NeuroNEXT Network

Standard Operating Procedure (SOP)
Clinical Data Management
Version 1.0
SOP NN DM 1001

Originators: NeuroNEXT CCC and DCC Personnel

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NN DM1001
NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR
CLINICAL DATA MANAGEMENT

SOP: NN DM 1001
Version No. 1.0
Effective Date:

CLINICAL DATA MANAGEMENT
Supercedes
Document: N/A
Effective Date: N/A

1. POLICY

All data for NeuroNEXT protocols will be managed in compliance with NeuroNEXT policies, and
applicable Sponsor and regulatory requirements. The NeuroNEXT Data Coordinating Center (DCC)
will instruct site personnel to collect, transcribe, correct, and transmit the data onto source documents,
CRFs, and other forms used to report, track and record clinical research data. The DCC monitors
clinical sites to ensure compliance with data management requirements and Good Clinical Practices.
The DCC is responsible for developing, testing, and managing clinical data management activities, as
required, at the study sites, the clinical coordinating sites, and at the DCC.

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

The DCC is responsible for all aspects of clinical data management, and for properly instructing key
study personnel (including the CCC, the CSS, and DCC staff) on how to collect, transcribe, correct
and transmit the data onto CRFs or other data collection forms and logs.

The DCC is responsible for establishing procedures to ensure that clinical data management activities
occur as required at the CCC, the CSS, and at the DCC.

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. 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, 2.10 The Principles of ICH GCP
ICH E6, 5.1 Quality Assurance and Quality Control
ICH E6, 5.5 Trial Management, Data Handling, Recordkeeping, and Independent Data
Monitoring Committee

5. REFERENCES TO OTHER APPLICABLE SOPS

NN SS 401 Site Selection and Qualification
NN SS 402 Site Initiation Visits and Site Training
NN SS403 Routine Monitoring Visits
NN PM 503 Study Materials Development
NN PM 504 Investigational Site Staff Training
NN CS 702 Application Development and Validation
NN CS 704 System Security Measures and Website Access
NN BIO 906 Report Writing
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
NN DM 1006 Adverse Event Coding
NN DM 1007 Standardization of Classification Systems

6. ATTACHMENTS AND REFERENCES
   NN DM 1001 – A Document History
   NN DM 1005 – B Data Change Request Form

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
   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                 Data Coordinating Center at The University of Iowa
   DM                  Data Management Team at the DCC
   Protocol Principal Investigator (PPI) Principal Investigator of a NeuroNEXT protocol
   PWG                 Protocol Working Group
### 8. SPECIFIC PROCEDURES

#### A. Data Management Overview

<table>
<thead>
<tr>
<th>#</th>
<th>Who</th>
<th>Task</th>
<th>Attachment/Reference</th>
<th>Related SOP</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>DCC DM</td>
<td>Develop and maintain the protocol Data Management Plan.</td>
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<td>NN DM 1002</td>
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<td>NN DM 1003</td>
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<td>2</td>
<td>PPI and DCC DM</td>
<td>Develop case report form templates (paper forms), protocol website specifications, and eCRF specifications.</td>
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<td>NN DM 1003</td>
</tr>
<tr>
<td>3</td>
<td>DCC DM</td>
<td>After the website and data entry systems have been developed, test software applications and provide validation documentation.</td>
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<td>NN CS 702</td>
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<td>4</td>
<td>DCC DM</td>
<td>Create User Manuals that describe data management activities and processes.</td>
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<td>5</td>
<td>DCC DM</td>
<td>Train and certify CSS, CCC, and DCC personnel in the proper procedures for entering and/or changing data, navigating the protocol website, and utilizing all applicable modules related to data entry.</td>
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<td>NN DM 1005</td>
</tr>
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<td>6</td>
<td>DCC DM</td>
<td>Create procedures and train CSS, DCC, and CCC personnel (if applicable) regarding the transfer of electronic data and/or paper CRF data.</td>
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<tr>
<td>7</td>
<td>DCC DM</td>
<td>Assist with the creation and management of data reports.</td>
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<td>NN BIO 906</td>
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#### B. Data Collection and Transcription

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<tr>
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<tbody>
<tr>
<td>1</td>
<td>DCC</td>
<td>Ensure that the clinical protocol, the Data Management Plan, User Manuals and guides, and/or Manuals of Operation describe in detail all methods for collecting, evaluating, changing and transmitting subject data to the DCC.</td>
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<td>NN PM 503</td>
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<td>NN DM 1002</td>
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<td>2</td>
<td>PPI and DCC DM</td>
<td>Develop protocol-specific CRFs, other appropriate data collection forms, and log sheets to capture all required study information.</td>
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<td>NN DM 1003</td>
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<tr>
<td>3</td>
<td>DCC</td>
<td>During the Qualification and/or Site Initiation Visit, confirm that sites satisfy requirements for data collection, storage, transmission, and retention.</td>
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<td>NN SS 401</td>
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<td>NN SS 402</td>
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<td>4</td>
<td>DCC</td>
<td>During the Site Initiation Visit, or when appropriate, train site staff on proper completion of all CRFs, data collection forms, and log sheets.</td>
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<td>NN SS 402</td>
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<td>5.</td>
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<td>If using remote data entry or other electronic systems, train CSS personnel on the use of those systems.</td>
<td>NN DM 1005-B</td>
<td>NN DM 1005</td>
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<td>6.</td>
<td></td>
<td>Train site staff on proper correction of incorrect entries.¹</td>
<td>NN DM 1005-B</td>
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Note:
¹Include the following CRF completion guidelines: Transcribe data to the paper CRF (or enter data into the eCRF) in a timely manner from the source documentation; record all subject data and information in black ballpoint pen on paper CRF; complete all fields according to protocol specifications and site initiation training; correct errors on paper CRF by striking through the error with a single straight line, making the correction and then dating and initialing the correction; ensure the original entry is not obliterated by the correction and if necessary, note an explanation or clarification in the CRF margin. “White-Out” or similar products that obscure original data or information may not be used to correct errors on source documents or paper CRFs under any circumstances.

C. Data Management and Retention

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<tbody>
<tr>
<td>1.</td>
<td>DCC DM</td>
<td>Specify a method for site staff to review (and/or audit) and correct data prior to transmission to the DCC.¹</td>
<td>NN SS 402</td>
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<td>2.</td>
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<td>If sites do not comply with data management procedures, work with the PPI/CCC to document noncompliance and (if necessary) institute training or termination procedures.</td>
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Note:
¹ Monitors must not make any changes to original subject documentation or CRF.
<table>
<thead>
<tr>
<th>Version</th>
<th>Description of Modification</th>
<th>Reason or Justification for Modification</th>
<th>Completion Date</th>
<th>Issue Date</th>
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<td>&lt;Provide a brief but complete summary of the modifications to the SOP&gt;</td>
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