# Research Master Trial Agreement

| **Institution/Organization ("Prime Recipient") (National Coordinating Center ("NCC")** | **Institution/Organization ("Subrecipient") (Regional Coordinating Center ("RCC")** | |
|---|---|---|
| Name: University of Cincinnati | Site No.: & Name | |
| Prime Award No.: 1U01NS086872-01 and 1U01NS086872-01 REVISED | Subaward No.: **008822-**(Vendor No.) | CFDA#: 93.853 |
| Awarding Agency: U.S. DHHS, NIH, National Institute Of Neurological Disorders And Stroke | Amount Funded This Action: $0 | |
| Subaward Period of Performance: From: 09/30/2013 – 07/31/2018 | | |

Project Title: NIH StrokeNet National Clinical Coordinating Center **Master Trial Agreement (MTA)**

Reporting Requirements (Check here if applicable): **X** (See Attachment 4) **FFATA – N/A MTA**

**Terms & Conditions**

1) Prime Recipient hereby awards a cost reimbursable subaward, as described above, to Subrecipient. The statement of work and budget for this subaward are shown in Attachments 5 and 6. In its performance of the subaward work, Subrecipient shall be an independent entity and not an employee or agent of Prime Recipient.

2) Prime Recipient Shall reimburse Subrecipient not more often than monthly for allowable costs. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), subaward number, and certification as to truth and accuracy of invoice. *Invoices that do not reference Prime Recipient's Subaward Number shall be returned to Subrecipient.* Invoices and questions concerning invoice receipt or payments should be directed to the appropriate party's Department Contact as shown in Attachments 3A & 3B.

3) A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to Prime Recipient's Financial Contact, as shown in Attachments 3A and 3B, NOT LATER THAN sixty (60) days after subaward end date. The final statement of costs shall constitute Subrecipient's final financial report.

4) All payments shall be considered provisional and subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Subrecipient.

5) Matters concerning the technical performance of this subaward should be directed to the appropriate party's Principal Investigator, as shown in Attachments 3A and 3B. Technical reports are required as shown above, "Reporting Requirements".

6) Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this subaward agreement, and any changes requiring prior approval, should be directed to the appropriate party's Contact, as shown in Attachments 3A & 3B. Any such changes made to this subaward agreement require the written approval of each party's Authorized Official as shown in Attachments 3A & 3B.

7) Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or director's, to the extent allowed by law.

8) Either party may terminate this subaward with thirty days written notice to the appropriate party's Administrative Contact as shown in Attachments 3A & 3B. Prime Recipient shall pay Subrecipient for termination costs as allowable under OMB Circular A-21 or A-122 or 45 CFR Part 74 Appendix E, "Principles for Determining Costs Applicable to Research and Development under Grants and Contracts with Hospitals" as applicable.

9) No cost extensions require the approval of the Prime Recipient. Any requests for a no-cost extension should be addressed to and received by the Administrative Contact, as shown in Attachments 3A & 3B, not less than thirty (30) days prior to the desired effective date of the requested change

10) The Subaward is subject to the terms and conditions of the Prime Award and other special terms and conditions, as identified in Attachment 2.

11) By signing below Subrecipient makes the certifications and assurances shown in Attachments 1 and 2. Subrecipient also assures that it will comply with applicable statutory and regulatory requirements specified in the Research Terms & Conditions Appendix C found at http://www.nsf.gov/bfa/dias/policy/rtc/appc.pdf.

| By an Authorized Official of Prime Recipient (NCC) | By an Authorized Official of Subrecipient (RCC) |
|---|---|
| Signature:<br>Name:<br>Title: | Signature<br>Name:<br>Title: |
| Date | Date |

**Attachment 1**
**Research Master Trial Agreement**
**Certifications and Assurances**

By signing the Subaward Agreement, the authorized official of Subrecipient certifies, to the best of his/her knowledge and belief that

## Certification Regarding Lobbying

1. No Federal appropriated funds have been paid or will be paid, by or on behalf of the Subrecipient, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

2. If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or intending to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the Subrecipient shall complete and submit Standard Form -LLL, "Disclosure Form to Report Lobbying", to the Prime Recipient.

3. The Subrecipient shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by Section 1352, Title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

## Debarment, Suspension, and Other Responsibility Matters

Subrecipient certifies by signing this Subaward Agreement that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this transaction by any federal department or agency.

## OMB Circular A-133 Assurance

Subrecipient assures Prime Recipient that it complies with A-133 and that it will notify Prime Recipient of completion of required audits and of any adverse findings which impact this subaward.

