NeuroNEXT Network

Standard Operating Procedure (SOP)

Specifications Development, Testing Plans, and Validation Documentation

Version 2.0

SOP NN DM 1004

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Christopher S. Coffey, PhD (DCC Principal Investigator)

Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)

Marianne Kearney Chase, BA (CCC Director of Clinical Operations)

Dixie J. Ecklund, RN MSN MBA (DCC Associate Director)

Katherine B. Gloer, PhD (DCC Quality Management Lead)

Janice Cordell, RN MPH (NINDS, NeuroNEXT Program Official)

September 21, 2016
Issue Date

October 21, 2016
Effective Date (*30 calendar days after the Issue Date*)

NN DM 1004

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SPECIFICATIONS DEVELOPMENT, TESTING PLANS, AND VALIDATION DOCUMENTATION

SOP: NN DM 1004 Version No. 2.0 Effective Date: 21Oct2016	SPECIFICATIONS DEVELOPMENT, TESTING PLANS, AND VALIDATION DOCUMENTATION	Supercedes Document: Version 1.0 Effective Date: 29Apr2012

1. POLICY

The Data Management (DM) Team at the NeuroNEXT Data Coordinating Center (DCC) participates in all aspects of clinical data management, including the development of User Specifications and Testing Plans for electronic CRFs and protocol websites, the testing of these applications, and the creation of validation documentation. Validation documentation consists of two primary components: 1. The FogBugz® tracking system, which provides a tracking mechanism and case history for specifications and testing plan development, testing results, and the location of the validation documentation (screenshots); and 2. The 'Validation Document' which contains screenshots representing testing results for each requirement listed in the testing plan.

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 Clinical Coordinating Center (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

For most projects, the DCC is generally responsible for the following aspects of data management: development of User Specifications and Testing Plans for electronic CRFs and protocol websites, the testing of these applications, and the creation of validation documentation.

The responsibility to conduct any or all of these activities may be delegated at the discretion of the Sponsor to the DCC or to subcontractors of the DCC, where applicable. 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	Good Clinical Practice: Consolidated Guidance, April 1996
ICH E6, 2.10	The Principles of ICH GCP
ICH E6, 5.1	Quality Assurance and Quality Control
FDA Guidance	Computerized Systems Used in Clinical Investigations, FDA, May 2007
FDA Guidance	Computerized Systems Used in Clinical Trials, FDA, April 1999
FDA Guidance	21 CFR Part 11, Electronic Records; Electronic Signatures – Scope and Application, FDA, August 2003
FDA Guidance	General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 2002

5. REFERENCES TO OTHER APPLICABLE SOPs

NN CS 702	Application Development and Validation
NN DM 1001	Clinical Data Management
NN DM 1002	Data Management Plan Development
NN DM 1003	Case Report Form Development
NN DM 1005	Data Collection and Data Handling

6. ATTACHMENTS AND REFERENCES

NN DM 1004 – 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
Clinical Study Site (CSS)	Clinical site that conducts research for a NeuroNEXT protocol within or outside the Network
DCC	Data Coordinating Center at The University of Iowa
DM	Data Management Team at the DCC
IT	Information Technology Team at the DCC
Protocol Principal Investigator (PPI)	Principal Investigator of a NeuroNEXT protocol

8. SPECIFIC PROCEDURES

A. Specifications Development for eCRFs

After the paper CRF templates for a project are approved by the CRF Development Committee and the Sponsor (if applicable), a user specifications document is created for each CRF template. User specifications (specs) are created by the DCC DM Team in consultation with the Study Team, and describe the user requirements for an electronic Case Report Form (eCRF) or website module.

To maintain continuity and to track the evolution of an eCRF application or website module throughout its life cycle, only one specifications document is used for each eCRF or module that is developed. A change table is added to each newly created user specifications document so that later modifications may be tracked. Modifications are inserted into the original specification document.

#	Who	Task	*Attachment/ Reference*	Related SOP
1.	DCC DM	Create only one specifications document for use throughout the life of an eCRF or website module. Collaborate with the IT Team during the spec development process to ensure that specifications clearly define and describe the user requirements.		NN DM 1001 NN DM 1002 NN DM 1003

#	Who	Task	*Attachment/ Reference*	Related SOP
2.	DCC DM	Develop the specification document.		
3.	DCC DM	Track future modifications to an eCRF in the change table in the spec document, and insert any modifications to the requirements into the spec document.		

B. Creation of Testing Plans

Comprehensive testing is critical for ensuring that an eCRF or other application is functioning according to specifications. For each specification document, a corresponding testing plan is created that describes the testing conditions for thoroughly testing all of the requirements that are detailed in the specifications document. The testing plan contains the following components that must be completed for each of the testing conditions:

Sequence Number – a unique identifier for each test condition.
Requirement Number – the same requirement number used in the Specifications Document.
Testing Conditions – the instructions to be followed in order to test the requirement.
Expected Result – the expected result after the test condition is completed.
Test Result (Pass/Fail) – a Pass/Fail result is recorded in this column at the time of the test. Pass indicates that the testing condition performed as expected.
Comments – any comments associated with the test; generally used to describe what happened when a test failed.

