1. POLICY

A. Purpose and Applicability

This SOP applies to all Network and Non-Network Clinical Study Sites (CSS) that have executed a NeuroNEXT Central IRB (CIRB) Authorization Agreement (Reliance Agreement or RA) to rely on the Partners Human Research Committee (PHRC) for review of one or more NeuroNEXT clinical trials.

The PHRC is comprised of the IRBs of Massachusetts General Hospital and Brigham and Women’s Hospital and is the CIRB for NeuroNEXT. All NeuroNEXT clinical trials will be reviewed by the CIRB. The general eligibility requirements for a CSS to rely on the CIRB are addressed in the Reliance Agreement. These requirements pertain to overall qualifications of the CSS and include completion by the CSS of a satisfactory NeuroNEXT Clinical Study Site IRB Information Sheet. CSSs with an executed RA have been determined by the NeuroNEXT Clinical Coordinating Center (CCC) and CIRB to meet the general requirements.

The purpose of this SOP is to set forth the process for a CSS to cede review to the CIRB of specific/individual NeuroNEXT clinical trial(s) as contemplated under its RA. The SOP describes the flow of protocol-specific information to and from the CSS to the CCC/CIRB and the information, timelines and documentation required for the initial protocol review. It also sets forth the process and requirements for other review decisions for the life of the protocol.

B. Process for Ceding Review of a Trial

a. Initial Protocol Review

i. The Protocol Principal Investigator (PPI) of a NeuroNEXT clinical trial will submit the draft protocol for the trial to the CIRB via the NeuroNEXT CCC-CIRB Liaison. This protocol will be designated by the CIRB as the ‘parent’ protocol.

ii. The CCC will provide a copy of the grant or other funding award for the clinical trial to the CIRB.

iii. The CIRB will perform an initial assessment of the protocol to determine “IRB-readiness” (e.g., completeness of all parts of the submission) and will work with the PPI via the CCC-CIRB Liaison as necessary to address any preliminary issues.

iv. The CIRB via the CCC-CIRB Liaison will send the IRB-ready protocol to all participating CSSs via the CSS designee(s). The CSS designee(s) will initiate an analysis of the protocol at the CSS to identify and inform the CIRB of 1) substantive issues (if any) and 2) local research context issues raised by the protocol. The CSS designee(s) must either be an individual(s) who has knowledge of and experience with the CSS’s local research context or involve such individuals at the CSS in the referenced analysis and determinations. Without limiting what is provided by the CSS, the CSS must, at minimum, provide complete information necessary to
inform the CIRB of the CSS’s local research context as relevant to the protocol. This information shall include:

1. Specific requirements of state or local laws, regulations, policies, standards or other factors applicable to the CSS or the trial that would affect the CSS’s conduct of the specific trial including, as applicable;
   a. Identification of legally authorized representatives who can provide consent for individuals to participate in research;
   b. Requirements for enrollment of adults with impaired decision-making capacity;
   c. Age of majority in the state;
   d. Circumstances under which children may consent to their own participation in research (emancipated minors, mature minors, etc.);
   e. Requirements for wards of the state or other special populations (child or adult) to participate in research;
   f. Requirements for obtaining assent of children to participate in research;
   g. Processes or requirements for enrollment of non-English-speaking participants;
   h. Other information about the local consent process, including practices regarding recruitment and compensation of participants;
   i. Requirements of confidentiality of specific types of health information;
   j. Special characteristics of the CSS or the community; and
   k. Other requirements or factors as applicable.

The CIRB via the CCC-CIRB Liaison may provide a questionnaire form for the CSS to complete to facilitate the provision of the above information.

2. Based on the CSS’s conduct of an investigator conflicts of interest analysis under the applicable policy as described in the NeuroNEXT Conflict of Interest and Financial Disclosure Requirements SOP (COI SOP 104):
   a. A copy of any report of investigator financial conflicts of interest (FCOI Report) made by the CSS to NINDS/the CSS of the PPI/other institution (as applicable under the COI SOP 104) pursuant to the Public Health Service regulations on Promoting Objectivity in Research, 42 CFR Part 50, Subpart F (Public Health Service Regulations);
   b. The specific information pertaining to the nature and management of reported FCOIs that is specified in 42 CFR § 50.605(b)(3) as will be in effect as of August 24, 2012, whether or not required under the current Public Health Service Regulations or included in such FCOI Report; and
c. A description of any other steps (together with supporting information) that the CSS has determined necessary to address financial interests of its investigators relating to the specific trial.

