NeuroNEXT Network

Standard Operating Procedure (SOP)

Informed Consent Form Preparation

Version 3.0

SOP NN RA 204

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date: Christopher S. Coffey *Electronically signed by: Christopher S. Coffey Reason: I approve this document Date: Mar 8, 2024 08:10 CST* 08-Mar-2024
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Signature and Date: Merit Cudkowicz *Electronically signed by: Merit Cudkowicz Reason: I approve this document Date: Feb 22, 2024 12:11 CST* 22-Feb-2024
Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)
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Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)

NEURONEXT NETWORK STANDARD OPERATING POLICY AND PROCEDURE FOR INFORMED CONSENT FORM PREPARATION

SOP: NN RA 204 Version No.: 3.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	INFORMED CONSENT FORM PREPARATION	Supersedes Document Version : 2.0 Effective Date : 08Apr2023

Signature and Date:

Dixie Ecklund

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Date: Feb 24, 2024 17:16 CST

24-Feb-2024

Name and Title: Dixie J. Ecklund, RN MSN MBA (DCC Associate Director)

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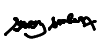

Electronically signed by: Stacey Grabert
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22-Feb-2024

Name and Title: Stacey Grabert, Pharm.D, MS, (CCC Director of Quality Assurance)

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Joan Ohayon

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11-Mar-2024

Name and Title: Joan Ohayon, RN, MSN, CRNP, MSCN (NINDS, NeuroNEXT Program Official)

NEURONEXT NETWORK STANDARD OPERATING POLICY AND PROCEDURE FOR INFORMED CONSENT FORM PREPARATION

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1. POLICY

The NeuroNEXT Single Institutional Review Board (SIRB) will develop a *general* Informed Consent Form (ICF) template to be used as the general template for all NeuroNEXT protocols. The template ICF will contain a locked section that includes standard language across all NeuroNEXT protocols that cannot be changed and additional sections that are to be used by the individual protocol designers/Protocol Principal Investigators (PPIs) to design the study-specific components of the form.

After receiving funding for a study to be conducted by NeuroNEXT, the PPI or their designee will work with the Clinical Coordinating Center (CCC) Project Manager (PM) and the CCC-SIRB liaison to develop a *protocol-specific* Model ICF based on the general ICF template. This protocol-specific Model ICF will serve as the template form for the protocol, and will contain protocol-specific 'locked' sections (e.g. purpose, study procedures, risks and benefits) as well as 'unlocked' sections where site-specific customization is anticipated (e.g. local compensation language, local injury, local privacy language etc.).

The PPI will then customize the protocol-specific Model ICF to create the PPI Site ICF, in collaboration with the CCC PM and CCC-SIRB liaison. The protocol-specific Model ICF and the PPI Site ICF will be submitted to the SIRB for review and approval as part of the Initial Review submission. The PPI Site ICF is also known as a Parent Site ICF, and is not required during Initial Review submission.

Each participating Clinical Study Site (CSS) will be provided with the protocol-specific Model Site ICF that includes the IRB-approved 'locked portion'. Each CSS is responsible for customizing the Model Site ICF for use at their site, and for submitting their Site ICF to the CCC for SIRB review and approval.

Note: If the PPI has created an ICF for submission to regulatory agencies prior to receiving funding for a study, the ICF will be modified after funding is received to conform to the ICF template developed by the SIRB for all NeuroNEXT protocols.

2. SCOPE

The policies and procedures described in this SOP apply to the NeuroNEXT CCC, SIRB, and Data Coordinating Center (DCC) within the context of their oversight and advisory roles for the NeuroNEXT Network, and to all NeuroNEXT and non-NeuroNEXT CSS investigators, staff, subcontractors, or other entities associated with the NeuroNEXT Network who manage, oversee, and conduct NeuroNEXT research regulated by FDA and/or applicable review committees.

3. ROLES AND RESPONSIBILITIES

The SIRB Liaison is responsible for creating a general ICF template for all NeuroNEXT protocols.

The PPI or his/her/their designee, working with the CCC PM and CCC-SIRB liaison, is responsible for preparing the protocol-specific Model ICF and PPI Site ICF.

The CCC-SIRB liaison is responsible for submitting both the protocol-specific Model ICF and PPI Site ICF to the SIRB for review.

