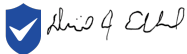# NeuroNEXT Network

Standard Operating Procedure (SOP)
Application Development and Validation
Version 3.0
SOP NN CS 702

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by

Signature and Date:	
DocuSigned by Christopher Coffey *Christopher Coffey* | I approve this document | 16-Feb-2023 | 11:05:19 AM PST C68AC8DD80334CF982AED1200765F147	16-Feb-2023
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)	
Signature and Date: DocuSigned by Merit Cudkowicz *Merit Cudkowicz* | I approve this document | 17-Feb-2023 | 1:48:58 AM EST 9F8FE4180E504C6AB0A67B835E80C644	17-Feb-2023
Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)	
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Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)	

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Name and Title: Dixie J. Ecklund, RN MSN MBA (DCC Associate Director)

Signature and Date:

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22-Feb-2023

Name and Title: Stacey Grabert, Pharm.D, MS, (CCC Director of Quality Assurance)

Signature and Date:

DocuSigned by Joan Ohayon

Joan Ohayon | I approve this document
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21-Feb-2023

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

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NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR APPLICATION DEVELOPMENT AND VALIDATION

1. POLICY

The purpose of this SOP is to provide guidelines to the NeuroNEXT Data Coordinating Center (DCC) Information Technology (IT) and Data Management (DM) Teams for application development and validation. Many of the processes referred to in this SOP are described in greater detail in other NeuroNEXT SOPs. Please refer to Section 5: References to Other Applicable SOPs for a listing of relevant SOPs.

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 E6(R2). 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. DCC policies conform to IT policies set forth by Information Technology Services at The University of Iowa and the Office of Information Technology in the University of Iowa College of Public Health.

3. ROLES AND RESPONSIBILITIES

The DCC IT and DM Teams and any authorized individuals at The University of Iowa who are involved in development and/or validation of NeuroNEXT applications are responsible for adhering to the procedures outlined in this SOP.

4. APPLICABLE REGULATIONS AND GUIDELINES

Microsoft Corporation	Visual Basic Language Specification (Visual Studio 2010)
Microsoft Corporation	MSDN: Design Guidelines for Class Library Developers
Microsoft Corporation	MSDN: Guidelines and Best Practices
21 CFR Part 11	Electronic Records; Electronic Signatures
FDA	Guidance for Industry: Part 11, Electronic Records; Electronic Signatures – Scope and Application (August 2003)
FDA	Guidance for Industry: Computerized Systems Used in Clinical Investigations (May 2007)
FDA	Guidance for Industry: Computerized Systems Used in Clinical Trials (April 1999)
FDA	Guidance for Industry: General Principles of Software Validation (January 2002)

5. REFERENCES TO OTHER APPLICABLE SOPs

NN CS 703	IT Environments
NN DM 1002	Data Management Plan Development
NN DM 1003	Case Report Form Development
NN DM 1004	Specifications Development, Testing Plans, and Validation Documentation
NN DM 1005	Data Collection and Data Handling

6. ATTACHMENTS AND REFERENCES

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DCC   CTSDMC FogBugz® User Manual

National Institute of Standards and Technology (NIST) Guides:

NIST   Guide to Secure Web Services, Special Publication 800-95 (August 2007)

NIST   Guide to SSL VPNs, Special Publication 800-113 (July 2008)

NIST   Guidelines on Securing Public Web Servers, Special Publication 800-44 (Version 2)
        (September 2007)

NIST   Technical Guide to Information Security Testing and Assessment, Special Publication 800-115 (September
        2008)

NIST   Information Security Handbook: A Guide for Managers, Special Publication 800-100
        (October 2006)

7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

CCC	Clinical Coordinating Center at Massachusetts General Hospital
Clone	A copy of the Production application environment that is used for testing and training purposes.
CTSDMC	Clinical Trials Statistical & Data Management Center at The University of Iowa DCC
DCC	Data Coordinating Center at The University of Iowa
Demo	A copy of the Production application environment that is used for training purposes. The Demo environment does not contain clinical study data.
Dev (Development)	IT environment used for development of applications
FogBugz®	Project management software licensed to the DCC
Milestone	A grouping (batch) of development project cases that comprise an application
Production	Application and database environment in which study data are collected.
Stage	IT environment used for final validation testing
Test	IT environment used for initial application testing

8. SPECIFIC PROCEDURES

User Specifications and Testing Requirements

To create an application that meets the needs of the NeuroNEXT user, the DCC requires that detailed user specifications and application testing requirements are submitted to the IT department prior to the initiation of any application development. User specifications may include, but are not limited to, the following information:

- all inputs the system will receive;
- all outputs the system will produce;
- all functions that the system will perform;
- all performance requirements of the application;
- the definition of internal, external and user interfaces;
- the definition of an error and how an error should be handled;
- the intended operating environment of the application;
- all ranges, limits, defaults and specific values that the application will accept.