Comments and information from the CSS (including any questionnaire on state/local requirements provided by the CCC-CIRB Liaison) must be submitted in writing to the CIRB via the CCC-CIRB Liaison within 2 weeks of the date the protocol was sent to the CSS.

v. Upon receipt of the comments/information from participating CSSs, the CIRB will review the protocol.

vi. While the protocol is under CIRB review, the CSS of the PPI will conduct relevant Local Ancillary Committee (AC) review as required by its policies. The PPI will provide evidence of such committee approval along with any relevant committee requirements that would affect the CSS’s conduct of the trial to the CIRB via the CCC-CIRB Liaison. Relevant committees may vary by protocol and may include: nursing, radiation safety, pharmacy, biomedical engineering, biosafety, Medicare or other cost/billing analysis, and contract review.

vii. The CIRB will work with the PPI via the CCC-CIRB Liaison to address any modifications or other issues necessary to approve the protocol. If the protocol is approved by the CIRB, the approval will be approval of the parent protocol.

viii. The CIRB via the CCC-CIRB Liaison will send the approved protocol and a model informed consent form (ICF) (which will include a model form of HIPAA authorization for use and disclosure of Protected Health Information) to all CSSs who submitted the information required in section B.a.iv above.

ix. Each CSS will then decide whether or not to participate in the protocol as approved. CSSs that decide to participate will:

1. Contact the CIRB via the CCC-CIRB Liaison in writing regarding their decision to participate;

2. Coordinate relevant Local AC review as required by local policies;

3. Customize the approved study-wide model ICF in the areas permitted by the form to include/reflect information specific to the CSS. Attach or include any CSS form of HIPAA authorization if the CSS elects to use its own form/language in place of the model HIPAA form/language included in the study-wide ICF, and

4. Submit an application via the CCC-CIRB liaison to be added as a study site, along with the customized model ICF and HIPAA authorization and evidence of approval from Local ACs (along with any relevant committee requirements that would affect the CSS’s conduct of the trial), to the CIRB via the CCC-CIRB Liaison.

ii. The CIRB will review the customized ICF including authorization language for consistency with the approved model ICF and will review the AC information and all other local information provided and, if all parts of the application are satisfactory, will approve each CSS as a site amendment to the parent protocol. The CIRB will provide an approved ICF for the CSS.

Note: The date for continuing review will be set by the review date of the parent protocol.

b. Continuing review
i. Dates for continuing review (expiration of CIRB approval) will be determined by date of parent protocol review;

ii. The CIRB via the CCC-CIRB Liaison will notify each participating CSS regarding information required for continuing review. Each participating CSS will submit its responsive information for continuing review to the CCC-CIRB Liaison;

iii. The CCC-CIRB Liaison will submit a single continuing review application to the CIRB that includes continuing review information from all participating CSSs; and

iv. The CIRB will conduct continuing review and communicate results to participating CSSs via the CCC-CIRB Liaison.

c. Amendments

i. The PPI will submit any study-wide protocol amendments to the CIRB via the CCC-CIRB Liaison;

ii. The PI at each participating CSS may submit site-specific administrative amendments (e.g., study staff changes) and requests for protocol exceptions to the CIRB via the CCC-CIRB Liaison. Any amendments proposed to the substantive content of the protocol must be coordinated with and submitted through the PPI; and

iii. The CIRB will review amendments and communicate regarding their approval status with the relevant CSS(s) via the CCC-CIRB Liaison. Amendments requiring notification of all participating CSSs, as determined by the CIRB, will also be communicated via the CCC-CIRB Liaison.

d. Non-Compliance, subject injuries, unanticipated problems, protocol deviations/violations, complaints, cessation/suspension/termination of protocol, changes made without CIRB approval to eliminate apparent immediate hazards to subject/s: see the Central IRB Reporting SOP 602

e. Study closure

i. The PPI will submit relevant material for study closure to the CIRB via the CCC-CIRB Liaison.

