

NeuroNEXT Network

Standard Operating Procedure (SOP)




Publication Policy Development

Version 3.0

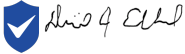
SOP NN GA 106

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date: <small>DocuSigned by Christopher Coffey</small>  I approve this document 14-Feb-2023 12:48:09 PM PST <small>C68AC8DD80334CF982AED1200765F147</small>	14-Feb-2023
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)	
Signature and Date: <small>DocuSigned by Merit Cudkowicz</small>  I approve this document 13-Feb-2023 8:22:40 AM EST <small>9F8FE4180E504C6AB0A67B835E80C644</small>	13-Feb-2023
Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)	
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Name and Title: Stacey Grabert, Pharm.D, MS, (CCC Director of Quality Assurance)

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

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR PUBLICATION POLICY DEVELOPMENT

1. POLICY

All publications based on work from the NeuroNEXT Network, must acknowledge the support of the NIH by including an acknowledgement such as: "This project has been funded in whole or in part with Federal funds from the National Institute of Neurological Disorders and Stroke, National Institutes of Health, under Grant No XXX XXXXXXXX." Grant numbers to be listed in this statement include; the NeuroNEXT Clinical Coordinating Center (CCC) and Data Coordinating Center (DCC) infrastructure grants, the Protocol Principal Investigator (PPI) study specific grant, as well as the infrastructure grant for each NeuroNEXT Clinical Study Site (CSS) that participated in the study.

All publications shall comply with the CSS NINDS Cooperative Agreement, HIPAA, the NeuroNEXT Publication and Data Sharing Guideline, and the NIH Public Access Policy.

Additionally, all publications from NeuroNEXT Network studies will comply with federal regulations on PubMed. In accordance with Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008), any publication arising from research funded in whole or in part under this agreement is subject to the NIH's Revised Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research, NOT-OD-08-033 (the "Policy"). As such, no later than 12 months after the official date of publication, an electronic version of the final peer-reviewed manuscript of such publication must be submitted to the National Library of Medicine's PubMed Central to be made publicly available. The full text of the Policy, is accessible at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html>, is incorporated herein by reference. For additional information, please visit <http://publicaccess.nih.gov/>.

Each Protocol Study conducted through the NeuroNEXT Network will be conducted as a multi-center study and a collaborative publication of results from each Study is anticipated. As such, each NeuroNEXT Clinical Study Site (CSS) will delay publication of its own data until such time that the collaborative publication is released or eighteen (18) months after the conclusion of the Protocol Study (defined as final database lock), whichever occurs first.

All data resulting from any Study conducted through the NeuroNEXT Network is required to be posted on www.clinicaltrials.gov, per current regulations.

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 Clinical Coordinating Center (CCC) and Data Coordinating Center (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 NEC is responsible to appoint the NeuroNEXT Publication and Data Sharing Committees. Members of this Committees are responsible for developing and disseminating knowledge derived from Network Studies. Members of the Committees are also responsible for updating or amending the Publication and Data Sharing Guidelines, in collaboration with the PPI and NEC as necessary, for study-specific publication instructions. The CSS Investigators who participate in each Study are responsible for complying with the policies developed by the Publication and Data Sharing Committees.

Membership on the Committees may rotate approximately every two years. In addition, the PPI of each NeuroNEXT study will be a member of the Publication and Data Sharing Committees for the duration of that study.

The PPI is responsible for working with the DCC to obtain data analysis required for primary study publication, and for submitting the primary study data for publication.

A CSS Investigator who participated in a Protocol Study may apply to the DCC at any time for access to his/her site's data, as described in the NeuroNEXT SOP on Data Sharing (NN GA 107). Any requests for study data sets beyond an individual site's data must be submitted to the Publication and Data Sharing Committees for review and approval.

If the CSS Investigator desires to publish independently, he/she shall submit proposed manuscripts to the Committees for review and comment at least thirty (30) days prior to submission for publication, and shall consider in good faith all comments provided by the Committee during the review period. In the event that the Committees identifies confidential information, the CSS will remove such confidential information from the publication. In the event that the Committee identifies that the manuscript contains patentable information, the CSS will delay publication for a period of not longer than an additional sixty (60) days to allow for patent protection to be sought. Authorship and other matters relating to publications shall be determined in accordance with academic standards and the NeuroNEXT Network Publication and Data Sharing Guideline.

4. APPLICABLE REGULATIONS AND GUIDELINES

Food and Drug Administration Amendment Act 2007 (clinicaltrials.gov reporting requirements)

5. REFERENCES TO OTHER APPLICABLE SOPS

NN GA 107 Data Sharing

6. ATTACHMENTS AND REFERENCES

NN GA 106- A Document History

7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

CCC	Clinical Coordinating Center at Massachusetts General Hospital
CSS	Clinical Study Site
DCC	Data Coordinating Center at The University of Iowa
GCP	Good Clinical Practice
HIPAA	Health Information Portability and Accountability Act
NIH	National Institutes of Health
PPI	Protocol Principal Investigator
SOP	Standard Operating Procedure

8. SPECIFIC PROCEDURES

A. Publication Review

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC	Maintains all study databases		
2.	NEC	Appoints Publication Committee members		
3.	Publication and Data Sharing Committees	Develops and adopts Network-wide publication and data sharing guidelines		
4.	Publication and Data Sharing Committees	Reviews requests for study data and proposed manuscripts		
5.	PPI	Works with the DCC to obtain data for primary publication		
6.	CSS	Requests access for datasets		

Certificate Of Completion

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 ohayonj@ninds.nih.gov
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Joan Ohayon

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Marianne Chase


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