The CCC PM and/or CCC-SIRB liaison are responsible for distributing the protocol-specific Model ICF to each participating CSS for site-specific customization.

Each CSS is responsible for submitting its Site ICF to the CCC for submission to the SIRB through the CCC-SIRB liaison.

The CCC-SIRB liaison is responsible for submitting Site ICFs to the SIRB for review.

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4. APPLICABLE REGULATIONS AND GUIDELINES

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research - The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979)

45 CFR 46.111	Criteria for IRB Approval of Research
45 CFR 46.116	General Requirements for Informed Consent
45 CFR 46.117	Documentation of Informed Consent
21 CFR Part 50	Protection of Human Subjects

5. REFERENCES TO OTHER APPLICABLE SOPS

NN SM 601	Single Institutional Review Board (SIRB) Reliance Process

6. ATTACHMENTS AND REFERENCES

NN RA 204-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
CCC-SIRB Liaison	This individual serves as a liaison between the CCC and the SIRB.
CFR	Code of Federal Regulations
CSS	Clinical Study Site
DCC	Data Coordinating Center at The University of Iowa
GCP	Good Clinical Practice
ICF	Informed Consent Form
ICH	International Council for Harmonisation
PPI	Protocol Principal Investigator
SIRB	Single Institutional Review Board Mass General Brigham

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8. SPECIFIC PROCEDURES

#	*Who*	*Task*	*Attachment/ References*	*Related SOP*
1.	SIRB Liaison	Develop template ICF to be used as a general template for all NeuroNEXT studies		
2.	PPI or their designee / CCC PM / CCC-SIRB liaison	Develop protocol-specific Model ICF and PPI Site ICF		
3.	CCC-SIRB liaison	Review protocol-specific Model ICF and PPI Site ICF for consistency and submit to SIRB for review and approval		
4.	SIRB CCC PM	Provide SIRB-approved protocol-specific Model ICF to all participating CSS for site-specific customization		
5.	CSS	Customize Model ICF with site-specific information and submit Site ICF to CCC		
6.	CCC	Review Site ICF for consistency and submit to SIRB for review and approval through the CCC-SIRB liaison		
7.	CCC-SIRB liaison	Transmit Site ICF to the SIRB		

NN RA 204

NEURONEXT NETWORK STANDARD OPERATING POLICY AND PROCEDURE FOR INFORMED CONSENT FORM PREPARATION

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Attachment NN RA 204 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Informed Consent Form Preparation SOP NN RA 204					
Version	**Description of Modification**	**Reason or Justification for Modification**	**Issue Date**	**Effective Date**	**Reviewer(s)**
1.0	New	N/A	06Apr2012	06May2012	N/A
1.0	Reviewed – no changes (2016)	N/A	06Apr2012	06May2012	N/A
2.0	Updated signature block to accommodate for electronic signatures. Changed CIRB to SIRB. Additional minor updates throughout.	Updates for v2.0	22Feb2023	08Apr2023	Catherine Gladden
3.0	Added sentence under section 1 – “The PPI Site ICF is also known as a Parent Site ICF and is not required during Initial Review submission.“	Periodic review	01Mar2024	15Apr2024	Alexi Drilea

NN RA 204 Informed Consent Form Preparation v3.0 2feb2024 clean

Final Audit Report 2024-03-11

Created:	2024-02-22
By:	Tania Leeder (tleeder@mgb.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAA1GuAcM2m25is92LmLq8fm2dmggjkc9RC
Number of Documents:	1
Document page count:	6
Number of supporting files:	0
Supporting files page count:	0

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2024-02-22 - 6:07:44 PM GMT

Document emailed to cudkowicz.merit@mgh.harvard.edu for signature
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2024-02-22 - 6:10:00 PM GMT

cudkowicz.merit@mgh.harvard.edu authenticated with Adobe Acrobat Sign.

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2024-03-08 - 2:10:20 PM GMT

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ohayonj@ninds.nih.gov authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-03-11 - 3:17:10 PM GMT

Signer ohayonj@ninds.nih.gov entered name at signing as Joan Ohayon

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Document e-signed by Joan Ohayon (ohayonj@ninds.nih.gov)

Signing reason: I approve this document

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