2. SCOPE

The policies and procedures described in this SOP apply to the NeuroNEXT Clinical Coordinating Center (CCC), including the CCC Central IRB, and the Data Coordinating Center (DCC) and to all NeuroNEXT Clinical Study Site investigators and staff (Network CSS), PPIs, and Non-NeuroNEXT Clinical Study Site investigators and staff (Non-Network CSS) who participate in a NeuroNEXT clinical trial.

3. ROLES AND RESPONSIBILITIES

Roles and responsibilities for the CCC, DCC and CIRB as they relate to CIRB Reliance are detailed in section 8.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.114

21 CFR 56.114
5. REFERENCES TO OTHER APPLICABLE SOPS

NN SM 602: Reporting SOP
NN GA 104: Conflict of Interest and Financial Disclosure Requirements SOP

6. ATTACHMENTS

NN SM 601 – A  Document History
NN SM 601 – B  NeuroNEXT CIRB Clinical Study Site IRB Information Sheet

7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

AC  Ancillary Committee
CCC  NeuroNEXT Clinical Coordinating Center at Massachusetts General Hospital
CCC-CIRB Liaison  NeuroNEXT Clinical Coordinating Center Central Institutional Review Board Liaison
CFR  Code of Federal Regulations
CIRB  NeuroNEXT Central Institutional Review Board
CSS  Clinical Study Site that conducts research for a particular NeuroNEXT protocol
CSS PI  Principal Investigator who is responsible for implementing and conducting a specific NeuroNEXT protocol at a Clinical Study Site
DCC  NeuroNEXT Data Coordinating Center at The University of Iowa
FCOI  Financial Conflict of Interest
HIPAA  Health Insurance Portability and Accountability Act
ICF  Informed consent form
Network CSS  CSS that is within the NeuroNEXT Network
Non-Network CSS  CSS that is not a member of the NeuroNEXT Network
NINDS  National Institute of Neurological Disorders and Stroke
PHRC  Partners Human Research Committee
PPI  Protocol Principal Investigator of a NeuroNEXT protocol

