Central Institutional Review Board
Reliance (Authorization) Agreement

National Coordinating Center
Central Institutional Review Board (CIRB):

University of Cincinnati
IRB Registration # 00000180 FWA #: 00003152 Expiration Date: 6/27/2016

Name of Research Project: Stroke Research Network – NIH StrokeNet

Name of Principal Investigator: Joseph P. Broderick, M.D.

Sponsor or Funding Agency: U.S. Department of Health and Human Services, National Institutes of Health (NIH) National Institute of Neurological Disorders and Stroke (NINDS)

Award Number: 1U01NS086872-01

Relying Institution (RI):
FWA #: _____ Expiration Date: _____

Regional Coordinating Center (RCC): _____

1. The **Central Institutional Review Board (CIRB)** for multicenter protocols is the single IRB of record. It has regulatory responsibility for assuring the protection of the rights and welfare of research participants. The National Institute of Neurological Disorders and Stroke (NINDS) selected the University of Cincinnati Institutional Review Board (IRB) to serve as the CIRB for the NIH StrokeNet (StrokeNet).
2. The **Relying Institution (RI)** is the local entity that sets standards to determine whether a research investigator can conduct research under its auspices. The officials signing below on behalf of the RI agree that their institution is an RI under this Agreement. Under the NIH StrokeNet, each and every RI falls under a Regional Coordinating Center (RCC); the RCC is charged with coordinating NIH StrokeNet research activities in multiple RIs.
3. This Reliance Agreement meets the federal requirements for designating the University of Cincinnati IRB as the reviewing CIRB for NIH StrokeNet affiliated research, which can include research conducted under multiple protocols and multicenter trials. This Agreement does not preclude the RI from conducting research not covered by this Agreement or from relying upon other IRBs for review of research not covered by this Agreement.
4. The RI agrees to cede IRB review of the NIH StrokeNet research to the CIRB. As such, the RI agrees to accept the decisions of the CIRB regarding review, approval and oversight of research covered by this Agreement. The CIRB is responsible for ensuring that its review meets the human subjects protection requirements set forth in the RI's Federalwide Assurance (FWA).
5. The RI agrees to maintain a valid Office for Human Research Protections (OHRP) approved FWA for human subjects research that covers the RI's NIH StrokeNet research and to comply with the terms set forth in that FWA. The RI also agrees to notify the CIRB of any modifications to the RI's FWA.
6. The RI is responsible for ensuring compliance with the CIRB's determinations and for following NIH StrokeNet written procedures for required reporting to appropriate officials at the CIRB.
7. Additional roles and responsibilities in which each institution shall serve under this Agreement shall be identified in attachments to this Agreement. These attachments shall be deemed incorporated into and made part of this Agreement.
8. This Agreement becomes effective upon the last signature date set forth below. This Agreement remains in effect until such time that either the CIRB or the RI provides 30 days' prior written notice of termination of this Agreement to the other party.

9. This Agreement may be amended only by a written document signed by each institution. Failure of a party to insist upon performance of a term in this Agreement does not constitute a waiver of the term or the relinquishment of rights, responsibilities and obligations under the term.
10. Following termination of this Agreement, the CIRB agrees to provide continued oversight for ongoing research covered by this Agreement for a reasonable period of time as necessary in accordance with relevant laws, regulations, and policies relevant to the operations of the CIRB. Following termination, the RI will remain responsible for compliance with all relevant and applicable state laws and regulations and institutional policies pertaining to research under the NIH StrokeNet, including informing the CIRB of any applicable state laws, state regulations and institutional policies, or changes thereto, that might impact the CIRB's continued oversight of ongoing research.
11. Each institution shall inform the other of any claim, suit or action arising from this Agreement or the research activities thereunder. Each institution shall reasonably assist the other in investigating such issue. If any provision of this Agreement is held to be invalid, illegal, or unenforceable, the remaining provisions of this Agreement shall remain in effect.
12. This document must be kept on file by both parties and provided to OHRP or other parties, including other regulatory agencies, as required upon request.
13. This Agreement is not assignable in whole or in part. Any attempt to do so renders the Agreement null and void.

