Health Services
LOS ANGELES COUNTY

ADOPTED

BOARD OF SUPERVISORS
COUNTY OF LOS ANGELES
31 MAY 3, 2016

LORI GLASGOW
EXECUTIVE OFFICER

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To ensure access to high-quality, patient-centered, cost-effective health care to Los Angeles County residents through direct services at DHS facilities and through collaboration with community and university partners.

May 03, 2016

The Honorable Board of Supervisors
County of Los Angeles
383 Kenneth Hahn Hall of Administration
500 West Temple Street
Los Angeles, California 90012

Dear Supervisors:

APPROVAL OF A RESEARCH MASTER TRIAL AGREEMENT WITH THE UNIVERSITY OF CINCINNATI
(ALL SUPERVISORIAL DISTRICTS)
(3 VOTES)

SUBJECT

Request approval to enter into two agreements with the University of Cincinnati; 1) a Research Master Trial Agreement in order to participate in the stroke network of the United States Department of Health and Human Services, National Institutes of Health, National Institute of Neurological Disorders and Stroke, and 2) a Central Institutional Review Board Authorization Agreement with the University of Cincinnati to give Los Angeles County Department of Health Services' patients opportunities to participate in research related to the prevention, treatment and rehabilitation of stroke patients at Harbor-UCLA Medical Center, LAC+USC Medical Center, Olive View-UCLA Medical Center and Rancho Los Amigos National Rehabilitation Center, under University of Cincinnati oversight.

IT IS RECOMMENDED THAT THE BOARD:

1. Authorize the Director of Health Services (Director), or his designee, to enter into a Research Master Trial Agreement (MTA) subaward with the University of Cincinnati (UC), the prime award recipient of the MTA award through the United States Department of Health and Human Services, National Institute of Health, National Institute of Neurological Disorders & Stroke (US DHHS NIH NINDS); and as a condition of the subaward, also enter each of the Department of Health Services (DHS) Hospitals into a Central

Institutional Review Board (CIRB) Authorization Agreement, which grants UC oversight to protect the rights and welfare of stroke research participants during medical trials at Harbor-UCLA Medical Center (H-UCLA MC), LAC +USC Medical Center (LAC-USC MC), Olive View-UCLA Medical Center (OV-UCLA MC) and Rancho Los Amigos National Rehabilitation Center (RLANRC), collectively known as DHS facilities, with no money changed between the parties, effective upon Board approval through July 31, 2018.

2. Delegate authority to the Director, or his designee, to amend MTA and CIRB Authorization Agreements to add/delete County of Los Angeles (County) facilities, and/or extend, amend, and/or terminate the Agreements or provisions, if deemed necessary, and accept future award agreements containing a fixed fee-per-patient, subject to review and approval as to form by County Counsel; and Chief Executive Office (CEO) Risk Management, as needed, and notification to your Board.

PURPOSE/JUSTIFICATION OF RECOMMENDED ACTION

Approval of the first recommendation will allow the Director, or his designee, to execute an MTA Agreement and instruct each hospital to enter into a CIRB Agreement with the UC, substantially similar to Exhibits I and II, respectively, which will streamline DHS facilities' access to establish stroke-related clinical trials being coordinated by UC CIRB. The MTA is basically a memorandum of understanding regarding the network and does not have any funding associated with it.

As a condition of the MTA Agreement, each DHS facility must also sign a CIRB Authorization Agreement with UC. UC CIRB, is intended to help DHS facilities reduce administrative burdens while continuing a high level of protection for human research participants.

The UC coordinates the Research Master Trial and CIRB Authorization Agreements for Regional Coordination Centers (RCCs) participating as subaward recipients in stroke research. The US DHHS NIH NINDS is the funding body that manages the NIH StrokeNet Trials through a network of 25 RCCs working with nearby facilities that span the country. As the prime award recipient and National Coordinating Center (NCC) of NIH StrokeNet Trials for US DHHS NIH NINDS, UC issues all agreements regarding the network.

In March 2013, the US DHHS NIH NINDS established a solicitation process to select RCCs for NIH StrokeNet Trials. Through a competitive solicitation process, the University of California Los Angeles (UCLA) and University of Southern California (USC) were selected to participate in stroke-related research in the Western Los Angeles and Eastern Los Angeles County regions, respectively. Accordingly, UCLA and USC Stroke teams will provide administrative support, telemedicine support, and in person site response for stroke patients.

In NIH StrokeNet Trials, UCLA will lead in the coordination of stroke research trials for Western Los Angeles County region institutions including H-UCLA MC and OV-UCLA MC. Similarly, USC will lead in coordination of stroke research trials for the Eastern Los Angeles County region institutions including LAC+USC MC and RLANRC. These trials provide both study related intervention and prevention treatments for stroke patients and give patients access to trials more quickly, as many of the efforts to establish trials will be streamlined by the CIRB Authorization Agreement. As studies become available through NIH StrokeNet Trials, DHS will be able to enroll patients in trial studies, providing a unique opportunity for patients to participate in stroke prevention, acute treatment and rehabilitation due to the County's affiliation with USC and UCLA.

Although all institutions participating in stroke-related studies with the UC must have a MTA and CIRB with the UC prior to the participation of any research trial study, funding for research will be requested under separate fixed fee-per-patient clinical trial agreements between DHS and UC. The network will have an assortment of acute stroke, prevention, and rehabilitation/recovery trials. Under the MTA, DHS facilities will select the trials to participate in as they become available. Participation in such studies will require review and acceptance by each facility's Institutional Review Board as required by their respective bylaws. Furthermore, there will be execution of a trial-specific agreement, with specific performance measures and a requirement of monthly reports to the UC regarding UCLA and USC Stroke Centers' activities. If a facility's review process raises additional requirements or concerns not addressed in the trial specific agreement or in other documentation, the County is free to decline participation in that study and not execute any particular trial-specific agreement with no adverse effect. Acceptance and execution will be performed by the Director, or his designee, in accordance with the delegated authority approved by the Board on July 28, 2015, subject to review and approval as to form by County Counsel, and prior notification to the Board.

Approval of the first recommended action will also allow DHS facilities to participate in highly beneficial stroke-related research and clinical care trials, as they become available, by streamlining the stroke research process, centralizing approval and review, lessening time and costs of clinical trials and assembling a comprehensive data sharing system at the UCLA/USC RCC.

Approval of the second recommended action will provide DHS delegated authority to amend MTA and CIRB Authorization Agreements, if requested by UC, and accept future award agreements containing a fixed fee-per-patient, subject to review and approval as to form by County Counsel and Chief Executive Office (CEO) Risk Management, as needed, and notification to your Board.

Implementation of Strategic Plan Goals

The recommended actions support Goal 1, Operational Effectiveness/Fiscal Sustainability, of the County's Strategic Plan.

FISCAL IMPACT/FINANCING

There are no costs associated with the execution of the MTA and CIRB Agreements. If DHS facilities choose to participate in future clinical trials, trial budgets will be requested and submitted to NINDS with the proposal and the award for a fixed fee-per-patient budget. The reimbursement of costs will be provided through the US DHHS NIH NINDS.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS

The UC will oversee and coordinate MTA and CIRB for the UCLA/USC RCCs, disseminate NIH StrokeNet protocols to all clinical sites participating in research studies, report site participation in NIH StrokeNet websites, monitor results to ensure clinical sites follow approved protocols and maintain quality control of data with coordination of grant related activities.

This Agreement does not include the usual County provisions because the UC requires the use of its own MTA and CIRB by the RCCs for the StrokeNet collaboration with DHS facilities.

DHS consulted with the CEO Risk Management Branch and has obtained approval of the mutual indemnification language proposed in the MTA.

Either party may terminate the MTA or CIRB Agreements with prior 30 days written notice.

County Counsel has approved Exhibits I and II as to form.

CONTRACTING PROCESS

UCLA and USC collaboratively responded to a solicitation released by US DHHS NIH's and were selected to participate in stroke-related research studies.

IMPACT ON CURRENT SERVICES (OR PROJECTS)

Board approval of the recommendations will enable the County to participate in leading stroke-related research for the improvement of stroke prevention, education, and care at DHS facilities.

Respectfully submitted,

Mitchell H. Katz, M.D.
Director

MHK:ls

Enclosures

c: Chief Executive Office
County Counsel
Executive Office, Board of Supervisors

November 2010 FDP	**Research Master Trial Agreement - Satellites**	
Institution/Organization ("Prime Recipient") (National Coordinating Center ("NCC")	**Institution/Organization ("Subrecipient") (Regional Coordinating Center Satellite ("RCC-S")**	
Name: University of Cincinnati	Site No : R___-S____ Name: ___	
Prime Award No.: NCC: 1U01NS086872-01, 1U01NS086872-01 REVISED and 5U01NS086872-02 FAIN No. U01NS086872 **RCC:___YR 1 and 2_____ FAIN**	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) - Satellites**		

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-S)
Signature: Name: Diane L. Sparks, RN, BS Title: Contracts Manager, Legal Liaison, NIH StrokeNet	Signature Name: Title:
Date	Date

Attachment 1
Research Master Trial Agreement - Satellites
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 - Satellites
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 Research Master Trial Agreement - Satellites Prime Recipient Contacts			Subaward Number:
Institution/Organization ("Prime Recipient") (National Coordinating Center ("NCC")			
Name: University of Cincinnati			
Address: 51 Goodman Avenue, Suite 530			
City: Cincinnati	State: Ohio		Zip Code+4: 45221-0222
EIN No.: 31-6000989	Institution Type : 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: Diane L. Sparks, RN, BS, Contracts Manager, Legal Liaison, NIH StrokeNet			
Address: 260 Stetson Street, Suite 5221 C, University of Cincinnati			
City: Cincinnati	State: Ohio		Zip Code+4: 45267-0525
Telephone: 513-558-3924		Fax: 513- 558-7882	
E-mail: diane.sparks@uc.edu			

Attachment 3B Research Master Trial Agreement - Satellites Subrecipient Contacts	Subaward Number:

Institution/Organization ("Subrecipient") (Regional Coordinating Center Satellite ("RCC-S")		
Site No.: **R11-S15** Name: **County Of Los Angeles**		
Address: 313 N Figueroa Street, 9th Fl		
City: Los Angeles	State: CA	Zip Code + 4: 90012-2602
EIN No.: 95-6000927	Institution Type : County Government	

RCC	**Award No.:** 1U10NS086497-01	
Site No. & Name: **R11 The Regents of the University of California - U.C. Los Angeles**		
Address: 11000 Kinross Ave Ste 102		
City: Los Angeles	State: CA	Zip Code + 4: 90095-2000
PI: Jeffrey L. Saver, MD, Gene Yong Sung, MD	Phone: (310) 794-6379 Saver 323.409.8552 Sung	E-mail JSaver@mednet.ucla.edu ; gsung@usc.edu
Study Coordinator: Ileana Grunberg, RN, UCLA; Clare Binley, USC	Phone: 310-794-0600 Grunberg 323-409-1532 Binley	E-mail: Igrunberg@mednet.ucla.edu Clare.Binley@med.usc.edu

All questions must be answered.
Is the Performance Site the Same Address as Above? ☐ Yes ☐ No
If no, is the Performance Site the same as PI address below? ☐ Yes ☐ No
If no to both questions, please complete 3B page 2
Is Subrecipient exempt from reporting compensation? ☐ Yes ☐ No

Congressional District: CA-034

DUNS No. 099446254 Parent DUNS No. Is registration current in SAM.gov? ☒ Yes ☐ No

Administrative Contact

Name:		
Address:		
City:	State: CA	Zip Code + 4:
Telephone:	Fax:	
E-Mail:		

Principal Investigator

Name: Dr. Gene Sung		
Address: LAC+USC Medical Center 1100 N State Street #A4E111		
City: Los Angeles	State: CA	Zip Code +4: 90033-5000
Telephone: 323-409-8552	Fax: 323-4418093	
E-Mail: E-Mail: gsung@usc.edu		

Study Coordinator

Name: Clare Binley	Phone: 323-409-1532	E-mail: clare.binley@med.usc.edu

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: CA	Zip Code + 4:
Telephone:	Fax:	
E-Mail:		

Attachment 3B Page 2 Research Master Trial Agreement - Satellites Place of Performance & Highest Compensated Officers	Subaward Number:

Institution/Organization ("Subrecipient") (RCC)

Name: **R11-S15 County Of Los Angeles**

Place of Satellite Performance:

Name: **Harbor-UCLA Medical Center**

Address: 1000 West Carson Street

City: Torrance	State: CA	Zip Code + 4: 90502-2004-

Telephone:

E-Mail: | Congressional District: CA-043

Place of Satellite Performance:

Name: **Olive View – UCLA Medical Center**

Address: 14445 Olive View Drive

City: Sylmar	State: CA	Zip Code + 4: 91342-1437-

Telephone:

E-Mail: | Congressional District: CA-029

Place of Satellite Performance:

Name: **Rancho Los Amigos National Rehabilitation Center**

Address: 7601 East Imperial Highway

City: Downey	State: CA	Zip Code + 4: 90242-3456

Telephone:

E-Mail: | Congressional District: CA-040

Place of Satellite Performance:

Name: **Los Angeles County + USC Medical Center**

Address: 2051 Marengo Street

City: Los Angeles	State: CA	Zip Code + 4: 90033-1352

Telephone:

E-Mail: | Congressional District: CA-034

Attachment 4
Research Master Trial Agreement - Satellites
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 - Satellites
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 - Satellites
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 and 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 - Satellites
Prime Award

RESEARCH PROJECT COOPERATIVE AGREEMENT (NCC)
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 (NCC)
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
RESEARCH PROJECT COOPERATIVE AGREEMENT (NCC)
Issue Date: 07/11/2014
Department of Health and Human Services, National Institutes of Health
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE
Grant Number: 5U01NS086872-02
Principal Investigator(s): Joseph Paul Broderick, MD

RESEARCH PROJECT COOPERATIVE AGREEMENT (RCC)
Issue Date:
Department of Health and Human Services, National Institutes of Health
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE
Grant Number:
Principal Investigator(s):

RESEARCH PROJECT COOPERATIVE AGREEMENT (RCC)
Issue Date:
Department of Health and Human Services, National Institutes of Health
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE
Grant Number:
Principal Investigator(s):

NIH StrokeNet

National Clinical Coordinating Center

www.nihstrokenet.org

National Clinical Coordinating Center

Toll-free Phone No.

1-855-472-0072

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, Ph.D.

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