8. SPECIFIC PROCEDURES
<table>
<thead>
<tr>
<th>#</th>
<th>Who</th>
<th>Task</th>
<th>Attachment/Reference</th>
<th>Related SOP</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>CSS Institutional Official</td>
<td>Sign CIRB Reliance Agreement and submit to CCC</td>
<td></td>
<td>Reliance Agreement</td>
</tr>
<tr>
<td>2.</td>
<td>CSS Investigators (PI and Co-Investigators)</td>
<td>Sign Investigator Commitment Statement at Exhibit A of the Reliance Agreement and submit to CCC</td>
<td></td>
<td>Reliance Agreement</td>
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<tr>
<td>3.</td>
<td>CSS PI/appropriate Institutional Representative</td>
<td>Facilitate completion of Clinical Study Site IRB Information Sheet by appropriate Institutional Representative/s and submit to CCC</td>
<td></td>
<td>Reliance Agreement</td>
</tr>
<tr>
<td>4.</td>
<td>PPI</td>
<td>Submit draft protocols to CCC-CIRB Liaison and coordinate relevant Local Ancillary Committee reviews</td>
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<td>Reliance Agreement</td>
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<tr>
<td>5.</td>
<td>CCC-CIRB Liaison</td>
<td>Submit draft protocols to CIRB</td>
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<td>COI SOP 104</td>
</tr>
<tr>
<td>6.</td>
<td>CIRB</td>
<td>Review draft protocol for readiness for CIRB review</td>
<td></td>
<td>COI SOP 104</td>
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<tr>
<td>7.</td>
<td>CIRB</td>
<td>Send IRB-ready draft protocol to CCC-CIRB Liaison for submission to interested CCSs for local comments</td>
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<td>Reliance Agreement</td>
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<tr>
<td>8.</td>
<td>CSS PI and Local Institutional Designee*</td>
<td>Review draft protocol and submit local comments to CCC-CIRB Liaison</td>
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<td>9.</td>
<td>CCC-CIRB Liaison</td>
<td>Submit local comments to CIRB</td>
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<td>10.</td>
<td>CIRB</td>
<td>Review final parent protocol and ICF. CIRB review may include required modifications or deferral. CIRB will work with CSS PPI through CCC-CIRB Liaison to secure IRB approval. CIRB will communicate approval status to CSS PPI via the CCC-CIRB Liaison.</td>
<td></td>
<td>Reliance Agreement</td>
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<tr>
<td>11.</td>
<td>CCC-CIRB Liaison</td>
<td>Submit final approved protocol and template ICF to all interested CCSs for final decision to participate</td>
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<td>12.</td>
<td>CSS PI</td>
<td>Communicate final decision to participate to CCC-CIRB Liaison</td>
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<td>13.</td>
<td>CSS PI</td>
<td>Coordinate protocol submission to Local Ancillary Committees for review and approval as applicable</td>
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<td>Reliance Agreement</td>
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<td>14.</td>
<td>CSS PI</td>
<td>Submit Protocol-specific Local Site Context IRB Form to CCC</td>
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<td>15.</td>
<td>CCC-CIRB Liaison</td>
<td>Communicate all CSS decisions to participate to CIRB</td>
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<td>16.</td>
<td>CCC-CIRB Liaison</td>
<td>Submit each additional CSS protocol and site-specific ICF to CIRB as ‘child’ amendments for approval</td>
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<td>17.</td>
<td>CIRB</td>
<td>Review each CSS ‘child’ amendment and ICF and communicate approval status to relevant CSSs via the CCC-CIRB Liaison</td>
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<td>18.</td>
<td>CCC-CIRB Liaison</td>
<td>Communicate CIRB approval status to relevant CSSs</td>
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<td>19.</td>
<td>CSS PI/Designee</td>
<td>Report non-compliance, subject injuries, unanticipated problems, protocol deviations/violations, complaints, cessation of research activities, changes made without CIRB approval to eliminate apparent immediate hazards to subject/s to CCC-CIRB Liaison</td>
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<td>20.</td>
<td>CCC-CIRB Liaison</td>
<td>Submit CSS reports of non-compliance, subject injuries, unanticipated problems, protocol deviations/violations, complaints, cessation of research activities, changes made without CIRB approval to eliminate apparent immediate hazards to subject/s to CIRB</td>
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<td>21.</td>
<td>CIRB, CCC, DCC</td>
<td>Communicate all reportable events to CSS that may affect subject safety or the conduct of the clinical trial at all sites</td>
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<td>22.</td>
<td>CSS PI</td>
<td>Submit continuing review applications to CCC-CIRB Liaison</td>
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<td>23.</td>
<td>CCC-CIRB Liaison</td>
<td>Submit continuing review applications to CIRB</td>
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<td>24.</td>
<td>CIRB</td>
<td>Review continuing review applications for all CSS. Communicate approval status to participating CSSs via CCC-CIRB Liaison.</td>
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<td>25.</td>
<td>CCC-CIRB Liaison</td>
<td>Communicate CIRB approval status of continuing review applications to participating CSSs</td>
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<td>26.</td>
<td>PPI</td>
<td>Submit study-wide protocol amendments to the CIRB via the CCC-CIRB Liaison</td>
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<td>27.</td>
<td>CCC-CIRB Liaison</td>
<td>Submit study-wide protocol amendments to the CIRB</td>
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<td>28.</td>
<td>CIRB</td>
<td>Review study-wide protocol amendments and communicate approval status to participating CSSs via CCC-CIRB Liaison</td>
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<td>29.</td>
<td>CCC-CIRB Liaison</td>
<td>Communicate CIRB approval status of study-wide amendments to participating CSSs</td>
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<td>30.</td>
<td>CSS PI</td>
<td>Submit site-specific administrative amendments (e.g., study staff changes) and requests for protocol exceptions to the CIRB via the CCC-CIRB Liaison</td>
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<td>31.</td>
<td>CCC-CIRB Liaison</td>
<td>Submit site-specific administrative amendments and requests for protocol exceptions to the CIRB</td>
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<tr>
<td>32.</td>
<td>CIRB</td>
<td>Review site-specific administrative amendments and requests for protocol exceptions and communicate approval status to relevant CSS(s) via the CCC-CIRB Liaison</td>
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<tr>
<td>33.</td>
<td>CCC-CIRB Liaison</td>
<td>Communicate CIRB approval status of site-specific administrative amendments and requests for protocol exceptions to participating CSSs</td>
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<tr>
<td>34.</td>
<td>PPI</td>
<td>Coordinate and submit substantive content amendments to the protocol as requested by CSS to the CIRB via the CCC-CIRB Liaison</td>
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<tr>
<td>35.</td>
<td>CCC-CIRB Liaison</td>
<td>Submit substantive content amendments to the protocol to the CIRB</td>
</tr>
<tr>
<td>36.</td>
<td>CIRB</td>
<td>Review substantive content amendments and communicate approval status to relevant CSS(s) via the CCC-CIRB Liaison.</td>
</tr>
<tr>
<td>37.</td>
<td>CCC-CIRB Liaison</td>
<td>Communicate CIRB approval status of substantive content amendments to the protocol to the CSSs [Amendments requiring notification of all participating CSSs, as determined by the CIRB, will also be communicated via the CCC-CIRB Liaison]</td>
</tr>
<tr>
<td>38.</td>
<td>PPI</td>
<td>Submit relevant material for study closure to the CIRB via the CCC-CIRB Liaison</td>
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<tr>
<td>39.</td>
<td>CIRB</td>
<td>Review relevant material for study closure and communicate approval status to the PPI via the CCC-CIRB Liaison</td>
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<tr>
<td>40.</td>
<td>CCC-CIRB Liaison</td>
<td>Communicate approval status of study closure material to the PPI</td>
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*Institutional Representative may be a site/local IRB member.
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<th>Effective Date</th>
<th>Issue Date</th>
<th>Modification</th>
<th>Reason or Justification for Modification</th>
<th>Description of Modification</th>
<th>Version</th>
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SOP NN SM 601
Central Institutional Review Board (CIRB) Reliance Process
NeuronEXT Network Standard Operating Procedure (SOP)

