

NeuroNEXT Network

Standard Operating Procedure (SOP)


Data Sharing

Version 2.0

SOP NN GA 107

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:



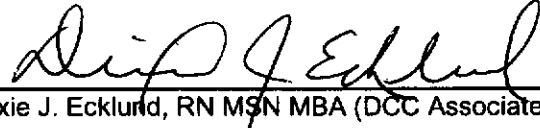
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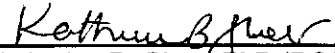
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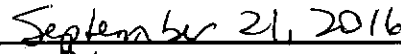
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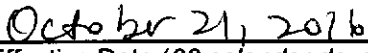
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Issue Date



Effective Date (30 calendar days after the Issue Date)

NN GA 107
NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR
DATA SHARING

SOP: NN GA 107 Version No: 2.0 Effective Date: 21Oct2016	DATA SHARING	Supersedes Document: Version 1.0 Effective Date: 21Apr2012
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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 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*.

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.

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.

All publications resulting from NeuroNEXT clinical trials will be reviewed by the NeuroNEXT Publication and Data Sharing Committee 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. The DCC may also initiate an ongoing quarterly transfer of site-specific data to a site, if requested and approved by the Protocol Steering Committee.

After the primary manuscript that describes the final study results has been accepted for publication in a peer-reviewed journal or 18 months after the conclusion of the Study Protocol (lock of the study data), whichever occurs first, any interested CSS that have participated in research on the study protocol may request access to the final study data. Baseline results will be handled with a similar process and according to a timeline agreed upon with the PPI. Any interested CSS that have participated in research on the study protocol may request access to the baseline data. These requests will be reviewed by the Publication and Data Sharing Committee as described in NN SOP GA 106 Publication 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 Biostatistics 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 Publication and Data Sharing Committee. NeuroNEXT 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 Central Institutional Review Board (CIRB), will implement strategies to minimize the risk of unauthorized disclosure of personal identifiers.

Sharing Data with the Scientific Community

During the course of the Network, situations may arise in which protocol-specific data must be transmitted to external individuals or groups who are not involved in the conduct of the protocol. In such situations, the external source must submit a formal written request for data sharing, and the request must be approved by the NeuroNEXT Executive Committee (NEC) and the Publication and Data Sharing Committee before any data are shared. Consideration will be given as to whether the data has been made available to CSS investigators prior to sharing with the scientific community. Prior to data sharing, the DCC and the external source must also execute a data sharing agreement that includes a description of the data that are requested and how the data will be used. All data that are shared with external sources will be HIPAA compliant and/or subject to IRB approval. Data will typically be shared as either .csv files or SAS® datasets that have been created in transport format. Because the SAS® statistical package is widely available, this format has proven to be an acceptable method for sharing data. Investigators who use other statistical packages can usually import SAS® dataset into their preferred statistical package. To facilitate this process, datasets may be sent with 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 data into other systems

Sharing De-Identified Datasets for Public Use

The DCC will submit de-identified datasets and associated documentation to NINDS for archiving and public access, consistent with the current NINDS Data Sharing policy. The DCC will provide documentation with each final dataset to ensure that other users can efficiently and accurately use the dataset, 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 1996 ICH E6 Consolidated Guidance. 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
NINDS	NINDS Data Sharing website: http://www.ninds.nih.gov/research/clinical_research/toolkit/data_sharing.htm

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
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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 datasets.		NN BIO 902 NN BIO 904
2.	DCC Biostatisticians and PPI	For most studies, DCC Biostatisticians will: <ul style="list-style-type: none"> 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 Committee. 		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: <ul style="list-style-type: none"> 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 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 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 and IT Team or Data Management Team	If approved by the PPI and the Protocol Steering Committee, perform a scheduled quarterly transfer of site-specific data to the requesting CSS.		
4.	DCC Biostatisticians	Share baseline data according to a timeline that is agreed upon with the PPI.		