**Attachment 2**
**Research Master Trial Agreement**
**Prime Award Terms and Conditions**
**NIH**

**Agency-Specific Certifications/Assurances**

1. By signing this Research Subaward Agreement Subrecipient makes the certifications and assurances specified in the Research Terms and Conditions Appendix C found at http://www.nsf.gov/bfa/dias/policy/rtc/appc_june11.pdf

**General terms and conditions** as of the effective date of this Research Subaward Agreement**:**

1. Conditions on activities and restrictions on expenditure of federal funds in appropriations acts are applicable to this subaward to the extent those restrictions are pertinent. This includes any recent legislation noted on the NIH Award Conditions website: http://grants.nih.gov/grants/policy/awardconditions.htm

2. 45 CFR Part 74 or 45 CFR Part 92 as applicable.

3. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the period of performance.
4. Research Terms and Conditions found at: http://www.nsf.gov/pubs/policydocs/rtc/termsidebyside_june11.pdf and Agency Specific Requirements found at http://www.nsf.gov/pubs/policydocs/rtc/nih_1210.pdf , except for the following:

   a. The right to initiate an automatic one-time extension of the end date provided by Article 25(c)(2) of the Research Terms and Conditions is replaced by the need to obtain prior written approval from the Prime Recipient;

   b. The payment mechanism described in Article 22 and the financial reporting requirements in Article 52 of the Research Terms and Conditions and Article 8 of the Agency-Specific Requirements are replaced with Terms and Conditions (1) through (4) of this Subaward Agreement; and

   c. Any prior approvals are to be sought from the Prime Recipient and not the Federal Awarding Agency.

5. Title to equipment costing $5,000 or more that is purchased or fabricated with research funds or Subrecipient cost sharing funds, as direct costs of the project or program, shall unconditionally vest in the Subrecipient upon acquisition without further obligation to the Federal Awarding Agency subject to the conditions specified in Article 34(a) of the Research Terms and Conditions.
6. Treatment of Program Income: ☒ Additive ☐ Other, Prime Recipient specify alternative from NIH Agreement

**NIH-Specific Requirements Promoting Objectivity in Research Applicable to Subrecipients (42 CFR Part 50 Subpart F)**

a. 42 CFR Part 50.604 requires that institutions conducting PHS-funded research "Maintain an up-to-date, written, enforced policy on financial conflicts of interest." Further, "If the Institution carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this subpart by incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators."

**Subrecipient must designate herein whether the financial conflicts of interest policy of the ___ Prime Recipient Institution, or X Subrecipient Institution (check one) will apply. If applying its own financial conflicts of interest policy, by execution of this Subaward Agreement, Subrecipient Institution certifies that its policy complies with 42 CFR Part 50.**

b. **Subrecipient shall report any financial conflict of interest to Prime Recipient's Administrative Representative, as designated on Attachment 3A**. Any financial conflicts of interest identified shall subsequently be reported to NIH. **Such report shall be made before expenditure of funds authorized in this Subrecipient Agreement and within 45 days of any subsequently identified financial conflict of interest.**

**Special terms and conditions:**

1. **Copyrights**

   **Subrecipient _X__ grants / ___ shall grant (check one) to Prime Recipient an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted material (including any computer software and its documentation and/or databases) first developed and delivered under this Subaward Agreement solely for the purpose of and only to the extent required to meet Prime Recipient's obligations to the Federal Government under its Prime Award.**

2. **Data Rights**
   **Subrecipient grants to Prime Recipient the right to use data created in the performance of this Subaward Agreement solely for the purpose of and only to the extent required to meet Prime Recipient's obligations to the Federal Government under its Prime Award.**

3. **Article 1) of the Research Subaward Agreement – first sentence is revised to read:** ~~Prime Recipient hereby awards a cost reimbursable subaward, as described above, to Subrecipient.~~ The statement of work and financial considerations ~~budget~~ for this subaward are shown in Attachments 5 and 6. In its performance of the subaward work, Subrecipient shall be an independent entity and not an employee or agent of Prime Recipient.

