocol, manual of procedures, data dictionary, annotated case report forms, scoring documents, and read me files are prepared for final deposit to the designated repository. All study datasets undergo a quality control process prior to final sharing and are transferred via secure file transfer. The NINDS data repository restricts access to study data to investigators/researchers with IRB-approved proposals or clearly defined plans for use of the data. To protect the rights and privacy of human subjects who participate in NN trials, study data will be redacted prior to sharing for public use to remove any personally identifying information as described in the DMS plan. 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 for sharing. Indirect identifiers that could lead to deductive disclosure of participant identities (e.g. dates) may be removed or otherwise de-identified (for example, using days/months from randomization instead of actual dates). Additional data redaction strategies may be implemented for sharing with the designated repository.

Registration of Trial Results on ClinicalTrial.gov

Per policy, as a condition of funding all NeuroNEXT PPIs and the PPI institution must ensure registration of all Network clinical protocols on ClinicalTrials.gov prior to the beginning of enrollment. The PPI and PPI institution must also ensure reporting of the final study results within 12 months after the date of the final data collection for pre-specified study outcome measures. The CCC and DCC will work with the Network PPI to upload a summary of trial results and to address any errors, deficiencies, or inconsistencies identified by NIH as part of the trial registration QC review process.

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 Frequently Asked Questions: Data Sharing, February 16, 2004. http://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.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 109	Sharing Data with Industry Collaborators
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

6. ATTACHMENTS

NN GA 107 – 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.
Data Management & Sharing (DMS) Plans	The plan submitted and approved by the funding institute to facilitate data sharing.

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 datasets.		NN BIO 902 NN BIO 904
2.	DCC Biostatisticians and PPI	For most studies, DCC Biostatisticians will: • perform the primary statistical analysis of the final study data; • communicate the results to the PPI in the form of tables or datasets; 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.		NN GA 106 NN BIO 906

3.	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 dataset 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 Committees.		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 the course of a study, but they will not receive subject-level data from other CSS.		
2.	DCC	Transfer site-specific data to the requesting CSS upon written request.		
3.	DCC Biostatisticians	Share baseline data according to a timeline that is agreed upon with the PPI.		
4.	CSS	At the time that the primary manuscript that describes the study results is published, the DCC may make datasets available to interested CSS in accordance with the approved DMS plan and upon approval of the PPI and the Protocol Steering Committee. • Requests for final study data will be reviewed by the Publication and Data Sharing Committees as described in SOP NN GA 106.		NN GA 106
5.	CSS	After the primary manuscript has been published, CSS that have participated in research on the study protocol may submit a statistical analysis request to the DCC to request assistance with secondary analyses.		
6.	DCC Biostatisticians	If agreed upon, the DCC may: • assist the CSS with secondary analyses; and • Collaborate on manuscripts describing the results of the secondary analysis for review by the Publication and Data Sharing Committees.		NN GA 106

C. Sharing Data during Ongoing Protocol

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	DCC Biostatisticians and DCC IT and DM Lead	Share protocol-specific data (incoming or outgoing) with external cores involved with a particular aspect of the study protocol.		

#	Who	Task	Attachment	Related SOP
2.	Requester (Incoming or Outgoing)	Submit a formal written request for data sharing to the DCC for approval by the Protocol PI and/or Protocol Steering Committee.		
3.				
4.	DCC Senior Leadership and External Requester	If the data sharing request is approved, and prior to any data sharing, execute a Data Transfer Agreement (DTA) that includes the following information: • a description of the terms and conditions of management of the data that is being requested • a description of the data that are requested; and • how the data will be used.		
5.	DCC Senior Leadership	Ensure that all data to be shared are HIPAA compliant and/or CIRB approved, as appropriate.		
6.	DCC Biostatisticians and DCC Lead IT and DM Lead	Create datasets in an agreed upon format (.csv files or SAS®) for sharing, and consult with the Requester to determine if there are any special requirements for sharing datasets. Provide supporting documentation such as • a copy of the protocol; • a data dictionary describing the contents of each dataset; and • a User's Manual that describes the process for importing datasets into other systems.		
7.	DCC Biostatisticians and DCC Lead IT and DM Lead	Transfer datasets though an agreed upon secured and encrypted portal (One Drive, FTP, etc.)		

D. Sharing De-Identified Datasets for Public Use

#	Who	Task	Attachment	Related SOP
1.	DCC	Redact datasets to remove all personally identifying information prior to sharing for public use. • Prior to creating the dataset, 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) that could lead to a deductive disclosure of participant identity.		
2.	DCC	Submit de-identified datasets and associated documentation to NINDS for archiving and public access, consistent with the current NINDS Data Sharing Policy and the approved Data Management and Sharing (DMS) Plan.		

#	Who	Task	Attachment	Related SOP
3.	DCC Biostatisticians	Provide documentation with each final dataset. Documentation may include, but is not limited to, the following information: • how the data were collected; • details of the code used to generate the dataset; • definitions of variables and variable field locations		

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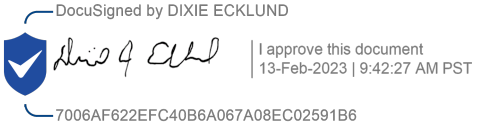
DIXIE ECKLUND dixie-ecklund@uiowa.edu Security Level: Email, Account Authentication (Required), Login with SSO	 Signature Adoption: Drawn on Device Signature ID: 7006AF62-2EFC-40B6-A067-A08EC02591B6 Using IP Address: 128.255.112.230 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/13/2023 8:21:00 AM Viewed: 2/13/2023 12:36:54 PM Signed: 2/13/2023 12:42:30 PM
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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: 71.178.185.120 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/13/2023 8:21:02 AM Viewed: 2/13/2023 2:10:04 PM Signed: 2/13/2023 2:10:44 PM
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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: 2/13/2023 8:21:01 AM Viewed: 2/13/2023 8:47:59 AM Signed: 2/13/2023 8:48:31 AM
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