#	Who	Task	Attachment	Related SOP
5.	CSS	<p>After the primary manuscript that describes the study results has been accepted by a peer-reviewed journal, a CSS that has participated in research on the study protocol may request that the PPI and the Protocol Steering Committee grant the CSS access to the final study data.</p> <ul style="list-style-type: none"> Requests for final study data will be reviewed by the Publication and Data Sharing Committee as described in SOP NN GA 106. 		NN GA 106
6.	CSS	<p>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.</p>		
7.	DCC Biostatisticians	<p>If agreed upon, the DCC may:</p> <ul style="list-style-type: none"> 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 Committee. 		NN GA 106

C. Sharing Data with the Scientific Community

#	Who	Task	Attachment	Related SOP
1.	DCC Biostatisticians and DCC IT Lead	<p>Share data with the scientific community according to the provisions set forth in the grant award, and only after the NeuroNEXT Executive Committee and the Publication and Data Sharing Committee have approved the request.</p>		
2.	External Requester	<p>Submit a formal written request for data sharing to the DCC for approval by the NeuroNEXT Executive Committee and the Publication and Data Sharing Committee.</p>		
3.	NeuroNEXT Executive Committee and Publication and Data Sharing Committee	<p>When evaluating the request, the NeuroNEXT Executive Committee and the Publication and Data Sharing Committee will consider whether the data have been made available to CSS investigators prior to sharing with the scientific community.</p>		
4.	DCC Senior Leadership and External Requester	<p>If the data sharing request is approved by the NeuroNEXT Executive Committee and the Publication and Data Sharing Committee, and prior to any data sharing, execute a data sharing agreement that includes the following information:</p> <ul style="list-style-type: none"> a description of the data that are requested; and how the data will be used. 		
5.	DCC Senior Leadership	<p>Ensure that all data to be shared are HIPAA compliant and/or CIRB approved, as appropriate.</p>		
6.	DCC Biostatisticians and DCC Lead	<p>Create .csv files or SAS® datasets for sharing, and consult with the External Requester to determine if there are any special requirements for sharing datasets.</p>		

#	Who	Task	Attachment	Related SOP
	IT	<p>If the Requester uses another statistical program, provide datasets with the following information to facilitate the importing of .csv files or a SAS® dataset into another program:</p> <ul style="list-style-type: none"> • 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. 		

D. Sharing De-Identified Datasets for Public Use

#	Who	Task	Attachment	Related SOP
1.	DCC	<p>Redact datasets to remove all personally identifying information prior to sharing for public use.</p> <ul style="list-style-type: none"> • Prior to creating the dataset, remove all direct identifiers (e.g. name, contact information, SSN) that may be present in study data. <p>Remove or otherwise de-identify any indirect identifiers (e.g. birth date, procedure dates) that could lead to a deductive disclosure of participant identity.</p>		
2.	DCC	<p>Submit de-identified datasets and associated documentation to NINDS for archiving and public access, consistent with the current NINDS Data Sharing Policy.</p>		
3.	DCC Biostatisticians	<p>Provide documentation with each final dataset. Documentation may include, but is not limited to, the following information:</p> <ul style="list-style-type: none"> • how the data were collected; • details of the code used to generate the dataset; • definitions of variables and variable field locations 		

Attachment NN GA 107 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Data Sharing SOP NN GA 107				
Version	Description of Modification	Reason or Justification for Modification	Issue Date	Effective Date
1.0	New	N/A	22Mar2012	21Apr2012
2.0	Clarified requirements and timing for sharing data with CSS PIs, and added provisions for sharing baseline results. Added that data will be shared with the scientific community according to the provisions in the grant award only after approval by the NEC and the Publication and Data Sharing Committee. Added that consideration will be given as to whether study data have been made available to CSS investigators prior to sharing with the scientific community. Added references to a new NN SOP for sharing data with industry collaborators (NN GA 109).	Updates for v2.0	21Sep2016	21Oct2016