Central Institutional Review Board:

University of Cincinnati

Authorized Official of Institution (IO)

Full Name: Jane Strasser, PhD

Institutional Title: Associate Vice President, Office of Research Integrity

Signature_____ Date _____

Relying Institution

_____

Authorized Official of Institution (IO)

Full Name:

Institutional Title:

Signature_____ Date _____

Attachment A

Responsibilities of the CIRB and Its Institution

For research covered by this Agreement, the CIRB and its institution, the University of Cincinnati (UC), will ensure:

1. The CIRB meets all applicable federal regulations and human subjects protection requirements, including all applicable federal regulations, state and local laws, UC's FWA, UC's institutional policies and procedures, NIH StrokeNet Standard Operating Procedures (SOP) and any applicable international requirements.
2. NIH StrokeNet affiliated research meets generally accepted ethical standards of human subjects protections and complies with all applicable federal regulations and NIH StrokeNet Standard Operating Procedures (SOP), as well as any applicable international or state laws, regulations or policies.
3. Initial and continuing review of the protocol and amendments, including the review of documents/information related to the approval and continuing oversight of the research.
4. That any site specific requirements as provided by the RI are appropriately incorporated into the CIRB's review.
5. Financial conflicts of interest (fCOI) are reviewed and addressed in accordance with NIH StrokeNet procedures.
6. Policies and procedures are available upon request from the RI or the RI's respective RCC.
7. The RI and the RI's respective RCC are informed of any changes in NIH StrokeNet or CIRB SOPs that may affect the conduct of the research at the RI.
8. The provision of a CIRB-approved informed consent document (ICD) for the RI. The ICD will indicate areas where RI may add language or otherwise customize the form for its own site. Any modifications will be subject to approval by the Central IRB, which will then provide a final approved consent form to RI for use at its site.
9. The CIRB performs the determinations required by the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act of 2009, and their implementing regulations (collectively, "HIPAA") with respect to the mechanisms for permitting the use and disclosure of Protected Health Information ("PHI") for the Clinical Studies included in this Agreement, namely authorization and waivers of authorization for use and disclosure of PHI, as applicable. PHI will not be shared among collaborating institutions unless there is an appropriate authorization to use or disclose such information for the purposes of research or an appropriate waiver of such authorization has been granted by a duly constituted review body in accordance with the HIPAA privacy rule.
10. Officials designated by the RI, including the Institutional Official (IO) and Principal Investigator (PI) at the RI, and designated officials at the RI's respective RCC, including the PI, are notified of any decision to conduct a for-cause audit the research at the RI, as well as the reason for the audit .
11. Review of unanticipated problems that might involve risks to subjects or others, protocol noncompliance issues, subject injuries, subject complaints, as well as protocol violations and deviations. The CIRB will make determinations regarding these issues and will report these determinations as required by federal and state laws, regulations and policy, as well as the NIH StrokeNet SOPs.
12. Accreditation of the CIRB is maintained. Designated officials at the RI, including the IO and Principal Investigator (PI) at the RI, and designated officials at the RI's respective RCC, including the PI, are notified within seven (7) days if there is a suspension, restriction, or change in accreditation status affecting the CIRB.
13. The RIs are informed of any communications between the CIRB and any federal and/or state and/or local regulatory agency(ies) relevant to either CIRB or RI responsibilities under this Agreement or any other requirements under this Agreement within seven (7) days.
14. Creation and maintenance of required records related to the review and approval of the research, including meeting minutes, are securely maintained in compliance with applicable requirements and made accessible to the RI and / or the RI's respective RCC within a reasonable timeframe upon request and as permitted under all applicable laws and policies.
15. Information received and reviewed under this Agreement is kept confidential as allowed by law.

Attachment B

Duties, Rights, and Responsibilities of the RI

The Relying Institution (RI) retains primary and ultimate responsibility for the protection of human subjects with respect to the conduct of the research covered by this Agreement and will ensure:

1. Compliance with RI's own institutional policies and procedures, all applicable federal regulations, state and local laws, terms of the RI's FWA, policies and procedures of the NIH StrokeNet and its CIRB, as well as any applicable international requirements as required.
2. NIH StrokeNet affiliated research meets generally accepted ethical standards of human subjects protections and complies with all applicable federal regulations, RI's FWA, and NIH StrokeNet SOPs, as well as any applicable international or state laws, regulations, policies, as required.
3. The CIRB is provided with site specific requirements pertinent to the CIRB's evaluation of NIH StrokeNet research.
4. That the RI has the appropriate resources to conduct the research and that the research meets all local requirements.
5. The CIRB is provided with the name and address of a local contact person who has the authority and responsibility to respond to relevant questions and provide relevant information, such as local context, as requested by the CIRB. This person shall also be responsible for submitting any local information updates to the CIRB in a timely manner, including changes to the RI's FWA.
6. Completion of a CIRB-approved informed consent document (ICD) for the RI. The ICD will indicate areas where RI may add language or otherwise customize the form for its own site. Any modifications will be subject to approval by the Central IRB, which will then provide a final approved consent form to RI for use at its site.
7. That any HIPAA authorization drafted by the RI for use in NIH StrokeNet research in place of the model form provided by the CIRB is approved by CIRB and lists the parties with whom subject PHI may be shared.
8. Investigators and other staff at the RI who are conducting research: 1) are appropriately qualified, including having received any special training required by pertinent laws, regulations, policies or NIH StrokeNet protocols; and 2) meet the federal requirements and institutional standards for eligibility to conduct research, including any required training in human subjects research protections.
9. Financial conflicts of interest (fCOI) have been appropriately identified and managed in accordance with federal and state laws and regulations, institutional policies and the NIH StrokeNet fCOI SOP.
10. The CIRB is notified of any suspension or restriction of a local investigator's privileges to conduct human subjects research within seven (7) days.
11. Adequate provisions are in place on treatment for injuries to research subjects.
12. The research is appropriately monitored to safeguard the rights and welfare of research subjects, and to maintain compliance with the determinations of the CIRB, and all applicable laws, regulations, and policies relating to human subjects research. Any findings related to the monitoring under this provision must be sent to the CIRB. The CIRB reserves the right to conduct for-cause audits of the RIs as deemed necessary.
13. Compliance with RI's own institutional policies and procedures for, as well as any pertinent NIH StrokeNet policies and procedures pertaining to, establishing and maintaining a local mechanism for local study participant complaints.
14. Subject complaints are reported to the CIRB if they appear to meet the criteria of an unanticipated problem involving risks to subjects or others.
15. Reporting of any unanticipated problems involving risks of harm to subjects or others of which it becomes aware to its IO, to the appropriate PI, the CIRB, and to sponsors.
16. Other events, including noncompliance issues and protocol violations, are reported to the CIRB in accordance with NIH StrokeNet SOPs.

17. The CIRB is informed of any communications regarding research covered by this Agreement to/from the FDA, OHRP, and/or any other federal and/or state and/or local regulatory agencies relevant to either CIRB or RI responsibilities under this Agreement or any other requirements under this Agreement within seven (7) days.
18. The CIRB is notified within seven (7) days of any events or actions affecting the RI's compliance with this Agreement.
19. Cooperation with any inquiry by the CIRB regarding research conducted under this Agreement. Such cooperation will include, but is not limited to, providing safety-related research records and information, meeting with representatives from the CIRB upon request, allowing an audit of the research and helping to develop and carry out all corrective action(s), as applicable.
20. The CIRB is consulted prior to the voluntary closure of a study if human subjects are enrolled in the research. The RI reserves the right to not conduct a study or to voluntarily terminate a trial so long as doing so is compliant with all applicable laws, regulations and policies.
21. Maintenance of all records of all human subjects research and related activities conducted under this Agreement, including any information provided to the CIRB for or in support of its review, in accordance with all applicable federal laws, regulations and/or state or local laws, institutional policies and the NIH StrokeNet document retention SOP. The RI will instruct its investigators to maintain records of all human subjects research and related activities conducted under this Agreement after completion of the research at all participating trial sites as required by law, the sponsor, and the RI's institutional policies. Upon request, the RI shall provide a copy of such records to the CIRB and to others as legally required.

Attachment C

Notice of Award

RESEARCH PROJECT COOPERATIVE AGREEMENT

Issue Date: 09/22/2013

Department of Health and Human Services, National Institutes of Health

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Grant Number: 1U01NS086872-01

Principal Investigator(s):
Joseph Paul Broderick, MD

Project Title: NIH StrokeNet National Clinical Coordinating Center