Attachment NN SM 601 - A. Document History
NeuroNEXT Clinical Study Site IRB Information Sheet

An entity applying to rely on the Partners Human Research Committee (PHRC) (the Central IRB for NeuroNEXT) for review of the entity’s human subject research conducted through the NeuroNEXT clinical trials network must complete this form and submit the following information to the PHRC.

Name of Institution:
Date:
Person completing this form (name, title and contact information)
   Note: form should be completed by, or in conjunction with, an institutional representative knowledgeable about the items addressed.

1. Site Name, Description, Location(s):
   a) Provide the full legal name and location of the organization requesting to rely on the PHRC.
   b) Are you a NeuroNEXT network site? □ Yes □ No
   c) State any other names by which the organization is known or does business and any corporate affiliations it has with other organizations, such as a university or hospital network.
   d) If the organization is or is part of a network or system, describe which entities or sites within the system will conduct the research and how regulatory oversight is provided or structured within the system with respect to those entities/sites.
      a. Do those other entities/sites operate under their own independent FWAs?
      b. If yes, each of those entities/sites will need to complete an Information Sheet.
   e) Please select which of the following best describe your entity.

   Type of Entity
   □ acute care hospital
   □ other hospital
   Describe:
   □ physician practice
   □ university
   □ small business
   □ other, explain:

   Public/Private
   □ public
   □ private

   For-profit/Non-profit
   □ for-profit
   □ non-profit

2. Research Program/FWA:
   a) Federal Wide Assurance (FWA)
      • Please provide number/s:
      • Please attach copy of your FWA

   b) Human Research Protection Program (HRPP):
Please provide a brief description of the administrative structure of your HRPP, including the components of the program and who is ultimately in charge. If available, please attach an HRPP organizational chart.

3. IRB information

a) Does the organization have its own IRB/s?  □ Yes  □ No
   □ If yes how many committees?