4. **Articles 2), 3), 4) and 9) are deleted in their entirety for the purpose of this Master Trial Agreement.**

5. **Article 6) is hereby deleted and revised to read: "For the purpose of this Master Trial Agreement, the terms and conditions are not negotiable and no additional language is permitted."**

6. **Article 8) is revised with the addition of the following sentence: "Termination of this Master Trial Agreement does not affect the RCC's Terms of Award from the Awarding Agency."**

7. **NIH StrokeNet Composition and National Coordinating Center Expectations**

   a. U.S. DHHS, NIH, NINDS Stroke Trial Network (NIH StrokeNet) consists of the National Coordinating Center (NCC) – University of Cincinnati, the Central IRB (CIRB) – University of Cincinnati, the Data Management Coordinating Center (DMCC) (to be determined in Jan. 2014), 25 Regional Coordinating Centers (RCC).

   b. In collaboration with the NINDS, the NCC will implement all procedures required to establish and implement a Central IRB for all Stroke Network trials. NINDS expects that all RCCs' satellite sites each enter into contractual agreements (Master Trial Agreements and Central IRB Reliance Agreement) with the National Coordinating Center (NCC).

   c. The NIH StrokeNet will run 5 years and consist of 4-5 Phase I & II clinical trials and 2-4 Phase III clinical trials. The NIH StrokeNet is a large Prevention, Acute Treatment & Rehabilitation projects network.

   d. Projects may come from various sources, including PIs in Network; PIs outside Network; NINDS industry partners or other collaborators ("Third Parties"); and current NINDS studies. Third Parties could fund projects for drug, biologic, device, or other technologies and establish a collaborative or other agreement with NINDS related to the trial. These agreements may require conditions applicable to the Subrecipient that are in conflict with policies referenced in this MTA, including but not limited to intellectual property issues.

   e. Separate Subawards will be issued by the NCC for individual clinical trial projects.

   f. A NINDS Protocol Working Group (PWG) and the NCC Steering Committee (SC) Working groups will be convened to collaborate with the PI of the proposed study (Protocol PI) to develop the Clinical Protocol

and associated per-patient budgets. The NCC will be responsible for fiscal oversight for overall project finances and protocol-specific funding. Trial specific per-patient budgets are defined as research related costs with payment amounts that will be non-negotiable.

**8. Publications and Acknowledgement of Support**

a. Network generated publications must be developed in compliance with procedures stipulated in the NIH StrokeNet NCC Standard Operating Procedures (SOPs). Note that a different publication process may be required for collaborations with Third Parties..

b. Collaborating institutions and organizations shall include acknowledgement of the Government's support in the publication or presentation of any material based on or developed under this Subaward as stipulated in Network SOPs.

c. All authors will be required to be registered with the International Committee of Medical Journal Editors (ICJME) and comply with Federal Drug Administration (FDA) Conflict of Interest (COI) requirements.

| Attachment 3A<br>Research Master Trial Agreement<br>Prime Recipient Contacts | Subaward Number: |
|---|---|

| | | |
|---|---|---|
| **Institution/Organization ("Prime Recipient") (NCC)** | | |
| Name: University of Cincinnati | | |
| Address: 51 Goodman Avenue, Suite 530 | | |
| City: Cincinnati | State: Ohio | Zip Code+4: 45221-0222 |
| EIN No.:<br>31-6000989 | Institution Type :<br>State Educational Institution | Registration current in SAM.gov? Yes |
| D-U-N-S No.: 04106-4767 | Congressional District: OH-001 | |

| | | |
|---|---|---|
| **Administrative Representative - Contract Manager** | | |
| Name: Diane Sparks | | |
| Address: One Stetson Square, 260 Stetson Street, Suite 5221C | | |
| City: Cincinnati | State: Ohio | Zip Code+4: 45267-0525 |
| Telephone: 513.558.3924 | Fax: 513-558-7882 | |
| E-Mail: diane.sparks@uc.edu | | |

| | | |
|---|---|---|
| **Principal Investigator:** | | |
| Name: Joseph Paul Broderick, MD | | |
| Address: University of Cincinnati, College of Medicine Dept of Neurology and Rehabilitative Medicine, 260 Stetson Street, Suite 2300 | | |
| City: Cincinnati | State: OH | Zip Code+4: 45267-0525 |
| Telephone: Rose Beckman 513-558-3907 | Fax: 513-558-7882 | |
| E-Mail: broderjp@ucmail.uc.edu | | |

