NeuroNEXT Network

Standard Operating Procedure (SOP)
Site Performance Monitoring
Version 1.0
SOP NN SS 404

Originators: NeuroNEXT CCC and DCC Personnel

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NN SS 404
NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SITE PERFORMANCE MONITORING

SOP: NN SS 404
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SITE PERFORMANCE MONITORING

Supercedes
Document: N/A
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1. POLICY

The NeuroNEXT Clinical Coordinating Center (CCC) will work with the Data Coordinating Center (DCC) and Protocol Principal Investigator (PPI) to monitor site performance at all Clinical Study Sites (CSS) participating in Network studies. The CCC will work with the DCC and PPI to create site performance goals and metrics for each Network study, and will ensure that these goals and metrics are communicated to each participating CSS. In instances where a CSS is not meeting performance goals or metrics, the CCC (in collaboration with the DCC and PPI) will assist the CSS in identifying root causes for performance issues. The CCC will work with the CSS to develop individual Corrective Action and Preventative Action (CAPA) plans and design more effective procedures to prevent similar issues in the future.

The CCC, DCC, and PPI will determine study-specific criteria for suspension and/or termination of CSS participation in a study for inadequate enrollment, non-compliance with the study protocol or Good Clinical Practice (GCP) principles, or other serious issues related to site performance.

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 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 CCC site intervention team, in collaboration with the DCC and PPI (or designee), will develop site performance metrics for each Network study.

The CCC site intervention team, working in collaboration with the CCC Project Manager (PM), PPI (or designee) and DCC, is responsible for pro-actively identifying potential issues at each CSS. If issues are identified, the CCC site intervention team is responsible for working with the CSS to analyze the root cause of the issue and to develop a CAPA plan.

The CCC site intervention team is responsible for assisting each CSS with implementation of CAPA plans.

The CCC, DCC and PPI (or designee) are responsible for determining criteria for suspension and/or termination of CSS participation in a study.

The PPI or his/her designee, under the direction of advice from the Protocol Steering Committee (PSC), is responsible for communicating any issues related to suspension or termination of CSS participation in a study, and for communicating any decisions regarding these matters to the CCC, the Central Institutional Review Board (CIRB), the DCC, the protocol study team, and the CSS.

The PSC is responsible for advising the PPI or his/her designee on issues related to suspension or termination of CSS participation in a study.

The DCC is responsible for performing study close-out visits, as needed.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50 General Responsibilities of Sponsors
21 CFR 312.53  Selecting Investigators and Monitors
ICH E6, 2.7  The Principles of ICH GCP
ICH E6, 5.1  Quality Assurance and Quality Control

5. REFERENCES TO OTHER APPLICABLE SOPS
   NN SS 405  Study Close Out Visits
   NN PM 501  Communication
   NN SM 602  Central Institutional Review Board Reporting

6. ATTACHMENTS AND REFERENCES
   NN SS 404 – A  Document History

7. TERMS AND ABBREVIATIONS
   The following terms and abbreviations are used in this document:
   
   CAPA  Corrective Action and Preventative Action plan
   CCC  Clinical Coordinating Center at Massachusetts General Hospital
   CIRB  Central Institutional Review Board (Partners Healthcare)
   CSS  Clinical Study Site
   DCC  Data Coordinating Center at The University of Iowa
   FDA  U.S. Food and Drug Administration
   GCP  Good Clinical Practice
   ICH  International Conference on Harmonisation
   PM  Project Manager
   PPI  Protocol Principal Investigator
   PSC  Protocol Steering Committee

8. SPECIFIC PROCEDURES
   A. Site Performance Monitoring

<table>
<thead>
<tr>
<th>#</th>
<th>Who</th>
<th>Task</th>
<th>Attachment / References</th>
<th>Related SOP</th>
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<tbody>
<tr>
<td>1.</td>
<td>CCC, DCC, and PPI or designee</td>
<td>Develop site performance metrics for each study</td>
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<td>2.</td>
<td>CCC Site Intervention Team</td>
<td>Proactively identify site performance issues, in collaboration with the CCC PM, DCC, and PPI</td>
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<td>3.</td>
<td>CCC, DCC, and PPI or designee</td>
<td>Perform root cause analysis and develop CAPA plans</td>
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<td>4.</td>
<td>CCC Site Intervention Team</td>
<td>Work with CSS to implement CAPA plans</td>
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<td>5.</td>
<td>CCC, DCC, and PPI or designee</td>
<td>Determine criteria for suspension and/or termination of CSS participation in study</td>
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### A. Closing a Site For Cause

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<td>1</td>
<td>PPI or designee</td>
<td>Discuss potential suspension and/or termination of CSS participation in study with PSC</td>
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<td>2</td>
<td>PSC</td>
<td>Advise PPI on issues related to CSS suspension and or termination from participation in study</td>
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<td>3</td>
<td>PPI or designee</td>
<td>Communicate with CCC, CIRB, DCC and Protocol Study Team members regarding CSS suspension or termination from participation in study</td>
<td>NN PM 501</td>
<td>NN SM 602</td>
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<td>4</td>
<td>PPI or designee</td>
<td>Communicate with CSS any decisions related to suspension or termination from participation in study</td>
<td>NN PM 501</td>
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<td>5</td>
<td>DCC Monitors</td>
<td>Perform study close out visits, as needed</td>
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