Management of the Development and Testing Process

The DCC utilizes a customized version of the FogBugz® web-based project management tool to manage tasks related to application development and testing. For each application to be developed, the associated user specifications and testing plan documents are attached to a work unit, or 'case', in the FogBugz® tool. Cases are periodically reviewed, prioritized, and batched into a group (Milestone) by the DM and IT Leads.

Once a case is placed into a Milestone, it is assigned to the appropriate developer(s) or staff member(s). The case is used to track progress through the development and testing life cycle. All cases in a Milestone are moved together throughout the development and testing environments to maintain the integrity of the application development and testing process.

Data Dictionary and Database Design for Case Report Form Development

The Data Dictionary is a metadata repository for the items specified in a Case Report Form (CRF) template. The Data Dictionary is created based on the user requirements, which define validation information and provide the description of all variables. The validation information consists of valid values, mandatory information, data types (e.g. integer, date, character), and override options. Variable information for the user interface design is also incorporated into the Data Dictionary, and may include web control type (e.g. radio button, text, or drop down box), form position, and item number.

Database tables, stored procedures, user interface forms, and code-behind files are initially created from information entered into the Data Dictionary. Each CRF application has unique requirements, and the preliminary eCRFs and files are modified by the developer to adhere to the user specifications. The database design must specify the primary key for the table, stored procedures, functions, triggers, and foreign key relationships between related tables. Because the database will be required to perform a variety of functions, the need for a normalized and relational database is considered throughout the database design process. This design facilitates access to the data and simplifies the performance of necessary analyses.

Application Development and Code Management

The DCC IT Development Team utilizes Microsoft® Visual Studio.NET® to develop applications. The IT Team has reviewed and, where appropriate, regards the naming conventions, coding strategies, and standards used in Visual Studio.NET® as accepted DCC IT development practice. New conventions, strategies, and standards are reviewed periodically by the entire DCC IT Team.

Applications are developed with a three-tier architecture (User Interface, Business, and Data) using object-oriented programming language. This architecture organizes the code to enable the sharing and reuse of components across applications, which in turn minimizes code duplication, creates a stable environment, and increases application performance.

The IT Team uses a version control program to manage application code. This program maintains a current version of the code, and tracks all changes to the code. The developer creates a script for any schema or stored procedure changes for a case and commits the information to the version control program. The program also tracks the addition of new data, and modifications to existing data, the time and date of a data change, and the User ID of the developer who made the change.

Application Environments

The DCC IT development process utilizes four application environments (Development [Dev], Test, Stage, and Production) to control development, coding changes, and validation testing processes that lead to final NeuroNEXT applications. The Dev environment, used only by the developer, is created for the initial development, testing, and preliminary validation of an application. Once the developer verifies that coding or modifications are complete and ready for further testing, the code is committed to the version control program and the FogBugz® case is updated. After all cases in a Milestone have been approved for deployment from the Dev environment, the IT Lead or IT Administrator moves the entire Milestone into a newly created Test environment for testing by the DM Team or other appropriate personnel. In the Test environment, cases are validated by testers from outside the IT Team. Upon completion of testing and any necessary code modifications, all cases in the Milestone are moved to the Stage environment. The Stage environment allows for a final validation in a setting as close to the current Production

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environment as possible. After all cases have passed testing in the Stage environment and the Milestone has passed the milestone checklist, the Milestone is moved to the Production environment.

Two additional application environments are created from the current Production environment. The Clone environment is an exact mirror of Production, and is used to perform end-user checks and for troubleshooting any issues that may arise with the application at the clinical sites. The Demo environment is also a mirror of the Production environment that is created to demonstrate the system function to outside parties or for site training purposes. The Demo environment is cleared of any study data before it is used for these purposes.

Future Coding Modifications

Once a NeuroNEXT application is moved to the Production environment, additional coding modifications may still be required. These changes may be requested by the user (e.g. a request for a new CRF item or application functionality), or may involve corrective maintenance (changes to eliminate errors or faults) or perfective maintenance (changes to improve the performance, maintainability, or another trait of the system). Any change to the program is documented, and becomes part of the application record.

Documentation of changes may include, but is not limited to, the following: the identity of the individual who initially reported a bug or requested a change in the application; the developer who was assigned to fix or investigate the issue; and a confirmation that the request was finally resolved. Modifications are tracked using FogBugz® and the version control program.

A. Coding Guidelines

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC IT	Review new naming conventions, coding strategies, and standards to be used for developing applications.		
2.	DCC IT	Develop applications utilizing three-tier architecture: User Interface, Business, and Data.		
3.	DCC IT	Code applications using object-oriented programming language.		

