NeuroNEXT Network
Standard Operating Procedure (SOP)
Informed Consent Form Preparation
Version 1.0
SOP NN RA 204

Originators: NeuroNEXT CCC and DCC Personnel

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NN RA 204

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

SOP: NN RA 204  
Version No.: 1.0  
Effective Date:  

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<th>INFORMED CONSENT FORM PREPARATION</th>
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1. POLICY

The NeuroNEXT Central Institutional Review Board (CIRB) 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-CIRB 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) and areas where site-specific customization is anticipated (e.g. local radiation risks).

The PPI will then customize the protocol-specific Model ICF to create the PPI Site ICF, in collaboration with the CCC PM and CCC-CIRB liaison. The protocol-specific Model ICF and the PPI Site ICF will be submitted to the CIRB for review and approval.

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 CIRB 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 CIRB for all NeuroNEXT protocols.

2. SCOPE

The policies and procedures described in this SOP apply to the NeuroNEXT CCC, CIRB, 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 CIRB is responsible for creating a general ICF template for all NeuroNEXT protocols.

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

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

The CCC PM and/or CCC-CIRB 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 CIRB through the CCC-CIRB liaison.

The CCC-CIRB liaison is responsible for submitting Site ICFs to the CIRB for review.
4. APPLICABLE REGULATIONS AND GUIDELINES


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 Central Institutional Review Board (CIRB) 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-CIRB Liaison: This individual serves as a liaison between the CCC and the CIRB.
- CFR: Code of Federal Regulations
- CIRB: Central Institutional Review Board (Partners Healthcare)
- CSS: Clinical Study Site
- DCC: Data Coordinating Center at The University of Iowa
- GCP: Good Clinical Practice
- ICF: Informed Consent Form
- ICH: International Conference on Harmonisation
- PPI: Protocol Principal Investigator

8. SPECIFIC PROCEDURES

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<tr>
<th>#</th>
<th>Who</th>
<th>Task</th>
<th>Attachment/References</th>
<th>Related SOP</th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>CIRB</td>
<td>Develop template ICF to be used as a general template for all NeuroNEXT studies</td>
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<td>2.</td>
<td>PPI or their designee / CCC PM / CCC-CIRB liaison</td>
<td>Develop protocol-specific Model ICF and PPI Site ICF</td>
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<td>3.</td>
<td>CCC-CIRB liaison</td>
<td>Review protocol-specific Model ICF and PPI Site ICF for consistency and submit to CIRB for review and approval</td>
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<td>4.</td>
<td>CCC CIRB liaison / CCC PM</td>
<td>Submit CIRB-approved protocol-specific Model ICF to all participating CSS for site-specific customization</td>
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<td>5.</td>
<td>CSS</td>
<td>Customize Model ICF with site-specific information and submit Site ICF to CCC</td>
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<td>6.</td>
<td>CCC</td>
<td>Review Site ICF for consistency and submit to CIRB for review and approval through the CCC-CIRB liaison</td>
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<td>7.</td>
<td>CCC-CIRB liaison</td>
<td>Transmit Site ICF to the CIRB</td>
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Model Informed Consent Form Preparation

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Attachment NN RA 204 - A. Document History