An electronic testing plan workbook is created to document the testing of an eCRF or website module throughout its life cycle. Each sheet in the workbook represents the testing that has been completed for a particular work effort within a specific testing environment. For new eCRF development, the testing plan worksheet contains test conditions for all user requirements. For modifications to an eCRF, the subsequent worksheets that are added to the testing plan refer only to test conditions for the modified or added requirements.

#	Who	Task	*Attachment/ Reference*	Related SOP
1.	DCC DM	Create a testing plan that describes the testing conditions that are used to test all of the requirements detailed in the specifications document. An Excel® spreadsheet workbook is the preferred tool that is used by the DCC to create testing plans.		NN DM 1001
2.	DCC DM	For form modifications, refer only to the modified requirements in subsequent testing plan worksheets.		

C. Application Development and Testing

After specifications have been finalized and a testing plan has been created, a case is created in the FogBugz® application to initiate the process of IT development, testing, and the eventual

move of the application to the Production environment, where the application is made available to Clinical Study Sites (CSS).

Prior to application development, the DM and IT Team Leads prioritize and batch together cases for development into a FogBugz® Milestone. Cases are then assigned to the IT Developers for coding. Internal correspondence between Data Managers and Developers is tracked in the associated development case during the application development and testing process.

When the case is available for testing, the tester completes each test condition listed on the testing plan worksheet, documents whether the test passed or failed, and adds comments to describe the nature of an error or bug. Once testing is completed, the testing plan worksheet is attached to the appropriate FogBugz® case.

#	Who	Task	*Attachment/ Reference*	Related SOP
1.	DCC DM	After the specifications have been finalized and a testing plan has been created, create a case in the FogBugz® application to initiate the IT development and testing process.		NN DM 1001
2.	DCC DM	Follow the procedures described in NeuroNEXT SOP NN CS 702 to test the application in the Test and Stage environments, and document all testing results in the testing plan workbook.		NN CS 702
3.	DCC DM	For failed test conditions, provide clear descriptions of what was tested, the result, and how the result differed from the expected result (if applicable) in the testing plan workbook.		
4.	DCC DM	If necessary, meet with the developer to clarify testing issues or to discuss possible modifications to the user specifications.		

D. Validation Document

The 'Validation Document' is generated during testing in the Stage environment.

#	Who	Task	*Attachment/ Reference*	Related SOP
1.	DCC DM	After testing is completed, create a validation document, if applicable.		NN DM 1001
2.	DCC DM	Create screen shots to document the testing of each requirement, when appropriate.		
3.	DCC DM	Label each screen shot with the corresponding Requirement number, the Sequence number tested, and the date of the screenshot.		

E. Save/Audit Testing

This testing ensures that each data item on an eCRF maps to the correct data field and data table in the database. Save/Audit Testing is performed by using the electronic data capture (EDC) website and SAS® software (SAS Institute Inc®, Cary, NC).

#	Who	Task	*Attachment/ Reference*	Related SOP
1.	DCC DM	Perform save/audit testing for all new studies and/or new eCRF development.		NN DM 1001

F. Milestone Review

While the Milestone is in the Stage environment, the DCC DM team performs targeted testing to help ensure that the application has not been affected by programming changes.

#	*Who*	*Task*	*Attachments /References*	*Related SOP*
1.	DCC DM	Create a FogBugz case to track the Milestone review.		
2.	DCC DM Tester	Perform a Milestone review in the Stage environment (using a Milestone checklist, if applicable) to check the functionality of all modules and the general performance of the website to ensure that the application has not been affected by programming changes. Reviews may include, but are not limited to, checks of: • Website access • Website configurations • eCRF submissions • Adverse Event Reporting System • Post-complete change functionality		
3.	DCC DM Tester	Meet with DCC DM Lead to discuss any issues that were discovered during the review.		
4.	DCC DM Lead	Determine if issues are significant enough to delay the move to Production, or can be addressed in a subsequent Milestone.		
5.	DCC DM Tester	In the FogBugz case, describe the issues to be addressed and assign the case to the DCC IT developer.		
6.	DCC IT	Resolve the issues described in the FogBugz case, and assign the case to the DCC Tester.		
7.	DCC DM Tester	Ensure that all issues have been resolved before assigning to the DCC IT Lead or designee for the move to Production.		

Attachment NN DM 1004 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Specifications Development, Testing Plans, and Validation Documentation SOP NN DM 1004				
Version	**Description of Modification**	**Reason or Justification for Modification**	**Issue Date**	**Effective Date**
1.0	New	N/A	30Mar2012	29Apr2012
2.0	Removed outdated procedures and revised several procedures related to specifications development, testing plans, application development and testing, validation documentation, and save/audit testing so that the SOP reflects current procedures. Clarified that relevant procedures in this SOP apply also to developing, testing, and validating website modules. Added a section on Milestone review.	Updates for v2.0	21Sep2016	21Oct2016