NeuroNEXT Network

Standard Operating Procedure (SOP)
Subject Eligibility and Enrollment
Version 1.0
SOP NN SM 603

Originators: NeuroNEXT CCC and DCC Personnel

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April 13, 2012
Issue Date

May 13, 2012
Effective Date (30 calendar days after the Issue Date)
1. POLICY

It is the policy of the NeuroNEXT Network that only those subjects who meet the eligibility criteria for a given NeuroNEXT study may be enrolled in that study. Documentation stating that each subject meets the inclusion/exclusion criteria must be available in his/her study subject file and/or in the source documentation, so that the eligibility of each subject can be ascertained.

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 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 participating Site Principal Investigator (PI) is responsible for ensuring written confirmation of a subject's eligibility to be enrolled in a clinical study prior to his/her enrollment in the study.

Study Site PIs are responsible for reviewing and personally signing and dating all Subject Eligibility Forms prior to enrolling a subject. If the task of reviewing subject eligibility is delegated to any site staff member, this must be clearly documented, and delegation of this task must be in compliance with the study protocol, Central Institutional Review Board (CIRB) policies, local institutional policies, and state and federal laws.

Appropriate Subject Eligibility Forms, containing all necessary elements for complete documentation of the subject eligibility review process required by each NeuroNEXT protocol, will be created by the Protocol Principal Investigator (PPI) in collaboration with the DCC and CCC. Screening and Enrollment Logs, and/or other tools, may be developed and implemented on a per protocol basis at the discretion of the PPI, DCC, CCC or study monitors to ensure proper tracking of eligibility and enrollment activities at study sites. Subject Eligibility Forms and other logs or tools will be distributed to each site by the study monitor at the Site Initiation Visit, or during trial participation.

Completed Subject Eligibility Forms must be filed in the subject’s file. Study monitors will review subject eligibility and enrollment documents during on-site monitoring visits, and remotely in the interim as necessary.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.60 General Responsibilities of Investigators
ICH E6, 4.5 Compliance with Protocol
ICH E6, 4.7 Randomization Procedures and Unblinding
ICH E6, 5.5 Trial Management, Data Handling and Record Keeping

5. REFERENCES TO OTHER APPLICABLE SOPS
NN GA 103 Document Development and Change Control
NN SS 402 Site Initiation Visits and Site Training
NN SS 403 Routine Monitoring Visits
NN SS 405 Study Close Out Visits

6. ATTACHMENTS AND REFERENCES
NN SM 603 - 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 Practices
ICH International Conference on Harmonisation
PPI Protocol Principal Investigator
Site PI Site Principal Investigator

8. SPECIFIC PROCEDURES
A. Subject Eligibility Documentation

<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>CCC, DCC, PPI or their designee</td>
<td>Prepare a Subject Eligibility Form to include all inclusion/exclusion criteria listed in the protocol.</td>
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<td>NN GA 103</td>
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<tr>
<td>2.</td>
<td>CCC, DCC, PPI or their designee</td>
<td>Prepare, as needed, a Screening and Enrollment Log for use at each study site.</td>
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<td>NN GA 103</td>
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<td>3.</td>
<td>CCC, DCC, PPI or their designee</td>
<td>Provide these forms to site study personnel prior to the site initiation visit.</td>
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<td>NN SS 402</td>
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B. Conduct of Screening Activities at the Site

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<tbody>
<tr>
<td>1.</td>
<td>CCC Project Manager, DCC Study Monitor</td>
<td>Instruct investigators, as appropriate per protocol, to use the Screening and Enrollment Log as a running list of all potentially eligible subjects screened for the study and to track each subject’s informed consent status if enrolled. Instruct investigators that logs submitted to the DCC should not contain personal identifying information.</td>
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<td>2.</td>
<td>CCC Project Manager, DCC Study Monitor</td>
<td>Instruct investigators to complete a Subject Eligibility Form for each potential subject, based on discussions with the subject and a review of his/her medical records.</td>
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<td>3.</td>
<td>DCC Study Monitor</td>
<td>Verify that logs and checklists and originals or copies of appropriate supporting documentation are held in each site's study file or specific subject file, as appropriate.</td>
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Attachment NN SM 603 - A. Document History