**Invoices - Study sites will not submit invoices to the RCC or the NCC for any study activities completed. Payments will be determined automatically on a monthly basis for all milestone/tasks completed as confirmed by the applicable DMCC. All payments are inclusive of F&A costs.**

| | | |
|---|---|---|
| **Authorized Official** | | |
| Name: Deborah J. Galloway, Associate Vice President | | |
| Address: 51 Goodman Avenue, Suite 530, University of Cincinnati | | |
| City: Cincinnati | State: Ohio | Zip Code+4: 45221-0222 |
| Telephone: 513 556 5054 | Telephone: 513-556-4346 | |
| E-mail: debi.galloway@uc.edu | | |

| Attachment 3B<br>Research Master Trial Agreement<br>Subrecipient Contacts | | | Subaward Number: |
|---|---|---|---|
| **Institution/Organization ("Subrecipient") (RCC)** | | | |
| Site No.: Name: | | | |
| Address: | | | |
| City: | State: | | Zip Code + 4: |
| EIN No.: | Institution Type : | | |
| **All questions must be answered.**<br>Is the Performance Site the Same Address as Above? ☐ Yes ☐ No<br>If no, is the Performance Site the same as PI address below? ☐ Yes ☐ No<br>If no to both questions, please complete 3B page 2<br>Is Subrecipient exempt from reporting compensation? ☐ Yes ☐ No<br><br>Congressional District<br><br>DUNS No. Parent DUNS No. Is registration current in SAM.gov? ☒ Yes ☐ No | | | |
| | | | |
| **Administrative Contact** | | | |
| Name: | | | |
| Address: | | | |
| City: | State: | | Zip Code + 4: |
| Telephone: | Fax: | | |
| E-Mail: | | | |
| | | | |
| **Principal Investigator** | | | |
| Name: | | | |
| Address: | | | |
| City: | State: | | Zip Code +4: |
| Telephone: | Fax: | | |
| E-Mail: | | | |
| | | | |
| **Study Coordinator** | | | |
| Name: | Phone: | | E-mail: |
| | | | |
| **Beginning July 1, 2013, please sign up for one of the two electronic payment methods identified below:** | | | |
| **ACH (Automated Clearing House)** – funds will be directly deposited into Subrecipient's bank account after an invoice has been approved and the terms have been met. A remittance advice will be emailed to Subrecipient prior to a deposit being made. The Prime Recipient does not charge vendors for this service. Please complete and return the form linked below if Subrecipient would like to be paid via ACH: http://www.uc.edu/content/dam/uc/af/controller/docs/EFTAgreementCTX.pdf. | | | |
| **ePayables** – funds will be available via a VISA "ghost" card system that uses a virtual credit card from the Bank of America. If you enroll in this program, a university credit card number will be assigned to Subrecipient. The card has unique security features, with $0 of available funds until an invoice is approved for payment. Once a payment is approved, an electronic remittance advice will be sent to Subrecipient along with approval to charge the credit card for that amount. Your credit card processor will charge Subrecipient all applicable processing fees. For further information about this program, please contact Tina Huston at 513-556-6772. | | | |
| | | | |
| **Authorized Official** | | | |
| Name: | | | |
| Title: | | | |
| Address: | | | |
| City: | State: | | Zip Code + 4: |
| Telephone: | Fax: | | |
| E-Mail: | | | |

| Attachment 3B Page 2<br>Research Master Trial Agreement<br>Place of Performance & Highest Compensated Officers | | Subaward Number: |
|---|---|---|
| | | |
| **Institution/Organization ("Subrecipient") (RCC)** | | |
| Name: | | |
| | | |
| **Place of Satellite Performance:** | | |
| Name: | | |
| Address: | | |
| City: | State | Zip Code + 4 |
| Telephone: | | |
| E-Mail: Congressional District: | | |
| | | |

**Attachment 4**
**Research Master Trial Agreement**
**Reporting & Performance Metrics Requirements**

1. See Statement of Work;

2. As required by the University of Cincinnati Principal Investigator and

3. In addition to the stated Public Health Service reporting requirements (42 CFR Part 50.604) all participants in the Network will be required to complete Financial Conflict of Interest forms per Network policies.

**Attachment 5**
**Research Master Trial Agreement**
**Statement of Work**

**RCC has primary authority and responsibility for**:

1. The Regional Coordinating Stroke Center (RCC) has primary and lead responsibilities to ensure that the RCC and each **satellite center** and **affiliated performance sites each** enter into contractual agreements (Master Trial Agreements (MTA) and Central IRB Reliance Agreement (CIRB RA) with the National Coordinating Center (NCC).

2. RCC has primary authority and responsibility to develop, implement and maintain the RCC for the NINDS Stroke Trials Network ("Stroke Network"). In doing so the RCC has the following primary and lead responsibilities:

    a. to recruit **satellite centers and clinical sites** to participate in RCC supported trials
    b. to coordinate and comply with Human Subject Protection activities at the request of the Network central Institutional Review Board (IRB) to protect patient safety including:
        i. to ensure that all sites engaged in research involving human subjects have an appropriate OHRP-approved Assurance and an IRB approval of the research consistent with 45 CFR Part 46
        ii. ensure all sites obtain informed consent for all study participants
        iii. to retain documentation of compliance with the requirements of 45 CFR Part 46 for all sites performing a given trial
        iv. to comply with any FDA policy and regulations as relevant to all clinical trials and as published at 21 CFR Parts 50 and 312
        v. manage and conduct the proposed clinical trial (or "study") in compliance with all established DHHS, NIH, NINDS policies and procedures

    c. to implement approved studies at the satellite centers/performance sites and obtain adequate patient recruitment to complete the study
    d. to provide scientific leadership and regular communication to **satellite centers** and **clinical sites** regarding protocols and study progress
    e. to provide administrative and budget support for protocol initiation
    f. for submission to NCC and NINDS Standard Operating Procedures (SOPs) describing the interactions and regional site management between the RCC and their **affiliated satellite and clinical sites**
    g. for monthly reporting to NCC regarding RCC Stroke Network activities
    h. for monthly reporting to NCC regarding RCC Stroke Network compliance with network polices for data quality control
    i. to participate in the preparation of publications and presentations
    j. to collaborate with Stroke Network clinical investigators and Interacting with non-Stroke Network investigators.

3. The RCC is responsible for ensuring all **satellite centers/clinical sites** affiliated with the RCC follow approved protocols and maintain quality control of data and ensure participant safety. Any problems concerning the compliance of **satellite centers/clinical sites** in the protocol or quality control of data should be reported immediately to the Administrative Program Official.

**4.** The NCC will disseminate Stroke Network protocols to all RCCs to allow sites the option to participate in each Stroke Network-supported study. The NCC will report site participation in Stroke Network supported studies on a Stroke Network website.

5. For any clinical trial supported by a Third Party (defined under 7(d) of the Special Terms and Conditions, above), all participating sites **must** sign a Trial Protocol Agreement **prior** to initiating the trial that will include conditions applicable to the specific clinical trial. These conditions may relate to data sharing and access, publication, confidentiality, and intellectual property. A site may choose whether or not to participate in Third Party-supported trials depending on its capacity for the subject matter and its willingness to agree to the conditions.

**RCC Performance metrics** including, but not limited to:

1. Active support of the NCC in the execution of Master Trial Agreements by 50% of the **performance sites** identified by the RCC.

2. Active support of the NCC in the execution of Central IRB Reliance Agreement at 50% of the **performance sites** identified by the RCC.

3. Demonstrate an average monthly enrollment of at least one participant per Stroke Network study conducted at the RCC over a consecutive three month period prior to the November 1, 2015 Administrative Continuation submission.

4. Demonstrate the RCC has collaboratively participated in development of at least one Stroke Network clinical trial protocol that has been submitted as a new grant application to the NINDS prior to the November 1, 2015 Administrative Continuation submission.

**Attachment 6**
**Research Master Trial Agreement**
**Financial Considerations**

1. Direct costs for approved NIH StrokeNet protocols are supported by grants from NINDS or other funding sources.

2. The NCC will distribute the per-patient cost to the NIH StrokeNet RCC sites and Satellites on a pre-determined fixed price unit basis as approved by NINDS *a*nd will be non-negotiable.

3. All fixed fee units will be inclusive of F & A costs recovery.

4. Protocol Clinical performance sites will not be required to submit invoices to the RCC or the NCC for any study activities completed. Payments for subject enrollment and other interval payments will be determined automatically on a monthly basis for all milestone/tasks completed as confirmed by the applicable Data Management Center.

**Attachment 7**
**Research Master Trial Agreement**
**Prime 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**

***RESEARCH PROJECT COOPERATIVE AGREEMENT***

**Issue Date: 09/27/2013**

**Department of Health and Human Services, National Institutes of Health**

**NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE**

**Grant Number: 1U01NS086872-01 REVISED**

**Principal Investigator(s):**
**Joseph Paul Broderick, MD**

## NIH StrokeNet

## National Clinical Coordinating Center

nihstrokenet.org

## National Clinical Coordinating Center

## Toll-free Phone No.

**1-855-472-0072**