NeuroNEXT Network

Standard Operating Procedure (SOP)

Site Initiation Visits and Site Training

Version 2.0

SOP NN SS 402

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NN SS 402

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SITE INITIATION VISITS AND SITE TRAINING

SOP: NN SS 402 Version No: 2.0 Effective Date: 21Oct2016	SITE INITIATION VISITS AND SITE TRAINING	Supercedes Document: Version 1.0 Effective Date: 06May2012

1. POLICY

The activities associated with the Initiation Visit for a NeuroNEXT Network study may be conducted at a kick-off meeting, during a visit by Clinical Coordinating Center (CCC) and/or Data Coordinating Center (DCC) personnel to the Clinical Study Site (CSS), and/or via teleconference or web-conferencing. During the Initiation Visit, the objectives and the methodology of the clinical study are reviewed with the site investigator and staff, and appropriate training of the site's research team is conducted in compliance with International Conference on Harmonisation/Good Clinical Practice guidelines.

The objectives of the Initiation Visit are to:

- verify that the site has completed study preparation procedures;
- verify that all regulatory documents are in place;
- verify that the site is eligible to receive the investigational product, if applicable;
- review the protocol, case report forms (CRFs) and other worksheets;
- review all regulatory requirements;
- provide the plan for study monitoring;
- provide the site with Study Team contact information;
- confirm the PPI/Sponsor's expectations for the conduct of the study.

An initiation visit checklist that summarizes all the topics that must be reviewed with the investigator and his/her staff may be developed to assist during the Initiation Visit.

Before subjects may be enrolled in a study, all Investigators, Coordinators, and other study staff members (where necessary) must participate in training regarding the conduct of the trial. The CSS will be made aware of any training and certifications that must be completed before personnel will be permitted to enroll subjects.

If a CSS adds a new staff member at any time during the trial, the new staff member will be trained regarding the conduct of the trial, and will be required to complete all necessary training and certifications required for the trial, prior to that person's direct involvement in the trial.

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 NeuroNEXT CCC and DCC are responsible for the following activities:

- Ensuring that all participating investigators understand and accept the obligations incurred in undertaking a clinical study
- Training the investigator and all other key site personnel in the use of the investigational product, if applicable, and the conduct of the clinical protocol
- Conducting the Initiation Visit and site training at the large-group Investigators Meeting, at clinical site(s), or via teleconference/webinar.

The CCC is responsible for providing the DCC with information about the site's study preparation, training activities and regulatory documents.

The responsibility to conduct any or all of these activities may be delegated at the discretion of the PPI/Sponsor to the NeuroNEXT CCC or DCC or to subcontractors of either. Those individuals and entities also take on responsibility for meeting regulatory requirements on behalf of the PPI/Sponsor, but the PPI/Sponsor has the ultimate responsibility and must therefore supervise those delegated activities effectively.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50	Responsibilities of Sponsors
ICH E6, 2.0	The Principles of ICH GCP
ICH E6, 4.5	Compliance with Protocol
ICH E6, 5.3	Medical Expertise
ICH E6, 5.5	Trial Management, Data Handling and Record Keeping
ICH E6, 5.7	Allocation of Responsibilities
ICH E6, 5.8	Compensation to Subjects and Investigators
ICH E6, 5.15	Record Access
ICH E6, 5.23	Multicenter Trials
FDA Guideline	The Monitoring of Clinical Investigations (January 1988)

5. REFERENCES TO OTHER APPLICABLE SOPS

NN RA 203	Site Regulatory File Maintenance
NN PM 504	Investigational Site Staff Training
NN PM 505	Investigational Product Management
NN SM 602	Central Institutional Review Board Reporting Responsibilities
NN DM 1005	Data Collection and Data Handling

6. ATTACHMENTS AND REFERENCES

NN SS 402 – 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
CIRB	Central Institutional Review Board
CRF	Case Report Form

CSS	Clinical Study Site
DCC	Data Coordinating Center at The University of Iowa
FDA	U.S. Food and Drug Administration
GCP	Good Clinical Practices
ICH	International Council for Harmonisation
PPI	Protocol Principal Investigator

8. SPECIFIC PROCEDURES

A. Initiation Visit Preparation

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	DCC Lead Coordinator	In collaboration with the CCC, schedule an Initiation Visit, allowing sufficient time for all activities, depending on the protocol. Review purpose of visit if necessary.		NN PM 501
2.	DCC Lead Coordinator	In collaboration with the CCC, confirm the status of the study regarding CIRB review and approval, status of other regulatory reviews, and if applicable, FDA status.		NN SM 602
3.	CCC Project Manager, DCC Lead Coordinator, DCC Monitor	Prior to the visit, prepare by reviewing the protocol, CRFs and any other relevant documents. If needed, prepare slide presentations.		

