NeuroNEXT Network

Standard Operating Procedure (SOP)

Regulatory Authority Submission and Contact

Version 1.0

SOP NN RA 201

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NN RA 201

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR REGULATORY AUTHORITY SUBMISSION AND CONTACT

SOP: RA 201 Version No. 1.0 Effective Date:	REGULATORY AUTHORITY SUBMISSION AND CONTACT	Supercedes Document: N/A Effective Date: N/A

1. POLICY

The NeuroNEXT Clinical Coordinating Center (CCC) and Data Coordinating Center (DCC) shall employ individuals who are appropriately qualified and trained to develop complete and accurate regulatory submissions prior to and during clinical trials. These individuals will work with NeuroNEXT Protocol Principal Investigators (PPI) who are Investigational New Drug/Investigational Device Exemption (IND/IDE) holders, or who intend to file an IND/IDE application as the regulatory Sponsor.

Periodic reports to US Food and Drug Administration (FDA) regarding ongoing studies shall be filed, by the Sponsor, as required by regulation, with the support of the NeuroNEXT CCC and DCC.

If study changes occur in critical aspects of the study design while the study is under review, or after the study has been initially approved and is underway, the Sponsor will submit an appropriate notification to the FDA (an Amendment or a Supplement to the IND/IDE as applicable). Reasons for submitting an amendment include:

- adding a new protocol to an existing IND/IDE;
- providing additional information to an IND/IDE currently in effect;
- changing the investigational plan; and
- adding a new clinical investigator or site.

All contact between the FDA and Sponsor, in person or via phone, e-mail or facsimile, shall be documented in writing, provided to the NeuroNEXT CCC study specific project manager, and maintained in the regulatory files for the study.

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 Sponsor is responsible for ensuring that appropriate FDA staff members are contacted early and as often as necessary to conduct effective and timely meetings with FDA and to develop complete and accurate regulatory submissions.

NeuroNEXT CCC and DCC personnel are responsible for complying with the regulatory requirements that underlie the submission types and the process for requesting FDA input on submissions and for obtaining the appropriate input in developing written correspondence and submissions.

The responsibility to conduct any or all of these activities may be delegated at the discretion of the Sponsor to the NeuroNEXT CCC and/or DCC or to their subcontractors. Those individuals and entities 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

21 CFR 312.2 Applicability

21 CFR 312.7	Promotion and Charging for Investigational Drugs
21 CFR 312.10	Waivers
21 CFR 312 Subpart B	Investigational New Drug Application
21 CFR 312 Subpart C	Administrative Actions
21 CFR 312.20	Requirements for an IND
21 CFR 312.21	Phases of an Investigation
21 CFR 312.23	IND Content and Format
21 CFR 312.30	Protocol Amendments
21 CFR 312.34	Treatment Use of an Investigational Drug
21 CFR 312 Subpart E	Drugs Intended to Treat Life-threatening and Severely Debilitating Illnesses
21 CFR 312 Subpart F	Miscellaneous
21 CFR 312.64	Investigator Reports
ICH E6, 5.10	Notification/Submission to Regulatory Authorities
FDA	Guidance for industry on Content and Format of Phase I Investigational New Drug Applications (INDs) for Phase I Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products (November 1995) at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM074980.pdf >
FDA	Guidance for industry on Formal Meetings with Sponsors and Applicants for PDUFA Products www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079744.pdf

5. REFERENCES TO OTHER APPLICABLE SOPS

NN GA 103	Document Development and Change Control
NN RA 205	Adverse Event Reporting
NN PM 501	Communications

6. ATTACHMENTS AND REFERENCES

NN RA 201-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
DCC	Data Coordinating Center at The University of Iowa
FDA	U.S. Food and Drug Administration
GCP	Good Clinical Practice
ICH	International Conference on Harmonization
IDE	Investigational Device Exemption
IRB	Institutional Review Board
IND	Investigational New Drug application
PPI	Protocol Principal Investigator

8. SPECIFIC PROCEDURES

A. IND Development and Submission

#	Who	Task	Attachment/ References	Related SOP
1.	NeuroNEXT PPI, CCC and/or DCC	Check the FDA website to ascertain whether any specific written guidance on content for required submissions already exists.		
2.	NeuroNEXT PPI, CCC and/or DCC	Follow the process in NN GA 102, Document Development and Change Control for drafting, reviewing and approving IND submissions.		NN GA 102
3.	NeuroNEXT PPI, CCC and/or DCC	Once the investigational plan and clinical protocol are final, prepare the IND submission collect required information, as needed.		
4.	NeuroNEXT PPI, CCC and/or DCC	Send the original IND and two (2) copies to the applicable center via registered mail or an appropriate courier service.		
5.	NeuroNEXT PPI, CCC and/or DCC	If FDA requires additional information prior to granting approval of the IND, provide the information within specified timeframes or as soon as possible.		
6.	NeuroNEXT PPI, CCC and/or DCC	If significant safety issues arise, ensure that reporting and notifications are carried out as required.		NN RA 205
7.	NeuroNEXT PPI, CCC and/or DCC	If FDA disapproves the IND, do not proceed with the study until all issues identified by FDA are resolved.		
8.	NeuroNEXT PPI, CCC and/or DCC	If the disapproval letter from FDA specifies that the study may proceed after certain corrections are made without its explicit approval, proceed with the study after the corrections are put into place.		
9.	NeuroNEXT PPI, CCC and/or DCC	If the terms of the disapproval letter require an FDA notification to proceed with the study, do not proceed until notification is documented.		

B. IND Amendments

#	Who	Task	Attachment	Related SOP
1.	NeuroNEXT PPI, CCC and/or DCC	Ascertain when additional information or changes to the study must be reported to FDA in an IND Amendment.		
2.	NeuroNEXT PPI, CCC and/or DCC	File amendment(s) as required.		
3.	NeuroNEXT PPI, CCC and/or DCC	If FDA (and/or Central IRB) approval is needed, do not implement changes until approval is documented.		
4.	NeuroNEXT PPI, CCC and/or DCC	Submit all required reports as indicated.		

C. FDA Communication

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	NeuroNEXT PPI, CCC and/or DCC	Contact appropriate FDA staff members prior to submission of initial IND submission.		
2.	NeuroNEXT PPI, CCC and/or DCC	Maintain written records of all correspondence between FDA and the Sponsor.		