B. Specifications and Requirements

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC DM and IT	Create end-user specifications and testing plans that include all requirements that are necessary for the intended use of the application.		
2.	DCC DM and IT	Review User specifications and requirements to ensure that all inputs, outputs, and functions have been specified.		NN DM 1002 NN DM 1004
3.	DCC DM and IT	Ensure identified data items include specific information regarding valid values or ranges, data types, skip-out relationships, and mandatory requirements.		
4.	DCC DM and IT	Confirm that logic checks are identified between data items on a form level and inter-form level.		
5.				

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C. Case Assignment

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC User and IT Leads	Prioritize and assign cases to a FogBugz® Milestone.	CTSDMC FogBugz® User Manual	NN CS 702 NN DM 1004
2.	DCC IT Lead	Assign each case in the Milestone to a DCC IT Developer.		
3.	DCC IT Lead and Developer	Review and discuss each case to ensure that user specifications are understood prior to development work.		NN DM 1004
4.	CTSDMC IT and DM Teams	When assigning cases to another user, follow status assignment guidelines described in the FogBugz® User Manual.	CTSDMC FogBugz® User Manual	

D. Database Design

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC IT and DM	For eCRF development, create database dictionary to reflect end-user specifications and requirements. This information includes, but is not limited to, variable names, description, data type, valid values or ranges, mandatory requirements, and logical skip-out values.		NN DM 1004 NN DM 1005
2.	DCC IT	Design database and tables. Tables include primary key assignments, stored procedures, functions, and foreign key relationships.		
3.	DCC IT	Verify that tables are appropriately normalized for the application.		
4.	DCC IT	Limit access to the database to appropriate users.		

E. Application Coding/Review

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC IT	Develop application according to DCC-accepted coding strategies and standards.		NN CS 703
2.	DCC IT	Develop application using object-oriented programming language and relate coding to user interface, business rules, and data models.		
3.	DCC IT Developer	In the Dev Environment, verify that the application meets specifications.		NN CS 703 NN DM 1004
4.	DCC IT Developer	After determining that the application meets specifications, commit code and scripts to the version control program. Update the case in FogBugz® and assign to the DCC IT Lead or designee.	FogBugz® User Manual	NN DM 1004

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#	Who	Task	Attachment/ Reference	Related SOP
5.	DCC IT Lead or designee	After all cases in the Milestone are ready for testing, deploy the application to the Test Environment. Assign to DCC DM Lead or designee.		NN CS 703 NN DM 1004

F. Application Testing

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC IT	Assign individual cases within the Milestone to DCC DM team members or appropriate personnel for testing.		
2.	DCC DM	In the Test environment, perform testing of all requirements that are specified in the Testing Plan.		NN DM 1004
3.	DCC DM	Document errors that are discovered during application testing. For cases with errors, and reassign the case to the DCC IT Developer for resolution.		
4.	DCC IT Developer	Correct any errors that were found during testing in the Test environment. After the application is redeployed to the Test environment, reassign the case for additional testing.		
5.	DCC DM	Confirm that the application meets all specifications. Reassign the case to the DCC IT Lead.		
6.	DCC IT Lead or designee	After all cases in Milestone are ready for validation testing, deploy the application to the Stage Environment. Assign the case to the DCC DM Lead or designee.		NN CS 703
7.	DCC DM	Perform final testing in Stage environment to validate the application.		NN DM 1004
8.	DCC DM	Document the observed results from application testing. If errors occur, reassign to the appropriate DCC IT team member for resolution.		
9.	DCC IT Developer	Correct any errors that were found during testing in the Stage environment. After the application is redeployed to the Stage environment, reassign the case for additional testing.		
10.	DCC DM	Create validation documentation of all test results in the Stage environment.		NN DM 1004
11.	DCC DM	Confirm that the application meets all specifications. Reassign the case to the DCC IT Lead or designee.		NN CS 703 NN DM 1004

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#	Who	Task	Attachment/Reference	Related SOP
12.	DCC IT Lead or designee	After the milestone review has been completed, deploy the application to the Production environment.		NN CS 703 NN DM 1004
13.	DCC IT Lead or designee	Create the Clone environment based on the Production application and database.		
14.	DCC IT Lead or designee	Assign to the DCC DM Lead or designee for final checks in the Clone environment.		
15.	DCC DM or designee	Perform spot-checks in the Clone environment. Collaborate with the DCC IT Team to resolve any issues that may be discovered.		
16.	DCC DM Lead	If applicable, assign cases to non-IT/DM study team members for final checks.		NN DM 1004
17.		Ensure that all validation documentation has been completed before closing the FogBugz® case.		

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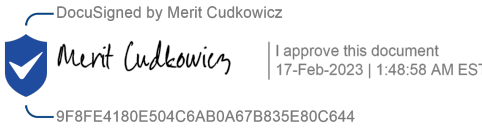| Signer Events	Signature	Timestamp
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