B. Investigative Site Training

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	CSS Personnel	Participate in training regarding the conduct of the trial, and complete any required certifications before enrolling any study subjects.		
2.	CCC Project Manager and DCC Lead Coordinator	During the Site Initiation Visit meeting, ascertain the investigator's understanding of all elements of trial conduct through discussions and questions.		
3.	CCC Project Manager and DCC Lead Coordinator	Review the required elements of the investigator's study file and the importance of maintaining accurate and up-to-date records		NN RA 203
4.	CCC Project Manager and DCC Lead Coordinator	Confirm existence of all applicable and required documentation in the investigator's study file.[1]		NN RA 203
5.	CCC Project Manager and DCC Lead Coordinator	Review the clinical protocol, informed consent form and CRFs.		
6.	CCC Project Manager	Review procedures for obtaining and documenting informed consent, including required signatures and disposition of copies.		

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
7.	CCC Project Manager and DCC Lead Coordinator	Reinforce the need for strict adherence to the protocol.		
8.	DCC Lead Coordinator, DCC Monitor	Review instructions for completion of CRFs, including corrections and queries. Emphasize the need for timely and accurate completion of CRFs.		NN DM 1005
9.	DCC Lead Coordinator, DCC Monitor	Review the use of relevant logs and forms with all site personnel.		
10.	CCC Project Manager and DCC Lead Coordinator, DCC Monitor	If applicable, instruct relevant site personnel (including research pharmacist) on the pharmacologic aspects of the investigational product.		NN PM 505
11.	CCC Project Manager, DCC Lead Coordinator, DCC Monitor	If applicable, review investigational product allocation and randomization, as defined in the protocol.		NN PM 505
12.	CCC Project Manager, DCC Lead Coordinator, DCC Monitor	If applicable, review procedures for product accountability, storage, dispensing, reconciliation, as well as discrepancy investigation requirements and inventory recordkeeping.		
13.	CCC Project Manager, DCC Lead Coordinator, DCC Monitor	If applicable, verify receipt and records pertaining to investigational product already on site.		NN PM 505
14.	DCC Lead Coordinator and DCC Monitor	If applicable, confirm physical requirements (e.g., product inventory and storage, document and record storage).		NN PM 505
15.	CCC Project Manager , DCC Lead Coordinator, DCC Monitor	Review protocol requirements regarding the recognition, handling, recording and reporting of adverse events, including regulations and reporting timeframes.		NN SM 602
16.	CCC Project Manager, DCC Lead Coordinator, DCC Monitor	Review laboratory assessments and reporting procedures (with laboratory personnel if appropriate). Specifically address unusual or critical requirements.		
17.	CCC Project Manager and DCC Lead Coordinator	Confirm that enrollment of the first subject may not occur until all Initiation Visit procedures and regulatory requirements have been completed.		

Note:

[1]For example, protocol and Investigator Statement, CIRB-approved informed consent form, CIRB approval letter, CIRB member roster and other regulatory authority approvals.

C. Documenting the Initiation Visit

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	CCC Project Manager, DCC Lead Coordinator, DCC Monitor	Record date(s) of visit(s) by monitors and other designees on a site visit log.		
2.	DCC Lead Coordinator, DCC Monitor	Complete an Initiation Visit Checklist during the visit, if applicable.		
3.	DCC Lead Coordinator, DCC Monitor	Review the completed checklist (if applicable) or other documentation of the Initiation Visit with the Sponsor, if applicable.		
4.	DCC Lead Coordinator, DCC Monitor	File the checklist or other documentation of the Initiation Visit in the appropriate section of the Regulatory Master File.		NN RA 203
5.	DCC Lead Coordinator, DCC Monitor	Send a post-visit letter summarizing the visit and listing pending items.		

Attachment NN SS 402 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Site Initiation Visits and Site Training SOP NN SS 402				
Version	**Description of Modification**	**Reason or Justification for Modification**	**Issue Date**	**Effective Date**
1.0	New	N/A	06Apr2012	06May2012
2.0	Added language to indicate that the Initiation Visit and site training could be conducted at the large-group Investigators Meeting. Modified assignments in the Specific Procedures section. Other minor edits.	Updates for version 2.0	21Sep2016	21Oct2016