   □ Does your organization rely on independent/commercial IRB(s):
     □ for some but <10% of total protocols
     □ for some but > 10% of total protocols
     □ for all (100%) of total protocols
     □ for multi-site clinical trials only

   □ Does your organization rely on other external IRB(s) (e.g., other academic medical center or university-based IRBs):
     □ for some but <10% of total protocols
     □ for some but > 10% of total protocols
     □ for all (100%) of total protocols
     □ for multi-site clinical trials only

b) Type and volume of research conducted at your institution:
   • Biomedical
     □ Approximate number of total active protocols _________________
       □ Approximate number FDA-regulated: _________________________
       □ Approximate number federally funded: _________________________
     □ Average new protocols/year _________________________
   • Social-behavioral
     □ Approximate number of total active protocols _________________
     □ Average new protocols/year _________________________

c) Please describe how the HRPP addresses conflicts of interest in the conduct of human research activities – specifically, how information about potential conflicts of interest are identified, reviewed, and processed by the IRB/HRPP in reviewing human research protocols:
   a. Who receives COI disclosures
      i. IRB
      ii. Other institutional committee
   b. Who considers COI disclosures to determine subsequent action?
      i. IRB
      ii. Other institutional committee
d) Please describe any institutional policies and procedures or generally-accepted ways you operationalize obtaining assent for children in research.
e) Please describe any institutional policies and procedures or generally-accepted ways you operationalize obtaining surrogate consent for adult individuals with impaired decision-making capacity.
f) Please indicate which of the following formal ‘ancillary’ committee approvals must be completed (as appropriate to protocol) before a project can be activated at your site?
   a. Nursing
   b. Pharmacy
   c. Radiation safety
   d. Biomedical engineering
   e. Biosafety
   f. Medicare analysis or cost/billing analysis
   g. Subcontracts/Contracts execution
   h. Other: ______________________________

g) Please include the following materials:
   a. URL for the IRB
   b. Boilerplate informed consent and HIPAA authorization language, if any
   c. Policy, if any, on provision of treatment and coverage of treatment costs for research-related injuries, and template informed consent language regarding research-related injury

h) Mechanisms for oversight:
   • Does the organization have a quality assurance/audit group responsible for overseeing ongoing research? ☐ Yes ☐ No
   • Other? Please describe.

4. Relationship to Researchers:
   a) Describe the organization’s relationship (e.g., employment or otherwise) with the researchers who will be conducting the research. Include the organization’s extent of control over the researchers (e.g., through employment, or grant/revocation of privileges).

   b) State how the organization and its researchers are insured for malpractice and general liability. Include the extent and duration of coverage.

5. Education/Training: Describe the organization’s human subject protection training and education requirements for researchers and study staff. Please include initial as well as continuing education requirements.

6. Compliance:
   a) Describe any governmental inquiries or investigations over the past three years that may be material to the activities that would be conducted under the proposed IRB Authorization Agreement. Include, without limitation, research compliance problems (e.g., OHRP or FDA inquiries or investigations and corrective actions). Provide the status of such matters, including how they were resolved if resolved.

7. HIPAA: State whether the organization is a covered entity under HIPAA, and if so, whether research is considered a covered function.

   ☐ Yes If so, is research considered a covered function? ☐ Yes ☐ No
8. Local Research Context:

a) Identify areas where there are unique state, local or institutional requirements; for example:
   a. Legally authorized representatives
   b. Age of majority in your state
   c. State laws regarding assent for children
   d. State laws regarding confidentiality of specific types of health information

b) Provide a description of how your institution ensures compliance with each state or local law.

c) Are there any special characteristics of your institution or community of which the cIRB should be made aware?

9. Accreditation: State whether the human research program of the organization has been accredited. If so, include the accrediting organization and date of accreditation.

☐ Yes Organization: ______________________________ Date: __________

☐ No

10. Responsible Institutional Officials/Investigator(s): Provide the names of and contact information for individuals at the organization who will be responsible for the organization’s proposed IRB arrangement with the Partners Human Research Committee. Include the official responsible for the organization’s conduct of research, the main administrative IRB contact, the chair of your IRB and any other relevant individuals.

NeuroNEXT Site PI ______________________________
   Name:
   Position:
   Contact information:
   Mailing address:
   Phone:
   Fax:
   Email:

Institutional Official for research
   Name:
   Position:
   Contact information:
   Mailing address:
   Email:
Phone:
Fax:

IRB administrative contact
  Name:
  Position:
  Contact information:
    Mailing address:
    Email:
    Phone:
    Fax:

IRB chair:
  Name:
  Position:
  Contact information:
    Mailing address:
    Email:
    Phone:
    Fax: