



Contract Number

20-572

SAP Number

Arrowhead Regional Medical Center

Department Contract Representative	William L. Gilbert
Telephone Number	(909) 580-6150
Contractor	National Coordinating Center – University of Cincinnati on behalf of Yale University
Contractor Representative	Wren Hanson
Telephone Number	513-558-6566
Contract Term	July 14, 2020 through April 30, 2024
Original Contract Amount	Revenue
Amendment Amount	
Total Contract Amount	Revenue
Cost Center	

Briefly describe the general nature of the contract: Subaward agreement from National Coordinating Center – University of Cincinnati on behalf of Yale University for ASPIRE clinical trials related to intracerebral hemorrhage patients, not to exceed \$10,810 per participating patient at Arrowhead Regional Medical Center, for the performance period of July 14, 2020, through April 30, 2024.

FOR COUNTY USE ONLY

Approved as to Legal Form



Charles Phan, Deputy County Counsel

Date 7/1/2020

Reviewed for Contract Compliance



Date

Reviewed/Approved by Department

William L. Gilbert, Director

Date

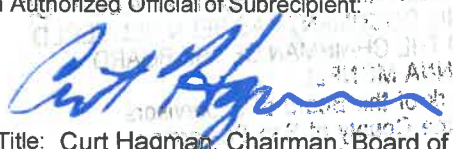
7/1/2020

FDP Fixed-Rate Clinical Trial Subaward Agreement

Pass-through Entity (PTE): National Coordinating Center ("NCC") University of Cincinnati on behalf of the Prime Recipient Yale University		Subrecipient: County of San Bernardino dba Arrowhead Regional Medical Center	
PTE Principal Investigator (PI): Pooja Khatri, MD on behalf of Kevin Navin Sheth (contact), MD		Subrecipient Principal Investigator (PI): Dan Miulli, DO, FACOS	
PTE Federal Award No: 1U01NS106513-01A1	FAIN: U01NS106513	Federal Awarding Agency: DHHS NIH NINDS	
Federal Award Issue Date: 07/01/2019	Total Amount of Federal Award to PTE \$13,018,629.00	CFDA No: 93.853	CFDA Title: Extramural Research Programs in the Neurosciences and Neurological Disorders
Study Title: Anticoagulation in ICH Survivors for Prevention and Recovery (ASPIRE) "Study"			
Subaward Estimated Project Period of Performance: Start: 07/01/2019 End: 04/30/2024		Amount Funded This Action: Pre-determined fixed price unit basis as approved by NINDS. See Attachment 5.	Subaward No. 012043-140000
Estimated Project Period (if incrementally funded): N/A Start: __ End: __		Incrementally Estimated Total:	Is this Award R & D ☒ Yes or ☐ No
Check all that apply: ☐ Reporting Requirements (Attachment 4) ☒ Subject to FFATA (Attachment 3B) ☐ Cost Sharing (Attachment			

Terms and Conditions

- 1) PTE hereby awards a fixed-rate subaward, as described above, to Subrecipient. The statement of work for this subaward is (check one) ☐ as specified in Subrecipient's proposal dated Click or tap to enter a date., or ☒ as shown in Attachment 5. In its performance of subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.
- 2) PTE shall provide funding in accordance with the Payment Schedule shown in Attachment 5. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include deliverables completed and milestone payment amount, subaward number, and certification, as required in 2 CFR 200.415 (a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments should be directed to the appropriate party's Choose an item. Contact, as shown in Attachments 3A and 3B.
- 3) A final invoice, marked "FINAL" must be submitted to PTE's Choose an item. Contact, as shown in Attachment 3A, NOT LATER THAN 60 days after subaward end date. PTE shall make the final payment to Subrecipient upon completion of all required deliverables and reports as indicated in Attachments 4 and 5.
- 4) PTE reserves the right to reject an invoice.
- 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 in Attachment 4.
- 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 Administrative Contact, as shown in Attachments 3A and 3B. Any such changes made to this subaward agreement require the written approval of each party's Authorized Official, as shown in Attachments 3A and 3B.
- 7) Substantive changes made to this Subaward Agreement require the written approval of each party's Authorized Official as shown in Attachments 3A and 3B. The PTE may issue non-substantive changes to the Period of Performance and budget (check one): ☒ Bilaterally, or ☐ Unilaterally. Unilateral modifications shall be considered valid 14 days after receipt unless otherwise indicated by Subrecipient.
- 8) Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.
- 9) Either party may terminate this Subaward Agreement in accordance with Attachment 2B, Termination and Suspension terms and provide notice to the appropriate Administrative Contact, as shown in Attachment 3A.
- 10) This Subaward Agreement is subject to the terms and conditions of the PTE Award and other special terms and conditions, as identified in Attachment 2A and 2B.
- 11) By signing this Fixed-Rate Clinical Trial Subaward Agreement Subrecipient makes the certifications and assurances shown in Attachments 1, 2A, and 2B.

By an Authorized Official of Pass-through Entity: Name: Diane L. Sparks, RN, BS Title: Contracts Manager, Legal Liaison, NIH StrokeNet, National Coordinating Center Date:	By an Authorized Official of Subrecipient:  Name: Title: Curt Hagman, Chairman, Board of Supervisors Date: July 14, 2020
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Attachment 1
Fixed-Rate Clinical Trial Subaward Agreement
Certifications and Assurances

By signing this Fixed-Rate Clinical Trial Subaward ("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 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 Pass-through Entity.
- 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 any individual participating in this Subaward is presently debarred, suspended, declared ineligible or voluntarily excluded from participation in this research Study by any federal department or agency.

Audit and Access to Records

Subrecipient certifies by signing this Subaward Agreement that it complies with the Uniform Guidance, will provide notice of the completion of required audits and any adverse findings which impact this Subaward Agreement as required by parts 200.501-200.521, and will provide access to records as required by parts 200.336, 200.337, and 200.201 as applicable.

SIGNED AND CERTIFIED THAT A COPY OF
THIS DOCUMENT HAS BEEN DELIVERED
TO THE CHAIRMAN OF THE BOARD
LYNNA MONEIL
Clerk of the Board of Supervisors
of the County of San Bernardino
By _____
Deputy



Attachment 2A
Fixed-Rate Clinical Trial Subaward Agreement
Prime Award Terms And Conditions NIH

General Terms and Conditions:

By signing this Subaward, Subrecipient agrees to the following:

1. To abide by the conditions on activities and restrictions on expenditure of federal funds in appropriations acts that are applicable to this Subaward to the extent those restrictions are pertinent. This includes any recent legislation noted on the Federal Awarding Agency's website:
<https://grants.nih.gov/policy/notices.htm>
2. 2 CFR 200 and 45 CFR Part 75.
3. The Federal Awarding Agency's grants policy guidance, including addenda in effect as of the beginning date of the period of performance or as amended found at: <https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>
4. Research Terms and Conditions, including any Federal Awarding Agency's Specific Requirements found at: <https://www.nsf.gov/awards/managing/rtc.jsp> except for the following:
 - a. No-cost extensions require the approval of the PTE. Any requests for a no-cost extension should be addressed to and received by the Choose an item. Contact, as shown in Attachments 3A and 3B, not less than 30 days prior to the desired effective date of the requested change.
 - b. Any payment mechanisms and financial reporting requirements described in the applicable Federal Awarding Agency Terms and Conditions and Agency-Specific Requirements are replaced with Terms and Conditions (1) through (4) of this Subaward; and
 - c. Any prior approvals are to be sought from the PTE and not the Federal Awarding Agency.
 - d. Title to equipment as defined in 2 CFR 200.33 that is purchased or fabricated with research funds or Subrecipient cost sharing funds, as direct costs of the project or program, shall vest in the Subrecipient subject to the conditions specified in 2 CFR 200.313.
 - e. Prior approval must be sought for a change in Subrecipient PI or change in Key Personnel (defined as listed on the NOA).
5. Treatment of Program Income: ☒Additive ☐Other, [Pass-through Entity 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 Institutions (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 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 (check one): ☐PTE Institution or ☒Subrecipient Institution will apply.

If applying its own financial conflicts of interest policy, by execution of this Subaward Agreement, Subrecipient certifies that its policy complies with 42 CFR Part 50 Subpart F.

- b) **Subrecipient shall report any financial conflict of interest to PTE'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 Subaward Agreement and within 45 days of any subsequently identified financial conflicts of interest.**

Copy of Award Notice (See Attachment 6)

Special terms and conditions:

[WHILE SPECIAL TERMS AND CONDITIONS MAY NOT BE REQUIRED BY THE FUNDING AGENCY, Institutions may include the following 4 clauses. These clauses are optional and may be deleted if not applicable.]

1. Copyrights

Subject to copyrights held by the publishing journal, Subrecipient ☒ grants / ☐ shall grant (check one) to Pass-through Entity 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 Pass-through Entity's obligations to the Federal Government under its Prime Award.

2. Data Rights

Subrecipient grants to Pass-through Entity 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 Pass-through Entity's obligations to the Federal Government under its Prime Award.

3. **Automatic Carry Forward:** ~~As this is a fixed-rate subaward agreement, carry forward of unexpended funds is automatic.~~ Carry-over of an unobligated balance into the next budget period is not applicable to this per subject Protocol Trial Agreement award.

4. In accordance with 48 CFR 3.908 Pilot Program for Enhancement of Contractor Employee Protections. Subrecipient is hereby notified that they are required to:

- a. Inform their employees working on any Federal award that they are subject to the whistleblower rights and remedies of the pilot program;
- b. Inform their employees in writing of employee whistleblower protections under 41 U.S.C §4712 in the predominant native language of the workforce; and;
- c. Contractors and grantees will include such requirements in any agreement made with a subcontractor or subgrantee

(To be considered/modified on a case by case basis if applicable)

The Invoicing and Payment Terms as referenced on the face page of this Subaward Agreement are revised as follows:

Definitions:

Prime Recipient ("PR") – Yale University retains prime responsibility for all federal compliance activities.

Pass-through Entity (PTE): National Coordinating Center ("NCC") – University of Cincinnati retains prime responsibility for trial administrative activities as defined in the PTE NCC Notice of Award FAIN# U01NS086872 <http://www.nihstrokenet.org/documents>.

National Data Management Center ("NDMC") – Medical University of South Carolina (WebDCU™)

The NDMC supports protocol data management, ensures data quality control (including data monitoring), and undertakes interim monitoring, analyses and reporting for the NCC, NINDS, and Data and Safety Monitoring Boards (DSMBs).

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 National Data Management Center (NDMC) Medical University of South Carolina (WebDCU™), and 25 Regional Centers (RCC). Each RCC has participating Satellites.
- b. The **NIH StrokeNet** will run 10 years. The NIH StrokeNet is a large stroke Prevention, Acute Treatment & Rehabilitation trial network.

FDP Fixed-Rate Clinical Trial Subaward Agreement Page 1, Article 2) is hereby revised:

- 2) PTE shall provide funding in accordance with the Payment Schedule shown in Attachment 5. ~~All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include deliverable completed and milestone payment amount, subaward number, and certification, as required in 2 CFR 200.415 (a). Invoices that do not~~

~~reference PTE Subaward number shall be returned to Subrecipient. Invoices and Questions concerning invoice receipt or payments should be directed to the appropriate party's Financial Contact, as shown in Attachments 3A and 3B.~~

FDP Fixed-Rate Clinical Trial Subaward Agreement Page 1, Articles 3) and 4) are deleted in their entirety for the purpose of this Protocol Trial Agreement

- 3) ~~A final invoice, marked "FINAL" must be submitted to PTE's Financial Contact, as shown in Attachments 3A and 3B, NOT LATER THAN 60 days after subaward end date. PTE shall make the final payment to Subrecipient upon completion of all required deliverables and reports as indicated in Attachments 4 and 5.~~
- 4) ~~PTE reserves the right to reject an invoice.~~

FDP Fixed-Rate Clinical Trial Subaward Agreement Page 1, Article 9) is revised with the addition of the following:

- 9) Either party may terminate this subaward with thirty days written notice to the appropriate party's Administrative Contact, as shown in Attachments 3A and 3B. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix IX, "Principles for Determining Costs Applicable to Research & Development under Grants and Contracts with Hospitals", as applicable.

Payment will be made for work completed and entered correctly (without outstanding issues) into the National Data Management Coordinating Center (NDMC) Medical University of South Carolina WebDCU™ Clinical Trials Management System. (CTMS)

Estimated Project Period of Performance Start 07/01/2019 End: 04/30/2024. The CTA is dependent on continued funding of the "Anticoagulation in ICH Survivors for Prevention and Recovery (ASPIRE)" clinical trial by the federal agency to the Prime and the trial is considered actively enrolling. If the trial ceases to be funded by the federal agency or actively enrolling, the CTA is automatically terminated upon the date specified by NINDS.

If the award is terminated early by the federal agency clinical trial costs will be reimbursed as specified in the termination document from the federal agency.

Attachment 2B

Fixed-Rate Clinical Trial Subaward Agreement

Special Terms and Conditions

Data Use /Ownership

“Data” shall mean all data and information generated by Subrecipient as a result of conducting the Study in accordance with the Protocol. Data does not include original Study subject or patient medical records, research notebooks, source documents, or other routine internal documents kept in the Subrecipients’s ordinary course of business operations, which shall remain the sole and exclusive property of the Subrecipient or medical provider. Subrecipient shall own and have the right to use the Data in accordance with the signed informed consent and authorization form, applicable laws, and the terms of this Subaward Agreement. Notwithstanding any licenses or other rights granted to Subrecipient herein, but in accordance with the Confidentiality and Publication sections herein, Subrecipient shall retain the right to use the Data and results for its publication, IRB, regulatory, legal, clinical, educational, and internal research purposes.

Use of Name

Neither party may use the name, trademark, logo, symbol, or other image or trade name of the other party or its employees, students and agents in any advertisement, promotion, or other form of publicity or news release or that in any way implies endorsement without the prior written approval of an authorized representative of the party whose name is being used. Such approval will not be unreasonably withheld.

Subrecipient will acknowledge the PTE’s support, including but not limited to financial support as may be required by academic journals, professional societies, funding agencies, and applicable regulations. Notwithstanding anything herein to the contrary, Subrecipient shall have the right to post PTE’s name, the Study Title, and the Period of Performance, and funding amount, on Subrecipient publicly accessible lists of research conducted by the Subrecipient.

Monitoring and Clinical Trial Auditing

Any site visits by **NDMC PTE** and/or its authorized designee (e.g., Study monitor) will be scheduled in advance for times mutually acceptable to the parties during normal business hours. **PTE NDMCs** and/or authorized designee’s access is subject to reasonable safeguards to ensure confidentiality of medical records and systems.

Upon becoming aware of an audit or investigation by a regulatory agency with jurisdiction over the Study, Subrecipient agrees to provide **PTE NDMC** with prompt notice of the audit or investigation. If legally permissible or allowable by the regulatory agency and permissible in accordance with the Subrecipient’s policy, **PTE NDMC** may be available or request to be present with approval from auditor during such audit, but **PTE NDMC** agrees not to alter or interfere with any documentation or practice of Subrecipient. Subrecipient shall be free to respond to any regulatory agency inquiries and will provide **PTE NDMC** with a copy of any formal response or documentation to the regulatory agency regarding the Study.

Confidentiality

It is anticipated that in the performance of this Agreement, the parties may need to disclose information which is considered confidential. The rights and obligations of the parties with respect to such information are as follows:

“Confidential Information” refers to information of any kind which is disclosed by one party, “the Discloser”, to the other party, “the Recipient”, for purposes of conducting the Study which:

- a) by appropriate marking, is identified as confidential and proprietary at the time of disclosure;
- b) if disclosed orally, is identified in a marked writing within thirty (30) days as being confidential; or
- c) parties will make reasonable efforts to mark Confidential Information as stated in (a) and (b) above. However, to the extent such marking is not practicable, then in the absence of written markings, information disclosed (written or verbal) that a reasonable person familiar with the Study would consider to be confidential or proprietary from the context or circumstances of disclosure shall be deemed as such. Notwithstanding the foregoing, Data and results generated in the course of conducting the Study are not Confidential Information for publishing purposes.

Subject to Publication Section, parties agree, for a period of three (3) years following the termination or expiration of this Subaward Agreement, to use reasonable efforts, no less than the protection given their own confidential information, to use Confidential Information received in accordance with this Section.

Parties agree to use Confidential Information solely as allowed by this Subaward Agreement, and for the purposes of conducting the Study. Parties agree to make Confidential Information available only to those of its, or its affiliated hospitals' employees, personnel, agents, consultants, and vendors, and approved subcontractors, as applicable, who require access to it in the performance of this Study, and are subject to similar terms of confidentiality.

The obligation of nondisclosure does not apply with respect to any of the Confidential Information that:

- a) is or becomes public knowledge through no breach of this Subaward Agreement;
- b) is disclosed by a third party entitled to disclose such information without known obligation of confidentiality;
- c) is already known or is independently developed without use of the Discloser's Confidential Information as shown by the Recipient's contemporaneous written records;
- d) is necessary to obtain IRB approval of Study or required to be included in the written information summary provided to Study subject(s) and/or informed consent form;
- e) is released with the prior written consent of the Discloser; or
- f) is required to support the medical care of a Study subject.

The Recipient may disclose the Discloser's Confidential Information to the extent that it is required to be produced pursuant to a requirement of applicable law, IRB, government agency, an order of a court of competent jurisdiction, or a facially valid administrative, Congressional, or other subpoena, provided that Recipient, subject to the requirement, order, or subpoena, promptly notifies the Discloser. To the extent allowed under applicable law, the Discloser may seek to limit the scope of such disclosure and/or seek to obtain a protective order. Recipient will disclose only the minimum amount of Confidential Information necessary to comply with law or court order as advised by its legal counsel.

No license or other right to a party's Confidential Information is created or granted hereby, except the specific right to conduct the Study as set forth by Protocol and under terms of this Subaward Agreement, nor shall any license or other right with respect to the subject matter hereof be created or granted except by the prior written agreement of the Parties duly signed by their authorized representatives.

Upon Discloser's written request, Recipient agrees to return all Confidential Information supplied to it by the Discloser pursuant to this Subaward Agreement except that Recipient may retain a duplicate original in a secure location for purposes of identifying and satisfying its obligations and exercising its rights under this Subaward Agreement.

Parties may disclose the existence of this Subaward Agreement and any additional information necessary to ensure compliance with applicable Federal, State and Institutional policies, regulations, and laws.

HIPAA/PHI

There ☒ will ☐ will not be personal health information (PHI) or personally identifiable information (PII) involved in this Study.

PTE shall be provided with patient information as allowed by law and will maintain the confidentiality of all such patient information, unless specifically required to disclose such information by law.

Record Retention

Subrecipient shall retain and preserve a copy of the Study-related financial and programmatic records, supporting documents, statistical records and all other records pursuant to record retention requirements as provided in 2 CFR 200.333 and 45 CFR 46.

Inventions, Discoveries and Patents

The determination of rights in ownership and disposition of inventions resulting from the performance of the Statement of Work ("Subject Inventions") and the administration of patents will be in accordance with 37 CFR 401 and the terms of this Subaward Agreement. Subrecipient shall disclose promptly to PTE any patentable Subject Inventions pursuant to the reporting requirements provided in Attachment 4.

Publication

Prior to enrollment of the first subject in the Study, ~~PTE~~ **PR** agrees to ensure that the Study is fully registered on www.clinicaltrials.gov in accordance with the requirements of the International Committee of Medical Journal Editors (ICMJE) and Public Law 110-85 (42USC282). Results of this Study will be reported in compliance with applicable laws. Each party shall have the right to publish and disseminate information derived from the performance of the Statement of Work under this Subaward Agreement.

Qualification for authorship shall be in keeping with generally accepted criteria. Subrecipient shall provide ~~PTE~~ **PR** with a copy of any proposed publication for review and comment at least thirty (30) days prior to submission. Activities, reports and publications resulting from this grant must adhere to the Acknowledgement standards set by the NIH. (<http://grants.nih.gov/grants/acknow.htm#requirements>)

☒ This Study is part of a multi-center clinical trial. The Subrecipient agrees that the first Publication of the results of the Study shall be made in conjunction with the presentation of a joint multi-center Publication of the Study results with the Principal Investigators from all sites contributing Data, analyses, and comments. However, Subrecipient may publish the Data and Study results individually in accordance with this Publication section upon first occurrence of one of the following: (i) multi-center Publication is published; (ii) no multi-center publication is submitted within twelve (12) months after conclusion, abandonment, or termination of the Study at all sites; or (iii) ~~PTE~~ **PR** confirms in writing there will be no multi-center Publication.

If no multi-center Publication occurs within twelve (12) months of the completion of the Study at all sites, upon request by Subrecipient, ~~PTE~~ **PR and NDMC** agrees to provide Subrecipient access to the aggregate Data from all Study sites.

Electronic Signatures and Records

The parties of this agreement accept facsimile, electronic, and/or PDF signatures in lieu of original signatures which comply with 2 CFR 200.335.

Human Subjects

Both parties shall comply with all applicable federal laws, regulations and policy statements, including but not limited to 21 CFR Parts 50 and 56, 45 CFR Part 46, and HIPAA. Subrecipient further agrees to conduct all federally-funded human subjects research under their DHHS Federal Wide Assurance number as provided in Attachment 3B and in accordance with all provisions contained therein.

Insurance

PTE and Subrecipient agree that sufficient general and professional liability insurance/malpractice insurance or self-insurance exists and shall be maintained to cover liability from the performance of their respective responsibilities hereunder. Parties agree that upon request evidence of adequate insurance will be provided.

Warranty

Neither party makes any warranty, express or implied, including, without limitation, any implied warranty of merchantability or any implied warranty of fitness for a particular purpose with respect to any research activity or article supplied by it or its Principal Investigator in connection with this Protocol, nor with respect to any patent, trademark, know-how, tangible research property, information or data provided to the other party hereunder, and each party hereby disclaims the same.

Safety Reporting

If monitoring is required for the Study, the PTE NDMC will send Subrecipient Principal Investigator any monitoring findings and data safety monitoring committee reports that (i) affect the safety and welfare of current or former Study subjects, or (ii) influence the conduct of the Study. Subrecipient and/or Subrecipient Principal Investigator will communicate such findings to the ~~IRB~~ CIRB and Study subjects, as appropriate.

Termination and Suspension

Either party may terminate this Subaward Agreement with thirty (30) business days written notice. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance 2 CFR 200, or 45 CFR 75, Appendix IX, "Principles for Determining Cost Applicable to Research & Development under Grants and Contracts with Hospitals", as applicable. This Study may be suspended or terminated in whole or in part immediately if the Subrecipient fails to comply with the terms and conditions of the Federal award; or at any time for any reason by the Subrecipient or PTE when, in their judgment or that of the Principal Investigator, Subrecipient Principal Investigator, the PTE's IRB, the Subrecipient's IRB, Scientific Review Committee, if applicable, or the Federal Awarding Agency, it is determined to be inappropriate, impractical, or inadvisable to continue, in order to protect the Study subjects' rights, welfare and safety, or the IRB otherwise disapproves the Study in accordance with the terms of this Agreement.

This study may be terminated or suspended immediately in whole or in part in the event that the Federal Awarding Agency reduces or terminates funding for the prime award.

Notwithstanding the above, any party may, in addition to any other available remedies:

- a) immediately terminate this Subaward Agreement upon the other party's material failure to adhere to the Protocol, except for deviation required to protect the rights, safety, and welfare of Study subjects; and/or
- b) terminate this Subaward Agreement upon the other party's material default or breach of this Subaward Agreement, provided that the defaulting/breaching party fails to remedy such material default, or breach of this Subaward Agreement within thirty (30) business days after written notice thereof;

In the event that this Subaward Agreement is terminated or suspended prior to completion of the Study, for any reason, Subrecipient shall:

- a) notify the IRB that the Study has been terminated or suspended;
- b) cease enrolling subjects in the Study;
- c) cease treating Study subjects under the Protocol as directed by PTE to the extent medically permissible and appropriate;
- d) terminate, as soon as practicable, all other Study activities; and cooperate with PTE to provide for an orderly wind-down of the Study;
- e) cease spending on the Subaward Agreement pending resolution of the suspension;
- f) provide adequate documentation to allow both parties to facilitate an orderly close out of the projects; and
- g) provide the information necessary for the PTE to meet its obligations to the Federal Awarding Agency.

If for any reason the Subrecipient Principal Investigator as indicated in Attachment 3B (or personnel considered essential for the work) is unavailable to direct the performance of the work under this Subaward Agreement, Subrecipient shall notify PTE. If the parties are unable to identify a mutually acceptable successor, this Subaward Agreement may be terminated by either party upon thirty (30) days written notice.

Subject Material

"Original Subject Material" means any biologic material of human origin including, without limitation, tissues, blood, plasma, urine, spinal fluid, or other fluids derived from the Study subjects in accordance with and pursuant to Subrecipient's performance of the Protocol.

☐ This clinical trial does not include the transfer of Subject Material.

☒ This clinical trial includes the transfer of Subject Material. All transfers of Subject Material hereunder shall be documented by execution by both parties or respective Principal Investigators of a Transfer Record consistent with the one attached to this Subaward Agreement as Attachment 7.

For the purposes of this Subaward Agreement, "Subject Material" shall include the Original Subject Material plus Unmodified Derivatives, and Progeny where Unmodified Derivatives means substances created by PR PTE which constitute an important unmodified functional sub-unit or expression product of the Original Subject Material and Progeny means unmodified descendant from the Original Subject Material.

Subrecipient agrees to make the Subject Material available to the PR PTE in accordance with the Protocol for the purposes of the Study. The Subject Material provided by Subrecipient shall remain the property of Subrecipient and may be used by the PR PTE, central laboratory, or their contracted party for the performance of the Study only as allowed by the Study subject's informed consent form or pertinent institutional review board(s). PR PTE agrees that any use of Subject Materials, other than as allowed by the Study subject's informed consent form, will require additional IRB review and approval. Any substances created by PR PTE which contain/incorporate any form of the Subject Material (a "Modification") shall be owned by PR PTE; provided, however, that the Subrecipient shall retain ownership of any form of the Subject Material contained therein.

PR PTE agrees to use the Subject Material in a safe manner and in compliance with all applicable laws and regulations, including, but not limited to current EPA, FDA, USDA and NIH guidelines. The Subject Material is supplied solely for research purposes, for use in animals and/or in vitro. Except as provided herein, nothing in this Subaward Agreement shall be construed as granting any rights to PR PTE, by license or otherwise, to any Subject Material. At the completion of the Study or termination of this Subaward Agreement, PR PTE will discontinue its use of the Subject Material and will, upon direction of the Subrecipient, return or destroy the Subject Material. PR PTE will also either destroy Modifications or remain bound by the terms of this Agreement as they apply to Modifications.

For the avoidance of doubt, PR PTE (or their subcontractors) shall not be entitled to use the Subject Material and/or Modifications thereof for commercial purposes without the prior written consent of the Subrecipient. For this Subaward Agreement, commercial purposes shall include the sale, lease, license, or other transfer of the Subject Material or Modifications to a for-profit organization or the use of the Subject Material or Modifications by any organization, including PR PTE, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, or license of the Subject Material or Modifications to a for-profit organization. PR PTE certifies that research with the Subject Material and/or Modifications will not be subject to the terms of any agreement or contract in which a third party, other than the federal government, gains rights to the Material and/or Modifications.

If the Study subject's informed consent form and/or pertinent institutional review board(s) does not allow for the disclosure of identifying information with the Subject Material, the Subject Material will be provided to the PR PTE de-identified and all Protected Health Information ("PHI"), as defined by the Federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191), as amended ("HIPAA", 45 C.F.R. 160 and 164), will have been removed and PR PTE will not be provided with any information that could be used to identify the subjects from whom the Subject Material was collected, although Subrecipient may retain a confidential link to the subjects' identities. Neither the PR PTE nor PR PTE's Investigator shall make any attempts to determine the identity of those subjects, or to contact the subjects.

Any Subject Material delivered pursuant to this Subaward Agreement is understood to be experimental in nature and may be hazardous. SUBRECIPIENT MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE SUBJECT MATERIAL AND/OR MODIFICATIONS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER RIGHTS, OR THAT THE SUBJECT MATERIAL AND/OR MODIFICATIONS WILL NOT POSE A SAFETY OR HEALTH RISK.

Subcontract/Assignment

~~Subrecipient may subcontract to other sites to conduct the Study in accordance with the Protocol with terms consistent with this Subaward Agreement with written approval of the PTE, which approval shall not be unreasonably withheld. Such subcontracts will be provided to the PTE upon written request.~~

Force Majeure

If either party hereto shall be delayed or hindered in, or prevented from, the performance of any act required hereunder for any

reason beyond such party's direct control, including but not limited to, strike, lockouts, labor troubles, riots, insurrections, war, acts of God, inclement weather, or other reason beyond the party's control (a "Disability") then such party's performance shall be excused for the period of the Disability. Any Study timelines affected by a Disability shall be extended for a period equal to the delay and any affected Budget shall be adjusted to account for cost increases or decreases resulting from the Disability. The party affected by the Disability shall notify the other party of such Disability as provided for herein.

Counterparts

This Subaward Agreement may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document, and is binding on all Parties notwithstanding that each of the Parties may have signed different counterparts.

Entire Agreement

Section and clause headings are used herein solely for convenience of reference and are not intended as substantive parts of this Subaward Agreement. This Subaward Agreement incorporates the Attachments referenced herein. This written Subaward Agreement constitutes the entire agreement between the parties concerning the subject matter, and supersedes all other or prior agreements or understandings, whether written or oral, with respect to that subject matter. Any changes made to the terms, conditions or amounts cited in this Subaward Agreement require the written approval of each party's authorized representative. In the event of a conflict between the terms of this Subaward Agreement and the Protocol, the Protocol shall govern all medical and scientific matters, and this Subaward Agreement will govern all other matters.

Study Drug

Study drug will be provided to Subrecipient ☒ at no cost to them/☐ at cost [PTE to choose]. Subrecipient assures by signing this Subaward Agreement, (i) that the drug provided will be used only for the Study identified on the Subaward Agreement Study Title field above; (ii) that the drug provided will be used only in accordance with the IRB approved protocol ("Protocol"); and (iii) that the drug is only dispensed to Study subjects who have signed the approved informed consent form. Subrecipient will further ensure that the drug is properly handled, secured and stored, and that the drug is not transferred, misbranded, sold, administered, handled or used by any unauthorized third party. Except as specified by the Protocol, Subrecipient will not modify the drug in any way including changing the container or closure.

The drug provider ☐ will/ ☒ will not reimburse for Study related Subject injury (if affirmative above, see attached letter from drug provider).

ADDITIONAL TERMS

This section can be used to include limited additional terms. However, FDP members should not include additional terms to other FDP members except for the following: project-specific terms, data transfer and use terms, or terms necessary after conducting a subrecipient risk assessment per your institution's policies. Please do not include indemnification, law and venue clauses, as public institutions can never accept these conditions.

Certificates of Confidentiality

FDP is piloting NIH Certificates of Confidentiality (CoC) language during 2018. You may choose to use either Option 1 or 2 below, or insert other language of your choosing.

Option 1

The Parties understand that all biomedical, behavioral, clinical, or other human subjects research funded wholly or in part by the National Institutes of Health ("NIH"), whether supported through grants, cooperative agreements, contracts, other transaction awards, or conducted by the NIH Intramural Research Program, that collects or uses identifiable, sensitive information (including identifiable biospecimens or individual-level genomic data) as defined by NIH Policy NOT-OD-17-109 (the "Policy") (hereinafter, "ISI"), and that was commenced or ongoing on or after December 13, 2016, is deemed under the Policy to be issued a Certificate of Confidentiality ("Certificate"). All institutions and investigators collecting or receiving ISI under a Project that has been issued a Certificate are required to protect the privacy of individuals who are subjects of such research in accordance with the Policy and subsection 301(d) of the Public Health Service Act (the "PHS Act").

In compliance with the Policy, Subrecipient hereby certifies that if a Certificate has been issued for this Project and Subrecipient collects or receives ISI in the performance of the Project, Subrecipient and its investigators understand that their use and disclosure of ISI is subject to a Certificate issued pursuant to the Policy, and Subrecipient and its investigators will comply with the Policy, the NIHGPS and 301(d) of the PHS Act, including but not limited to the disclosure restrictions therein, in their use and disclosure of ISI. This term survives the expiration of this Agreement and the close of the Project.

Option 2

The Parties agree that this research funded in whole or in part by the National Institutes of Health ("NIH"), is subject to NIH Policy NOT-OD-17-109 (the "Policy") and therefore is deemed under the Policy to be issued a Certificate of Confidentiality ("Certificate") should the conditions outlined within apply. Accordingly, the subrecipient is required to adhere to the Policy and protect the privacy of individuals who are subjects of such research in accordance with the Policy and subsection 301(d) of the Public Health Service Act (the "PHS Act").

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). (ADM 3 Network Publication Policy) <http://www.nihstrokenet.org/docs/default-source/strokenet-sops/adm-sop-03-publication.pdf?sfvrsn=2>
- b. Note that a different publication process may be required for collaborations with Third Parties.
- c. 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.
- d. All authors will be required to comply with journal specific Conflict of Interest (COI) reporting requirements.

Attachment 3A FDP Fixed Price Research Clinical Trial Subaward Agreement Pass-through entity (PTE) Contacts				Subaward Number: 012043-140000
Pass-through Entity (PTE) (National Coordinating Center ("NCC"))				
Name:	University of Cincinnati			
Address:	51 Goodman Avenue, Suite 530			
City/State/Zip+4:	Cincinnati, OH 45221-0222			
EIN No.:	31-6000989	Institution Type :	State Educational Institution	
DUNS No.:	041064767	Congressional District:	OH-001	
Registration current in SAM.gov?	Yes			
PTE's Administrative Contact - Contract Manager				
Name:	Diane Sparks			
Address:	University of Cincinnati, College of Medicine Dept of Neurology and Rehabilitative Medicine, 260 Stetson Street, Suite 5221			
City/State/Zip+4:	Cincinnati, OH 45267-0525			
Telephone:	513-558-3924			
E-Mail:	Diane.sparks@uc.edu			
PTE's Principal Investigator				
Name:	Joseph Paul Broderick, MD			
Address:	University of Cincinnati, College of Medicine Dept of Neurology and Rehabilitative Medicine, 260 Stetson Street, Suite 5221			
City/State/Zip+4:	Cincinnati, OH 45267-0525			
Telephone:	Rose Beckman 513-559-3907			
E-Mail:	broderjp@ucmail.uc.edu			
PTE Financial Contact				
Name:	Keri Davidson Pinger			
Address:	University of Cincinnati, College of Medicine Dept of Neurology and Rehabilitative Medicine, 260 Stetson Street, Suite 5221			
City/State/Zip+4:	Cincinnati, OH 45267-0525			
Telephone:	513-558-3915			
E-Mail:	strokenettrialpymts@ucmail.uc.edu			
Is above address used to submit invoices? ☐ Yes ☒ No (If no, include invoicing address below with instructions.)				
Invoicing Address: Study sites will not submit invoices to PTE for study activities completed. Payments will be determined automatically on a monthly basis for all required tasks completed as confirmed by the NDMC CTMS WebDCU™. All payments are inclusive of F&A costs.				
Pass-through Entity's Authorized Official				
Name:	Diane Sparks, RN, BS, Contracts Manager, Legal Liaison, NIH StrokeNet			
Address:	University of Cincinnati, College of Medicine Dept of Neurology and Rehabilitative Medicine, 260 Stetson Street, Suite 5221			
City/State/Zip+4:	Cincinnati, OH 45267-0525			
Telephone:	513-558-3924			
E-Mail:	Diane.sparks@uc.edu			
Fully Executed Agreements/Amendments should returned to: Pass-through Entity's PTE's Administrative Contact - Contract Manager / Authorized Official				

Attachment 3B FDP Fixed Price Research Clinical Trial Subaward Agreement Subrecipient Place of Performance					Subaward Number: 012043-140000	
Subrecipient (Regional Coordinating Center ("RCC") or Satellite ("SS"))						
Name:	San Bernardino, County of dba Arrowhead Regional Medical Center					
Address:	400 N Pepper Ave					
City/State/Zip+4:	Colton, CA 92324-1801					
EIN No.:	95-6002748	Institution Type :	County Government			
Is Subrecipient currently registered in SAM? ☒ Yes ☐ No						
Is Subrecipient exempt from reporting compensation? ☐ Yes ☐ No (If no, please complete 3B page 2)						
DUNS No.:	075100599	Congressional District:	CA-031			
Parent DUNS No.:		Congressional District:				
RCC Site No. & Name: 11 University Of California, Los Angeles						
Address:	10889 Wilshire Blvd Ste 700					
City/State/Zip+4:	Los Angeles, CA 90095-0001					
PI:	Jeffrey L. Saver, MD; Gene Yong Sung, MD	Phone:		E-mail:		
Study Coordinator:	Clare Binley; Ileana Grunberg	Phone:	323-409-1532; 310-794-0600	E-mail:	clare.binley@med.usc.edu; lgrunberg@mednet.ucla.edu	
Subrecipient Administrative Contact						
Name:	Michael Neeki, DO Director of Research					
Address:	400 North Pepper Ave					
City/State/Zip+4:	Colton, CA 92324-1801					
Telephone:	9095801453					
E-Mail:	NeekiM@armc.sbcounty.gov					
Subrecipient Principal Investigator (PI)						
Name:	Dan Miulli, DO, FACOS					
Address:	400 North Pepper Ave					
City/State/Zip+4:	Colton, CA 92324-1801					
Telephone:	9095801366					
E-Mail:	MiulliD@armc.sbcounty.gov					
Subrecipient Financial Contact						
Name:	Arvind Oswal, CFO					
Address:	400 North Pepper Ave					
City/State/Zip+4:	Colton, CA 92324-1801					
Telephone:	9095806170					
E-Mail:	OswalA@armc.sbcounty.gov					
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: https://www.uc.edu/content/dam/uc/af/controller/docs/DirectDepositForm.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.						
Subrecipient Authorized Official						
Name:	Curt Hagman, Chairman, Board of Supervisors					
Address:	385 N. Arrowhead Avenue, Fifth Floor					
City/State/Zip+4:	San Bernardino, CA 92415-0103					
Telephone:	(909) 387-4866					
E-Mail:	Curt.Hagman@bos.sbcounty.gov					

Attachment 3B Page 2 FDP Fixed Price Research Clinical Trial Subaward Agreement Highest Compensated Officers	Subaward Number: 012043-140000
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Subrecipient is currently registered in SAM.gov and has reported this information if required there.

Institute: San Bernardino, County of dba Arrowhead Regional Medical Center

PI: Dan Miulli, DO, FACOS

Highest Compensated Officers

The names and total compensation of the five most highly compensated officers of the entity(ies) must be listed if the entity in the preceding fiscal year received 80 percent or more of its annual gross revenues in Federal awards; and \$25,000,000 or more in annual gross revenues from Federal awards; and the public does not have access to this information about the compensation of the senior executives of the entity through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. See FFATA § 2(b)(1) Internal Revenue Code of 1986.

Officer 1 Name
Officer 1 Compensation
Officer 2 Name
Officer 2 Compensation
Officer 3 Name
Officer 3 Compensation
Officer 4 Name
Officer 4 Compensation
Officer 5 Name
Officer 5 Compensation

Attachment 3B Page 3 FDP Fixed Price Research Clinical Trial Subaward Agreement Place of Performance		Subaward Number: 012043-140000
Institution/Organization ("Subrecipient") (RCC) or (RCC-S)		
Name:	San Bernardino, County of dba Arrowhead Regional Medical Center	
Clinical Performing Sites R__-S__-CPS__:		
Name:	Arrowhead Regional Medical Center	
Address:	400 N Pepper Ave	
City/State/Zip+4:	Colton, CA 92324-1801	
Congressional District:	CA-031	

Attachment 4

Fixed-Rate Clinical Trial Subaward Agreement Reporting Requirements

Pass-through Entity will check all that apply that the Subrecipient will agree to: - All Prime reporting requirements apply to Pass-through Entity only.

- ☐ A Final technical/progress report will be submitted to the Pass-through Entity's Choose an item. identified in Attachment 3 within Choose an item. days after the end of the period of performance.
- ☐ Monthly technical/progress reports will be submitted to the Pass-through Entity's Choose an item. identified in Attachment 3, within Choose an item. days of the end of the month.
Choose an item.
- ☐ Quarterly technical/progress reports will be submitted within thirty (30) days after the end of each project quarter to the Pass-through Entity's Choose an item. identified in Attachment 3.
- ☐ Technical/progress reports on the project as may be required by Pass-through Entity's Choose an item. in order that Pass-through Entity may be able to satisfy its reporting obligations to the Federal Awarding Agency.
- ☐ Annual technical/progress reports will be submitted within Choose an item. days prior to the end of each project period to the Pass-through Entity's Choose an item. identified in Attachment 3. Such report shall also include updated Other Support for key personnel, certification of appropriate education in the conduct of human subject research of any new key personnel, and annual IRB or IACUC approval, if applicable.
- ☐ In accordance with 37 CFR 401.14, Subrecipient agrees to notify PTE's Choose an item. identified in Attachment 3A within Choose an item. days after Subrecipient's inventor discloses invention(s) in writing to Subrecipient's personnel responsible for patent matters. The Subrecipient will submit a final invention report using Awarding Agency specific forms to the PTE's Choose an item. identified in At of the end of the period of performance so that it may be included with the PTE's final invention report to the Awarding Agency. A negative report ☐ is ☐ is not required.
- ☐ A Certification of Completion, in accordance with 2 CFR 200.201(b)(3), will be submitted within Choose an item. days after the end of the project period to the Pass Through Entity's Choose an item. identified in Attachment 3 (for Fixed-Rate subawards only.)
- ☐ Property Inventory Report; frequency, type, and submission instructions listed here and only to be used when required by PTE Federal Award Click or tap here to enter text..

Other Special Reporting Requirements

Attachment 5
Fixed-Rate Clinical Trial Subaward Agreement

Statement of Work

Indirects

Payment Schedule

Statement of Work is available at <https://www.nihstrokenet.org/aspire-trial/resources>

Indirect Information

Indirect Cost Rate (IDC) Applied 42 % ☐ TDC, or ☐ MTDC, or ☒ OTHER

- 1) A uniform institutional allowance was determined by the NCC for F&A recovery and was applied to applicable cost elements within each fixed unit per patient cost.
- 2) The NIH StrokeNet used the 25 Regional Coordinating Center on campus and off campus rates. Determined an average of each and averaged those two numbers which came out to 42%.
- 3) This is a fixed fee per patient clinical trial. All fixed price (fee) units will be inclusive of F & A costs recovery.

Payment Schedule

<http://www.nihstrokenet.org/clinical-trials/trials>

<http://www.nihstrokenet.org/aspire-trial/resources>

Attachment 6
Fixed-Rate Clinical Trial Subaward Agreement
Prime Award

RESEARCH PROJECT COOPERATIVE AGREEMENT (RCC)

Year 1 Award Issue Date: 07/01/2019

**Department of Health and Human Services, National Institutes of Health
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE**

Grant Number:

1U01NS106513-01A1

Yale University ("Prime Recipient")

Principal Investigator(S):

**Hooman Kamel, MD
Kevin Navin Sheth (contact), MD**

Project Title: Anticoagulation in ICH Survivors for Prevention and Recovery (ASPIRE)

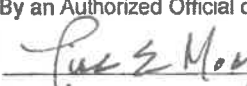
August 14, 2019 (date of FEO Subaward from Yale)

FDP Cost Reimbursement Research Subaward Agreement

Federal Awarding Agency: National Institutes of Health (NIH)	
Pass-Through Entity (PTE): Yale University	Subrecipient: University of Cincinnati
PTE PI: Kevin Sheth, MD	Sub PI: Pooja Khatri, MD
PTE Federal Award No: 1U01NS106513-01A1 Revised	Subaward No: GR106686 (CON-80001816)
Project Title: Anticoagulation in ICH Survivors for Prevention and Recovery (ASPIRE)	
Subaward Period of Performance (Budget Period): Start: 02/01/2019 End: 04/30/2020	Amount Funded This Action (USD): \$ 1,032,321.00
Estimated Project Period (if incrementally funded): Start: 02/01/2019 End: 04/30/2024	Incrementally Estimated Total (USD): \$ 13,018,629.00

Terms and Conditions

- PTE hereby awards a cost reimbursable subaward, as described above, to Subrecipient. The Statement of Work and budget for this Subaward are as shown in Attachment 5. In its performance of Subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.
- Subrecipient shall submit invoices not more often than monthly and not less frequently than quarterly for allowable costs incurred. Upon the receipt of proper invoices, the PTE agrees to process payments in accordance with this Subaward and 2 CFR 200.305. 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 required in 2 CFR 200.415 (a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments shall be directed to the party's Financial Contact, shown in Attachment 3A.
- A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Financial Contact, as shown in Attachment 3A, not later than 60 days after the Budget Period end date. The final statement of costs shall constitute Subrecipient's final financial report.
- All payments shall be considered provisional and are 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.
- Matters concerning the technical performance of this Subaward shall be directed to the appropriate party's Principal Investigator as shown in Attachments 3A and 3B. Technical reports are required as shown in Attachment 4.
- Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this Subaward, and any changes requiring prior approval, shall be directed to each party's Authorized Official Contact, as shown in Attachments 3A and 3B. Any such change made to this Subaward requires the written approval of each party's Authorized Official, as shown in Attachments 3A and 3B.
- The PTE may issue non-substantive changes to the Period of Performance and budget Unilaterally. Unilateral modification shall be considered valid 14 days after receipt unless otherwise indicated by Subrecipient when sent to Subrecipient's Administrative Contact, as shown in Attachment 3B.
- Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.
- Either party may terminate this Subaward with 30 days written notice to the appropriate party's Authorized Official Contact, as shown in Attachments 3A and 3B. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix IX, as applicable.
- By signing this Subaward, including the attachments hereto which are hereby incorporated by reference, Subrecipient certifies that it will perform the Statement of Work in accordance with the terms and conditions of this Subaward and the applicable terms of the Federal Award, including the appropriate Research Terms and Conditions ("RTCs") of the Federal Awarding Agency, as referenced in Attachment 2. The parties further agree that they intend this Subaward to comply with all applicable laws, regulations and requirements.

By an Authorized Official of Pass-through Entity:  Name: Lauren Pite Title: Associate Director, Subaward Management Team Date: 8/14/2019	By an Authorized Official of Subrecipient: David S. Gearing, Sr., MHA Digitally signed by David S. Gearing, Sr., MHA DN: cn=David S. Gearing, Sr., MHA, o=University of Cincinnati, ou=2005 Grants and Contracts, email=ds.gearing@uc.edu, c=US Date: 2019.08.13 12:39:56 -0400 Name: David S. Gearing, SR., MHA Title: Director Business Affairs, Sponsored Research Services Date: 08/13/2019
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Attachment 1

Certifications and Assurances

Subaward Number:

GR106686 (CON-80001816)

Certification Regarding Lobbying (2 CFR 200.450)

By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief, that 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 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 in accordance with 2 CFR 200.450.

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 PTE.

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 31 U.S.C. 1352. 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 (2 CFR 200.213 and 2 CFR 180)

By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief that neither the Subrecipient 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, in accordance with 2 CFR 200.213 and 2 CFR 180.

Audit and Access to Records

Per 2 CFR 200.501- 200.521, Subrecipient certifies that it will provide notice of any adverse findings which impact this Subaward and will provide access to records as required by parts 2 CFR 200.336, 200.337, and 200.201 as applicable. If Subrecipient is not subject to the Single Audit Act, then Subrecipient will provide notice of the completion of any required audits and provide access to such audits upon request.

Program for Enhancement of Contractor Employee Protections (41 U.S.C 4712)

Subrecipient is hereby notified that they are required to: inform their employees working on any federal award that they are subject to the whistleblower rights and remedies of the pilot program; inform their employees in writing of employee whistleblower protections under 41 U.S.C §4712 in the predominant native language of the workforce; and include such requirements in any agreement made with a subcontractor or subgrantee.

The Subrecipient shall require that the language of the certifications above in this Attachment 1 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.

Use of Name

Neither party shall use the other party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may use factual information regarding the existence and purpose of the relationship that is the subject of this Subaward for legitimate business purposes, to satisfy any reporting and funding obligations, or as required by applicable law or regulation without written permission from the other party. In any such statement, the relationship of the parties shall be accurately and appropriately described.

Attachment 2
Federal Award Terms and Conditions

Subaward Number

GR106686 (CON-80001816)

Required Data Elements

The data elements required by Uniform
Guidance are incorporated in the attached Federal Award.

Federal Award Issue Date FAIN CFDA No.
07/01/19 U01NS106513 93.853

This Subaward Is:

☒ Research & Development ☒ Subject to FFATA

CFDA Title

Extramural Research Programs in the Neurosciences and Neurological Disorders

Key Personnel Per NOA

General Terms and Conditions

By signing this Subaward, Subrecipient agrees to the following:

1. To abide by the conditions on activities and restrictions on expenditure of federal funds in appropriations acts that are applicable to this Subaward to the extent those restrictions are pertinent. This includes any recent legislation noted on the Federal Awarding Agency's website:
<http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>
2. 2 CFR 200 and 45 CFR Part 75.
3. The Federal Awarding Agency's grants policy guidance, including addenda in effect as of the beginning date of the period of performance or as amended found at:
<http://grants.nih.gov/policy/notices.htm>
4. Research Terms and Conditions, including any Federal Awarding Agency's Specific Requirements found at:
<https://www.nsf.gov/awards/managing/rtc.jsp> except for the following:
 - a. No-cost extensions require the written approval of the PTE. Any requests for a no-cost extension shall be directed to the Administrative Contact shown in Attachment 3A, not less than 30 days prior to the desired effective date of the requested change.
 - b. Any payment mechanisms and financial reporting requirements described in the applicable Federal Awarding Agency Terms and Conditions and Agency-Specific Requirements are replaced with Terms and Conditions (1) through (4) of this Subaward; and
 - c. Any prior approvals are to be sought from the PTE and not the Federal Awarding Agency.
 - d. Title to equipment as defined in 2 CFR 200.33 that is purchased or fabricated with research funds or Subrecipient cost sharing funds, as direct costs of the project or program, shall vest in the Subrecipient subject to the conditions specified in 2 CFR 200.313.
 - e. Prior approval must be sought for a change in Subrecipient PI or change in Key Personnel (defined as listed on the NOA).
5. Treatment of program income: Additive

Multiple PIs (MPI)

☒ This subaward is subject to an MPI Leadership Plan. Both parties will follow the finalized MPI Leadership Plan.
The MPI plan is attached as part of Attachment 2.

Special Terms and Conditions:

Copyrights:

Subrecipient Shall Grant to PTE 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 solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Subrecipient grants to PTE the right to use any written progress reports and deliverables created under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its Federal Award.

Data Rights:

Subrecipient grants to PTE the right to use data created in the performance of this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Data Sharing and Access (Check if applicable):

☒ Subrecipient agrees to comply with the Federal Awarding Agency's data sharing and access requirements as reflected in the NOA (or in the special terms below) and the Data Management/Sharing Plan submitted to the Federal Awarding Agency and attached.

Promoting Objectivity in Research (COI):

Subrecipient must designate herein which entity's Financial Conflicts of Interest policy (COI) will apply: ☒ Subrecipient

If applying its own COI policy, by execution of this Subaward, Subrecipient certifies that its policy complies with the requirements of the relevant Federal Awarding Agency as identified herein:

Subrecipient shall report any financial conflict of interest to PTE's Administrative Representative or COI contact, as designated on Attachment 3A. Any financial conflicts of interest identified shall, when applicable, subsequently be reported to Federal Awarding Agency. Such report shall be made before expenditure of funds authorized in this Subaward and within 45 days of any subsequently identified COI.

Work Involving Human or Vertebrate Animals (Select Applicable Options)

☒ Human Subjects ☐ Vertebrate Animals ☐ No Human or Vertebrate Animals

Subrecipient agrees that any non-exempt human and/or vertebrate animal research protocol conducted under this Subaward shall be reviewed and approved by its Institutional Review Board (IRB) and/or its Institutional Animal Care and Use Committee (IACUC), as applicable and that it will maintain current and duly approved research protocols for all periods of the Subaward involving human and/or vertebrate animal research. Subrecipient certifies that its IRB and/or IACUC are in full compliance with applicable state and federal laws and regulations. The Subrecipient certifies that any submitted IRB / IACUC approval represents a valid, approved protocol that is entirely consistent with the Project associated with this Subaward. In no event shall Subrecipient invoice or be reimbursed for any human or vertebrate animals related expenses incurred in a period where any applicable IRB / IACUC approval is not properly in place.

The PTE requires verification of IRB and/or IACUC approval be sent to the Administrative Contact as follows:

IRB

Human Subjects Data (Select One)

Human Subjects Data will be exchanged under this Subaward (check all that apply):

- ☒ From Subrecipient to PTE
☐ From PTE to Subrecipient

The PTE will set forth the terms of the exchange of Human Subjects Data (Select One):

Additional Terms

MULTIPLE PI LEADERSHIP PLAN

Rationale and Justification. The multiple PI leadership structure will take advantage of Dr. Sheth and Dr. Kamel's complementary expertise.

- Dr. Sheth is a nationally recognized leader in the study of intracerebral hemorrhage (ICH). He has had leadership roles in ICH studies funded by grants from the American Heart Association/American Stroke Association (AHA/ASA), American Academy of Neurology, and NIH. He was awarded the Robert G. Siekert Award from the AHA/ASA based on his report of the multicenter Prognosis in Intracerebral Hemorrhage Study (PICH). He has published over 30 peer-reviewed papers on ICH, served on the AHA/ASA Writing Group for Performance Measures in ICH, and currently serves on the steering committee for the NIH-funded Ethnic and Racial Variations in ICH (ERICH). Dr. Sheth has an established track record of leading multicenter trials in patients with severe cerebrovascular illness. He served as the PI of the Glyburide Advantage in Malignant Edema and Stroke (GAMES) Pilot trial and the phase 2 GAMES-RP trial. Enrollment in these two trials was completed ahead of schedule. He currently serves as the PI for the phase 3 CHARM trial which is comparing glyburide versus placebo in patients with large strokes.
- Dr. Kamel is a nationally recognized leader in the study of cardioembolic stroke. He has served as an invited participant in the Heart Rhythm Society Research Forum on Atrial Fibrillation (AF) and continues to serve as an invited member of the International AF SCREEN Collaboration and the Canadian Stroke Prevention Intervention Network's AF screening efforts. His research on the relationship between atrial disease and stroke has been funded by funding from the AHA/ASA and multiple active grants from NIH. He serves as the Protocol PI and Chair of the Executive Committee for ARCADIA, a recently launched StrokeNet trial comparing apixaban and aspirin for prevention of recurrent stroke in patients with ischemic stroke of undetermined source and evidence of atrial cardiopathy. He was awarded the Robert G. Siekert Award from the AHA/ASA based on a study on supraventricular arrhythmias and stroke risk. He has published over 40 peer-reviewed papers on cardioembolic stroke and served as a co-author on consensus statements on AF from the Heart Rhythm Society and the International AF-Screen Collaboration.

Delineation of Roles. The leadership structure involves non-overlapping, complementary roles.

- Dr. Sheth will serve as the contact PI and assume overall responsibility for the trial on behalf of the study sponsor, Yale University. He will serve as the primary contact for NINDS, the StrokeNet NCC and NDMC, and study sites. Dr. Sheth will assume responsibility for study recruitment. He will assume overall responsibility for keeping the protocol up to date, delegating certain specific aspects of this role to Dr. Kamel. Dr. Sheth will present the study rationale and design at the initial investigators' meeting, annual meetings, and scientific conferences, and will prepare the main manuscripts describing the methods and results of the pre-specified aims of the study. He will work closely with the NCC and NDMC on the development of the safety monitoring plan and adverse events reporting procedures. Lastly, Dr. Sheth will serve as chair of the Trial Operations Committee and chair of the Executive Committee.
- Dr. Kamel will serve as the lead PI for specific aspects of protocol development and study execution that will benefit from his unique expertise. He will take primary responsibility for updating aspects of the protocol related to subject eligibility or AF diagnosis and management in light of scientific developments. He will take primary responsibility for working with the NCC and NDMC on operationalizing all aspects of the trial related to eligibility, screening, and outcome ascertainment. He will serve as chair of the Publications Committee, co-chair of the Executive Committee, and co-chair of the Trial Operations Committee.

Procedures for Resolving Conflicts. Drs. Kamel and Sheth have worked together collegially on numerous scientific and programmatic endeavors over the past 6 years, including the studies that generated pilot data for ASPIRE. Nevertheless, we will have in place the following unambiguous procedures for resolving any conflicts.

- The Executive Committee will be the arbiter of all disputes.
- Agreement will generally be sought by consensus.
- In the unlikely event that consensus cannot be reached within the Executive Committee regarding substantive issues, an additional conference will be held to specifically discuss the disputed issue.
- If consensus still cannot be achieved after a follow-up, the Executive Committee will vote to determine resolution of disagreement. The contact PI, Dr. Sheth, will have the authority to frame the dispute in terms of a yes/no resolution and present it for a simple majority vote involving all Executive Committee members.

Data/Resource Sharing Plan

One of the primary goals for the establishment of NIH StrokeNet is to promote sharing of data for completed trials by the clinical research community within and beyond the network. To this end, harmonizing and standardizing the protocols from the trials (including data collection) and using Common Data Elements (CDE) as proposed by NINDS and other CDE initiatives will facilitate and enable the merging of data sets for further investigation by interested parties. In the following, we describe how the StrokeNet NDMC will prepare the study data for submission to the NINDS data repository.

Shortly after locking the study database, the NDMC statisticians will generate data files from each data table (corresponding to each eCRF) in the database. In compliance with the HIPAA regulations, each data file will be stripped of any and all personal identifiers and will undergo a de-identification process. The NDMC has a standard operating procedure for de-identification. This includes replacing all dates with days from enrollment/randomization, replacing study subject and site IDs with a unique random numbers, removing text fields, and collapsing fields that contain small event rates or small subgroups.

The final version of the study protocol, the annotated case report forms, the data dictionary and a user guide (or a "Readme" file) regarding the data files, such as explanation of derived variables, will be included in the submission to the NINDS. The timeline of submission in general will be within one year after the primary manuscript of the trial results is accepted for publication. During that year, the trial investigators will have opportunities to digest the study results and generate further exploratory hypotheses, and submit manuscript proposals, if so desired. The rationale for the timeline is to ensure that priority is given to the study investigators in manuscript development.

Upon completion of a trial and dissemination of primary results, the de-identified analysis data files will be made available to the public via the NINDS data repository (<https://www.ninds.nih.gov/Current-Research/Research-Funded-NINDS/Clinical-Research/Archived-Clinical-Research-Datasets>).

In order to expedite and track external data sharing, the ASPIRE website will serve as a resource and informational site for potential external investigators and collaborators. The website will include the ASPIRE publication policy, the data sharing procedures and policies, timelines, and contact information. All published ASPIRE manuscripts, abstracts, and brief descriptions of ongoing projects will be posted on the website, maintained by the StrokeNet NCC.

Attachment 3A
Pass-Through Entity (PTE) Contacts

Subaward Number:

GR106686 (CON-800016)

PTE Information

Entity Name: Yale University

Legal Address: Office of Sponsored Projects
25 Science Park, 3rd Floor, 150 Munson Street
P.O. Box 208327
New Haven, CT 06520-8327

Website: <https://your.yale.edu/research-support/office-sponsored-projects>

PTE Contacts

Central Email: gcat3@yale.edu

Principal Investigator Name: Kevin Sheth, MD

Email: kevin.sheth@yale.edu

Telephone Number: (203) 737-8051

Administrative Contact Name: Jeanette Culbreath, Subaward Manager

Email: Jeanette.Culbreath@yale.edu

Telephone Number: (203) 785-7320

COI Contact email (if different to above):

Financial Contact Name: Shared Services

Email: yss.subcontracts@yale.edu

Telephone Number: (203) 432-5394

Email invoices? ☒ Yes ☐ No Invoice email (if different):

Authorized Official Name: Elizabeth Riuz, Award Manager

Email: elizabeth.ruiz@yale.edu

Telephone Number: (203) 785-4689

PI Address:

Neurology
PO Box 208018
New Haven, CT 06520-8018

Administrative Address:

Same as legal address

Invoice Address:

Yale Shared Services
25 Science Park, 3rd Floor, 150 Munson Street
PO Box 208383, New Haven, CT 06520-8383

PLEASE SEND SUBAWARD INVOICE PAYMENT INQUIRIES TO: SharedServices@yale.edu

Attachment 3B**Research Subaward Agreement
Subrecipient Contacts**

Subaward Number:

GR106686 (CON-80001816)

Subrecipient Place of Performance for FFATA reporting

Name: University of Cincinnati

Address: Sponsored Research Services, University Hall, Suite 530, 51 Goodman Dr., PO Box 210222

City: Cincinnati State: OH Zip Code+4: 45221-0222 Zip Code Look-up

EIN No.: 1-316000989-A1 DUNS: 041064767 Parent DUNS:

Institution Type: Public/State Controlled Inst. of Higher Ed. Congressional District: OH-001

Is Subrecipient currently registered in SAM.gov? Yes No

Is Subrecipient exempt from reporting executive compensation? Yes No If no, complete 3B, page 2

Subrecipient Administrative Contact

Name: Sue Cutter, Assistant Director, Business Affairs

Address: Grants and Contracts Management Division, Sponsored Research Services
University Hall, Suite 530, 51 Goodman Dr. PO Box 210222

City: Cincinnati State: OH Zip Code: 45221-0222

Telephone: 513-556-2847 Email: sue.cutter@uc.edu

Subrecipient Principal Investigator

Name: Pooja Khatri, MD

Address: 260 Stetson St.

City: Cincinnati State: OH Zip Code: 45219

Telephone: 513-558-6411 Email: khatrip@ucmail.uc.edu

Subrecipient Financial Contact

Name: John Ungruhe, Director-Accounting Division

Address: Sponsored Research Services, University Hall, Suite 530, 51 Goodman Dr., PO Box 210222

City: Cincinnati State: OH Zip Code: 45221-0222

Telephone: 513-556-4817 Email: john.ungruhe@uc.edu

Central email: ospaward@uc.edu

Please sign up for one of the two electronic payment methods identified below:

ACH (Automated Clearing House) – Please print and complete direct deposit form per instructions provided and return.

www.uc.edu/af/controller/acctpayable.html

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.

Subrecipient Authorized Official

Name: David S. Gearing, Director, Grants and Contracts

Address: Sponsored Research Services, University Hall, Suite 530, 51 Goodman Dr., PO Box 210222

City: Cincinnati State: OH Zip Code: 45221-0222

Telephone: 513-556-5969 Email: ospaward@uc.edu

FDP Fixed Rate CI Ver 11-16-18
Central email: ospaward@uc.edu

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Attachment 3B Page 2
Research Subaward Agreement
Highest Compensated Officers

Subaward Number:

GR106686 (CON-80001816)

Subrecipient:

Institution Name: University of Cincinnati

PI Name: Pooja Khatri

Highest Compensated Officers

The names and total compensation of the five most highly compensated officers of the entity(ies) must be listed if the entity in the preceding fiscal year received 80 percent or more of its annual gross revenues in Federal awards; and \$25,000,000 or more in annual gross revenues from Federal awards; and the public does not have access to this information about the compensation of the senior executives of the entity through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. See FFATA § 2(b)(1) Internal Revenue Code of 1986.

Officer 1 Name:

Officer 1 Compensation:

Officer 2 Name:

Officer 2 Compensation:

Officer 3 Name:

Officer 3 Compensation:

Officer 4 Name:

Officer 4 Compensation:

Officer 5 Name:

Officer 5 Compensation:

Attachment 4
Reporting and Prior Approval Terms

Subaward Number:

GR106686 (CON-80001816)

Subrecipient agrees to submit the following reports (PTE contacts are identified in Attachment 3A):

Technical Reports:

- ☐ Monthly technical/progress reports will be submitted to the PTE's Principal Investigator within 15 days of the end of the month.
- ☐ Quarterly technical/progress reports will be submitted within 30 days after the end of each project quarter to the PTE's Principal Investigator.
- ☒ Annual technical / progress reports will be submitted within 60 days prior to the end of each budget period to the PTE's Principal Investigator. Such report shall also include a detailed budget for the next Budget Period, updated other support for key personnel, certification of appropriate education in the conduct of human subject research of any new key personnel, and annual IRB or IACUC approval, if applicable.
- ☒ A Final technical/progress report will be submitted to the PTE's Principal Investigator within 60 days of the end of the Project Period or after termination of this award, whichever comes first.
- ☒ Technical/progress reports on the project as may be required by PTE's Principal Investigator in order for the PTE to satisfy its reporting obligations to the Federal Awarding Agency.

Prior Approvals:

Carryover:

Carryover is restricted for this subaward by the: Federal Awarding Agency

Submit carryover requests to the Administrative Contact.

Other Reports:

- ☒ In accordance with 37 CFR 401.14, Subrecipient agrees to notify PTE's Principal Investigator within 60 days after Subrecipient's inventor discloses invention(s) in writing to Subrecipient's personnel responsible for patent matters. The Subrecipient will submit a final invention report using Federal Awarding Agency specific forms to the PTE's Principal Investigator within 60 days of the end of the Project Period to be included as part of the PTE's final invention report to the Federal Awarding Agency.

A negative report is required: No

- ☐ Property Inventory Report (only when required by Federal Awarding Agency), specific requirements below.

Other Special Reporting Requirements:

Attachment 5
Statement of Work, Cost Sharing, Indirects & Budget

Subaward Number:

GR106686 (CON-80001816)

Statement of Work

☒ Below ☐ Attached, pages

If award is FFATA eligible and SOW exceeds 4000 characters, include a *Subrecipient Federal Award Project Description*

Dr. Pooja Khatri, NIH StrokeNet Principal Investigator will lead the primary elements of trial operations conducted through the NIH StrokeNet National Coordinating Center at the University of Cincinnati. For this project within the NCC component of the overall proposal, effort for Dr. Khatri is listed as no salary funds requested, due to the fact that his effort is already accounted by an overall infrastructure award. The StrokeNet infrastructure funds experienced individuals who can perform the following necessary activities for efficient trial execution.

Budget Information

Indirect Information Indirect Cost Rate (IDC) Applied %

Cost Sharing

Rate Type:

If Yes, include Amount: \$

Budget Details

☐ Below ☒ Attached, pages

Budget Totals

Direct Costs \$

Indirect Costs \$

Total Costs \$

All amounts are in United States Dollars

RESEARCH & RELATED BUDGET - Budget Period 1

OMB Number: 4040-0001
Expiration Date: 10/31/2019

ORGANIZATIONAL DUNS: 0410647670000

Enter name of Organization: University of Cincinnati

Budget Type: ☐ Project ☒ Subaward/Consortium

Budget Period: 1 Start Date: 07/01/2019 End Date: 04/30/2020

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary (\$)	Months			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
						Cal.	Acad.	Sum.			
Dr.	Pooja		Khatri		187,000.00	0.01			0.00	0.00	0.00

Project Role: PD/PI

Additional Senior Key Persons: Total Funds requested for all Senior Key Persons in the attached file

Total Senior/Key Person 0.00

B. Other Personnel

Number of Personnel	Project Role	Months			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
		Cal.	Acad.	Sum.			
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
1	Secretarial/Clerical	0.74			2,604.00	1,177.01	3,781.01
1	ASPIRE Project Manager (TBD) 100%	12.00			81,056.00	36,476.00	117,532.00
1	TBN Pharmacist 25%	3.00			24,828.00	11,173.00	36,001.00
1	TBN Pharmacy tech 50%	6.00			22,089.00	9,941.00	32,030.00
2	cIRB admin 1.5 FTE (TBD)	18.00			96,675.00	35,769.19	132,444.19
1	cIRB reg safety 12% (TBD)	1.44			17,760.00	6,571.00	24,331.00
1	Contract admin 30% (TBD)	3.60			15,240.00	5,638.80	20,878.80

8 Total Number Other Personnel

Total Other Personnel 366,998.00

Total Salary, Wages and Fringe Benefits (A+B) 366,998.00

C. Equipment Description

List items and dollar amount for each item exceeding \$5,000

Equipment item

Funds Requested (\$)

Additional Equipment:

Total funds requested for all equipment listed in the attached file

Total Equipment

D. Travel

Funds Requested (\$)

1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)

6,000.00

2. Foreign Travel Costs

Total Travel Cost

6,000.00

E. Participant/Trainee Support Costs

Funds Requested (\$)

1. Tuition/Fees/Health Insurance

2. Stipends

3. Travel

4. Subsistence

5. Other

Number of Participants/Trainees

Total Participant/Trainee Support Costs

F. Other Direct Costs**Funds Requested (\$)**

1. Materials and Supplies	402,412.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	22,811.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Shipping of study drug/placebo from NCC Central Pharmacy to sites	74,702.00
9. Site Start-up payments	375,000.00
10. Translation	50,359.00
Total Other Direct Costs	925,284.00

G. Direct Costs**Funds Requested (\$)****Total Direct Costs (A thru F)** 1,298,282.00**H. Indirect Costs**

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)
MTDC	60.00	1,058,640.77	637,735.32
MTDC	60.50	216,830.04	128,624.68
Total Indirect Costs			766,360.00

Cognizant Federal Agency
(Agency Name, POC Name, and
POC Phone Number) DHHS, Mr. Arif Karim, 214-767-3600**I. Total Direct and Indirect Costs****Funds Requested (\$)****Total Direct and Indirect Institutional Costs (G + H)** 2,064,642.00**J. Fee****Funds Requested (\$)****K. Total Costs and Fee****Funds Requested (\$)****Total Costs and Fee (I + J)** 2,064,642.00**L. Budget Justification**

(Only attach one file.)

Khatiri ASPIRE Budget Justification 72

Add Attachment

Delete Attachment

New Attachment

RESEARCH & RELATED BUDGET - Budget Period 2

OMB Number: 4040-0001
Expiration Date: 10/31/2019

ORGANIZATIONAL DUNS: 0410647670000

Enter name of Organization: University of Cincinnati

Budget Type: ☐ Project ☒ Subaward/Consortium

Budget Period: 2 Start Date: 09/01/2020 End Date: 08/31/2021

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary (\$)	Months			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
						Cal.	Acad.	Sum.			
Dr.	Pooja		Khatr		187,000.00	0.01			0.00	0.00	0.00
Project Role: PD/PI											

Additional Senior Key Persons:					Total Funds requested for all Senior Key Persons in the attached file	
					Total Senior/Key Person	0.00

B. Other Personnel

Number of Personnel	Project Role	Months			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
		Cal.	Acad.	Sum.			
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
1	Secretarial/Clerical	0.74			2,604.00	1,177.01	3,781.01
1	ASPIRE Project Manager (TBD) 100%	12.00			82,977.00	37,340.00	120,317.00
1	TBN Pharmacist 25%	3.00			26,315.00	10,526.00	36,841.00
1	TBN pharm tech 50%	6.00			22,878.00	9,151.00	32,029.00
2	cIRB admin 1.5 FTE (TBD)	18.00			96,675.00	35,769.75	132,444.75
1	cIRB reg safety 12% (TBD)	1.44			17,760.00	6,571.20	24,331.20
1	Contract admin 30% (TBD)	3.60			15,240.00	5,638.80	20,878.80

8	Total Number Other Personnel	Total Other Personnel	370,622.76
		Total Salary, Wages and Fringe Benefits (A+B)	370,622.76

C. Equipment Description

List items and dollar amount for each item exceeding \$5,000

Equipment item

Funds Requested (\$)

Additional Equipment:

Add Attachment

Delete Attachment

View Attachment

Total funds requested for all equipment listed in the attached file

Total Equipment

D. Travel

Funds Requested (\$)

1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)

6,000.00

2. Foreign Travel Costs

Total Travel Cost

6,000.00

E. Participant/Trainee Support Costs

Funds Requested (\$)

1. Tuition/Fees/Health Insurance

2. Stipends

3. Travel

4. Subsistence

5. Other

Number of Participants/Trainees

Total Participant/Trainee Support Costs

F. Other Direct Costs		Funds Requested (\$)
1. Materials and Supplies		280,436.00
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		813,004.00
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Shipping of study drug/placebo from NCC Central Pharmacy to sites		47,054.00
9.		
10.		
Total Other Direct Costs		1,140,494.00

G. Direct Costs	Funds Requested (\$)
Total Direct Costs (A thru F)	1,517,116.76

H. Indirect Costs				Funds Requested (\$)
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)		
MTDC	60.50	704,113.00		425,988.00
Total Indirect Costs				425,988.00

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number) DRHS, Mr. Arif Karim, 214-767-3600

I. Total Direct and Indirect Costs	Funds Requested (\$)
Total Direct and Indirect Institutional Costs (G + H)	1,943,104.76

J. Fee	Funds Requested (\$)

K. Total Costs and Fee	Funds Requested (\$)
Total Costs and Fee (I + J)	1,943,104.76

L. Budget Justification			
(Only attach one file.)	Khatri ASPIRE Budget Justification 72	Add Attachment	View Attachment

RESEARCH & RELATED BUDGET - Budget Period 3

OMB Number: 4040-0001
Expiration Date: 10/31/2019

ORGANIZATIONAL DUNS: 0410647670000

Enter name of Organization: University of Cincinnati

Budget Type: ☐ Project ☒ Subaward/Consortium

Budget Period: 3 Start Date: 09/01/2020 End Date: 08/31/2021

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary (\$)	Months Cal. Acad. Sum.	Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
Dr.	Pooja		Khatri		187,000.00	0.01	0.00	0.00	0.00

Project Role: PD/PI

Additional Senior Key Persons:

Additional Senior Key Persons

Total Funds requested for all Senior
Key Persons in the attached file

Total Senior/Key Person 0.00

B. Other Personnel

Number of Personnel	Project Role	Cal.	Months Acad. Sum.	Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
	Post Doctoral Associates					
	Graduate Students					
	Undergraduate Students					
1	Secretarial/Clerical	0.74		2,604.00	1,177.00	3,781.00
1	ASPIRE Project Manager (TBD) 100%	12.00		93,307.00	29,858.00	123,165.00
1	TBN Pharmacist 25%	3.00		28,560.00	9,139.00	37,699.00
1	TBN pharm tech 50%	6.00		24,265.00	7,765.00	32,030.00
2	cIRB admin 1.5 FTE (TBD)	18.00		96,675.00	35,770.00	132,445.00
1	cIRB reg safety 12% (TBD)	1.44		17,760.00	6,572.00	24,332.00
1	Contract admin 30% (TBD)	3.60		15,240.00	5,639.00	20,879.00

8 Total Number Other Personnel

Total Other Personnel 374,331.00

Total Salary, Wages and Fringe Benefits (A+B) 374,331.00

C. Equipment Description

List items and dollar amount for each item exceeding \$5,000

Equipment item	Funds Requested (\$)

Additional Equipment:

Add Attachment

Delete Attachment

View Attachment

Total funds requested for all equipment listed in the attached file

Total Equipment

D. Travel

Funds Requested (\$)

1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	6,000.00
2. Foreign Travel Costs	
Total Travel Cost	6,000.00

E. Participant/Trainee Support Costs

Funds Requested (\$)

1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other	
Number of Participants/Trainees	Total Participant/Trainee Support Costs

F. Other Direct Costs

Funds Requested (\$)

1. Materials and Supplies	461,693.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	1,556,906.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Shipping of study drug/placebo from NCC Central Pharmacy to sites	46,684.00
9.	
10.	
Total Other Direct Costs	2,065,283.00

G. Direct Costs

Funds Requested (\$)

Total Direct Costs (A thru F) 2,445,614.00

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)
MTDC	60.50	888,708.00	537,668.00
Total Indirect Costs			537,668.00

Cognizant Federal Agency
(Agency Name, POC Name, and
POC Phone Number)

DHHS, Mr. Arif Karim, 214-767-3600

I. Total Direct and Indirect Costs

Funds Requested (\$)

Total Direct and Indirect Institutional Costs (G + H) 2,983,282.00

J. Fee

Funds Requested (\$)

K. Total Costs and Fee

Funds Requested (\$)

Total Costs and Fee (I + J) 2,983,282.00

L. Budget Justification

(Only attach one file.)

Khatri ASPIRE Budget Justification 72

Add Attachment

Delete Attachment

View Attachment

RESEARCH & RELATED BUDGET - Budget Period 4

OMB Number: 4040-0001
Expiration Date: 10/31/2019

ORGANIZATIONAL DUNS: 0410647670000

Enter name of Organization: University of Cincinnati

Budget Type: ☐ Project ☒ Subaward/Consortium

Budget Period: 4 Start Date: 09/01/2021 End Date: 09/31/2022

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary (\$)	Months			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
						Cal.	Acad.	Sum.			
Dr.	Pooja		Khattri		187,000.00	0.01			0.00	0.00	0.00
Project Role: PD/PI											

Additional Senior Key Persons: Total Funds requested for all Senior Key Persons in the attached file
Total Senior/Key Person 0.00

B. Other Personnel

Number of Personnel	Project Role	Months			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
		Cal.	Acad.	Sum.			
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
1	Secretarial/Clerical	0.74			2,604.00	1,177.01	3,781.01
1	ASPIRE Project Manager (TBD) 100%	12.00			95,356.00	30,514.00	125,870.00
1	TBN Pharmacist 25%	3.00			29,213.00	9,348.00	38,561.00
1	TBN pharm tech 50%	6.00			24,265.00	7,765.00	32,030.00
2	cIRB admin 1.5 FTE (TBD)	18.00			96,675.00	35,769.75	132,444.75
1	cIRB reg safety 12% (TBD)	1.44			17,760.00	6,571.24	24,331.24
1	Contract admin 30% (TBD)	3.60			15,240.00	5,639.00	20,879.00

3 Total Number Other Personnel 377,897.00
Total Salary, Wages and Fringe Benefits (A+B) 377,897.00

C. Equipment Description

List items and dollar amount for each item exceeding \$5,000

Equipment Item

Funds Requested (\$)

Additional Equipment:

Add Attachment

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View Attachment

Total funds requested for all equipment listed in the attached file

Total Equipment

D. Travel

Funds Requested (\$)

1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)

6,000.00

2. Foreign Travel Costs

Total Travel Cost

6,000.00

E. Participant/Trainee Support Costs

Funds Requested (\$)

1. Tuition/Fees/Health Insurance

2. Stipends

3. Travel

4. Subsistence

5. Other

Number of Participants/Trainees

Total Participant/Trainee Support Costs

F. Other Direct Costs		Funds Requested (\$)
1. Materials and Supplies		515,113.00
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		2,147,791.00
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Shipping of study drug/placebo from NCC Central Pharmacy to sites		47,547.00
9.		
10.		
Total Other Direct Costs		2,710,451.00

G. Direct Costs	Funds Requested (\$)
Total Direct Costs (A thru F)	3,094,348.00

H. Indirect Costs				Funds Requested (\$)
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)		
MTDC	60.50	946,557.00		572,667.00
Total Indirect Costs				572,667.00

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

DRHS, Mr. Arif Karim, 214-767-3600

I. Total Direct and Indirect Costs	Funds Requested (\$)
Total Direct and Indirect Institutional Costs (G + H)	3,667,015.00

J. Fee	Funds Requested (\$)

K. Total Costs and Fee	Funds Requested (\$)
Total Costs and Fee (I + J)	3,667,015.00

L. Budget Justification			
(Only attach one file.)	Khatri ASPIRE Budget Justification 72	Add Attachment	View Attachment

RESEARCH & RELATED BUDGET - Budget Period 5

OMB Number: 4040-0001
Expiration Date: 10/31/2019

ORGANIZATIONAL DUNS: 0410647670000

Enter name of Organization: University of Cincinnati

Budget Type: ☐ Project ☒ Subaward/Consortium

Budget Period: 5 Start Date: 09/01/2022 End Date: 08/31/2023

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary (\$)	Months Cal. Acad. Sum.	Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
Dr.	Pooja		Khatri		187,000.00	0.01	0.00	0.00	0.00

Project Role: PD/PI

Additional Senior Key Persons: Total Funds requested for all Senior Key Persons in the attached file

Total Senior/Key Person 0.00

B. Other Personnel

Number of Personnel	Project Role	Cal.	Months Acad. Sum.	Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
	Post Doctoral Associates					
	Graduate Students					
	Undergraduate Students					
1	Secretarial/Clerical	0.74		2,604.00	1,177.00	3,781.00
1	ASPIRE Project Manager (TBD) 100%	12.00		95,698.00	30,623.00	126,321.00
1	TBN Pharmacist 25%	3.00		29,743.00	9,518.00	39,261.00
1	TBN pharm tech 50%	6.00		24,265.00	7,765.00	32,030.00
2	cIRB admin 1.5 FTE (TBD)	18.00		96,675.00	35,769.50	132,444.50
1	cIRB reg safety 12% (TBD)	1.44		17,760.00	6,571.00	24,331.00
1	Contract admin 30% (TBD)	3.60		15,240.00	5,638.50	20,878.50

8 Total Number Other Personnel

Total Other Personnel 379,047.00

Total Salary, Wages and Fringe Benefits (A+B) 379,047.00

C. Equipment Description

List items and dollar amount for each item exceeding \$5,000

Equipment Item	Funds Requested (\$)

Additional Equipment:

Total funds requested for all equipment listed in the attached file

Total Equipment

D. Travel

Funds Requested (\$)

1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	6,000.00
2. Foreign Travel Costs	
Total Travel Cost	6,000.00

E. Participant/Trainee Support Costs

Funds Requested (\$)

1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other	
Number of Participants/Trainees	
Total Participant/Trainee Support Costs	

F. Other Direct Costs**Funds Requested (\$)**

1. Materials and Supplies	287,152.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	1,191,804.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Shipping of study drug/placebo from NCC Central Pharmacy to sites	56,013.00
9.	
10.	
Total Other Direct Costs	1,534,969.00

G. Direct Costs**Funds Requested (\$)****Total Direct Costs (A thru F)** 2,920,016.00**H. Indirect Costs**

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)
MTDC	60.50	728,211.00	440,568.00

Total Indirect Costs 440,568.00

Cognizant Federal Agency
(Agency Name, POC Name, and
POC Phone Number)

DHHS, Mr. Arif Karim, 214-767-3600

I. Total Direct and Indirect Costs**Funds Requested (\$)****Total Direct and Indirect Institutional Costs (G + H)** 2,360,584.00**J. Fee****Funds Requested (\$)****K. Total Costs and Fee****Funds Requested (\$)****Total Costs and Fee (I + J)** 2,360,584.00**L. Budget Justification**

(Only attach one file.)

Khatri ASPIRE Budget Justification 72

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RESEARCH & RELATED BUDGET - Cumulative Budget

		Totals (\$)
Section A, Senior/Key Person		0.00
Section B, Other Personnel		1,868,895.76
Total Number Other Personnel	40	
Total Salary, Wages and Fringe Benefits (A+B)		1,868,895.76
Section C, Equipment		
Section D, Travel		30,000.00
1. Domestic	30,000.00	
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		8,376,481.00
1. Materials and Supplies	1,946,806.00	
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs	5,732,316.00	
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	272,000.00	
9. Other 2	375,000.00	
10. Other 3	50,359.00	
Section G, Direct Costs (A thru F)		10,275,376.76
Section H, Indirect Costs		2,743,251.00
Section I, Total Direct and Indirect Costs (G + H)		13,018,627.76
Section J, Fee		
Section K, Total Costs and Fee (I + J)		13,018,627.76

SAMPLE INVOICE (on Institutional Letterhead)

Bill to: Yale University
c/o Shared Services – SubK Invoices
PO Box 208383
New Haven, CT 06520-8383
Email: YSS.subcontracts@yale.edu

Invoice Date:
Invoice Number:
Subaward Period of Performance:
Award Amount:
Investigator:
Subaward Number:

Billing Period: From _____ to _____

Expenditures for the Period: _____

	Current Costs	Cumulative Costs
Faculty Salaries		
Staff Salaries		
Employee Benefits		
Equipment		
Travel		
Meals		
Materials and Supplies		
Services		
Other Expenses		

Total Direct Costs	\$	\$
Indirect Costs Rate: %	\$	\$
Total Amount	\$	\$
Total This Invoice:	\$	
Total Cumulative:		\$
Total Payments received to date:		\$

(Required certification)

By signing this report, I certify to the best of my knowledge and belief that the report is true, complete, and accurate, and the expenditures, disbursements and cash receipts are for the purposes and objectives set forth in the terms and conditions of the Federal award. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims or otherwise. (U.S. Code Title 18, Section 1001 and Title 31, Sections 3729-3730 and 3801-3812).

Name and Title

Date

For questions regarding invoicing, please contact (insert name and phone number)

Attachment 6

Notice of Award (NOA) and any additional documents

- ☒ The following pages include the NOA and if applicable any additional documentation referenced throughout this Subaward.
- ☐ Not incorporating the NOA or any additional documentation to this Subaward.



NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Grant Number: 1U01NS106513-01A1 REVISED
FAIN: U01NS106513

Principal Investigator(s):
Hooman Kamel, MD
Kevin Navin Sheth (contact), MD

Project Title: Anticoagulation in ICH Survivors for Prevention and Recovery (ASPIRE)

Fiore, Kimberly O
YALE UNIVERSITY
Proposal Manager
25 Science Park
New Haven, CT 065110000

Award e-mailed to: osp@yale.edu

Period Of Performance:
Budget Period: 07/01/2019 – 04/30/2020
Project Period: 07/01/2019 – 04/30/2024

Dear Business Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to YALE UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Neurological Disorders And Stroke of the National Institutes of Health under Award Number U01NS106513. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Ada O'Donnell
Grants Management Officer
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Additional information follows

SECTION I – AWARD DATA – 1U01NS106513-01A1 REVISED

Award Calculation (U.S. Dollars)

Salaries and Wages	\$188,243
Fringe Benefits	\$60,802
Personnel Costs (Subtotal)	\$249,045
Consultant Services	\$23,500
Materials & Supplies	\$7,500
Travel	\$342,507
Subawards/Consortium/Contractual Costs	\$2,926,447

Federal Direct Costs	\$3,548,999
Federal F&A Costs	\$483,210
Approved Budget	\$4,032,209
Total Amount of Federal Funds Obligated (Federal Share)	\$4,032,209
TOTAL FEDERAL AWARD AMOUNT	\$4,032,209

AMOUNT OF THIS ACTION (FEDERAL SHARE) \$0

SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
1	\$4,032,209	\$4,032,209
2	\$3,246,233	\$3,246,233
3	\$4,270,266	\$4,270,266
4	\$1	\$1
5	\$1	\$1

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name: Extramural Research Programs in the Neurosciences and Neurological Disorders
CFDA Number: 93.853
EIN: 1060646973A1
Document Number: UNS106513A
PMS Account Type: P (Subaccount)
Fiscal Year: 2019

IC	CAN	2019	2020	2021	2022	2023
NS	8472428	\$4,032,209	\$3,246,233	\$4,270,266	\$1	\$1

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:

PCC: VIVALJCR / **OC:** 414L / **Released:** ODonnella 08/07/2019

Award Processed: 08/08/2019 12:04:32 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1U01NS106513-01A1 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III – TERMS AND CONDITIONS – 1U01NS106513-01A1 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in this Notice of Award.
- Conditions on activities and expenditure of funds in other statutory requirements, such as

- those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VI Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) U01NS106513. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

This award provides support for one or more NIH defined Phase III Clinical Trials. The NIH Policy for research supported as an NIH Phase III Clinical Trial has been amended in Section II.B. of the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended October 2001 (see http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).

A description of plans to conduct analyses, as appropriate, by sex/gender and racial/ethnic groups must be included in clinical trial protocols. Cumulative subject accrual and progress in conducting subset analyses must be reported to NIH in the annual Progress Reports. Final analyses of sex/gender and racial/ethnic differences must be reported in the required Final Progress Report or Competitive Renewal Applications (or Contract Renewals/Extensions) as stated in Section II.B. of the Guidelines.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – NS Special Terms and Conditions – 1U01NS106513-01A1 REVISED

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISED AWARD: Preaward cost authority is approved for necessary and appropriate charges to this grant beginning 02/01/2019.

RESTRICTION: Of the **\$4,032,209** awarded in Year 1, a total of **(50%) \$2,016,105** is currently available for expenditures necessary for planned start-up activities, including manufacturing of the study drug. The balance of funds for Year 1 **(50%) \$2,016,104** is restricted until completion of the following performance milestones & approval by the NINDS Program Official:

- Registration of the trial on Clinicaltrials.gov; and
- DSMB approval of the protocol to proceed; and
- NINDS Approval of Case Report Forms for Common Data Elements; and
- Version 1.0 of a Manual of Procedures (MOP) developed for site distribution; and
- Complete Clinical Trial Agreements (CTAs) executed AND cIRB approval for **at least 50 participating centers** so they are able to be initiated and begin enrolling participants upon receipt of the study drug.

The initial award will be committed for three years in order to demonstrate feasibility.

During the third year of the award, the Principal Investigator will submit an application for an Administrative Continuation Review for the remainder of the original total budget. The following items should be sent to the NINDS Program Official by November 1, 2021:

- A letter co-signed by the Business Official and Principal Investigator requesting an additional two years of support;
- A one-page research plan for the additional two years; and
- A budget and justification for the remaining proposed period of support.

NINDS program staff will review these documents administratively. Approval will be contingent upon a demonstrated ability to conduct and complete the study.

Program Official: Joanna Vivalda
Project Scientist: Claudia Moy, PhD.

This award includes funds for twelve months of support. The competing budget period is awarded for less than 12 months. Future year budget periods will start on May 1. Allowable preaward costs may be charged to this award, in accordance with the conditions outlined in the NIH Grants Policy Statement and with institutional requirements for prior approval. The NIH Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/nihgps/index.htm>

Inflationary increases for future year commitments are not allowable. See NIH Guide Notice: NOT-OD-13-064- <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-064.html>

Where consortia are included, they are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at: <http://grants.nih.gov/grants/policy/nihgps/index.htm>

In future years, awards under the Streamlined Non-Competing Award Process (SNAP) must submit a non-competing application via the eRA Commons by the 15th of the month preceding the month in which the budget period ends. The non-competing application can be submitted using the Research Performance Progress Report (RPPR) format via the RPPR link in eRA Commons.

The use of the eRA Research Performance Progress Report (RPPR) Module for submitting Type 5 Progress Reports is required for all awards with start dates on or after October 17, 2014. See Guide Notice: NOT-OD-15-014 <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-014.html>

The funds in this award shall not be used to pay the salary of an individual at a rate in excess of Executive Level II (\$192,300) per year effective January 7, 2018. See NIH Guide Notice: NOT-OD-19-099 <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-099.html>

To register to use the Commons go to <https://commons.era.nih.gov/commons/>; Questions regarding the Commons should be addressed to Commons Support at 1-866-504-9552 or commons@od.nih.gov.

Other documents applicable to this grant should be faxed to (301) 451-5635 or mailed to:

Grants Management Branch
National Institutes of Neurological Disorders and Stroke
6001 Executive Boulevard, Suite 3290, MSC 9537
Rockville, MD 20852 (Express Mail)
Bethesda, MD 20892-9537 (Regular Mail)

For additional information, you may access the NIH home page at <http://www.nih.gov/> and the NINDS Home Page at <http://www.ninds.nih.gov>.

Terms of Award for Phase 3 and Other Large Clinical Trials

- A. The NINDS has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in NINDS-supported clinical trials. Therefore, **prior to subject accrual**, the Awardee will provide the following for review and approval by the NINDS:
- The detailed plan for data and safety monitoring (see Section B below).
 - The clinical research protocol, including details of study design, proposed interventions, patient eligibility and exclusion criteria, plans for the management of side effects, procedures for assessing and reporting adverse events, and data analysis plans. Refer to the protocol template.
 - Written responses to the concerns and suggestions raised by the NIH study section in the summary statement of the application.
 - The plans for ensuring data quality, e.g. through site monitoring (i.e., verifying study data through comparison to source documents, pharmacy audit, etc.). Refer to the data quality document.
 - Study Manual of Procedures
 - If the Recombinant DNA Advisory Committee (RAC) or the Secretary's Advisory Committee for Xenotransplantation (SACX) has reviewed the clinical protocol, the Awardee should provide information about the review and approval.
 - Clinical research projects involving the testing in the United States of new investigational therapeutics, new indications for FDA-approved drugs, vaccines, devices or other medical interventions under a research protocol should be performed under an IND/IDE, unless otherwise agreed upon by the US FDA. If not exempt, the Awardee must provide the NINDS with the name and organization of the IND/IDE holder, the date the IND/IDE was filed with the FDA, the FDA IND/IDE number, and any correspondence and comments from the FDA regarding this protocol while the IND or IDE is active.
 - In studies where a pharmaceutical/biotechnology company is providing the study agent/device, a written agreement by a company official affirming this arrangement.

Within 30 days of receipt of all of these documents, NINDS staff will review the study documentation and inform the Awardee in writing of any remaining issues that need to be resolved. In some cases, the NINDS will send a team of site visitors to the PI's site to help ensure that the study is ready to proceed.

B. Data and Safety Monitoring Requirements

Independent monitoring of interim data is strongly recommended for all clinical trials. A final data monitoring plan must be agreed upon by the Awardee and the NINDS before study enrollment commences. Monitoring plans may include oversight by a NINDS

Data and Safety Monitoring Board (DSMB), a non-NINDS Study Monitoring Committee (SMC) or Independent Medical Monitoring. If the monitoring plan includes NINDS Data and Safety Monitoring Board (DSMB) oversight, the NINDS' approval of the DSMB's recommendation to start the trial should be provided to the Awardee **prior to subject accrual**. Any exceptions should be approved by the Director of the Office of Clinical Research. For further information, refer to the NINDS Guidelines for Data and Safety Monitoring in Clinical Trials.

C. Use of NINDS Common Data Elements (CDEs)

The NINDS strongly encourages researchers who receive funding from the Institute to use the NINDS Common Data Elements (CDEs) available at www.commondataelements.ninds.nih.gov or document how they will ensure their data collection is compatible with the CDEs. Investigators should use the common definitions and the standardized case report forms and other instruments identified by the CDE Project. The CDE Project has developed uniform formats by which clinical data can be systematically collected, analyzed and shared across the research community.

The NINDS Program Official must approve awardee's plan for using CDEs before enrolling the first study participant. Justification must be clearly provided in the plan if any general CDE or disease-specific (as available) will not be used.

D. Futility Assessments

All major clinical trials, *i.e.* phase 3 trials or trials costing more than \$1 million/year, are required to include plans for futility assessments. Because major clinical trials consume significant resources of the NINDS, and because it may be unethical to keep study subjects involved in a trial if it is unlikely to come to a definitive conclusion, the NINDS requires the study investigators to incorporate into their analysis plan two types of futility assessments, if applicable.

First, the analysis plan must include periodic evaluations of the likelihood of successfully completing study accrual on time. Before the study opens to accrual, the investigators should specify both the target and minimally acceptable accrual goals for the study. The goals must be approved by the DSMB. The DSMB should continually monitor study accrual and give serious consideration to terminating the study if it fails to meet the minimally acceptable goals. Second, the analysis plan must include at least one evaluation of the likelihood (*e.g.* conditional power) of the study being able to reach a firm conclusion regarding the primary outcome of the trial. There may be exceptions to this requirement if the trial (1) is worth continuing to completion to observe important secondary outcomes or (2) is designed in such a way that early termination for futility would not result in significant savings of either funding or subject risks/inconveniences.

E. Changes in Protocol Design and Status

To help ensure the safety of subjects enrolled in NINDS-funded studies, the Awardee must provide the NINDS with copies of documents related to all major changes in the status of ongoing protocols, including:

- Amendments to the protocol
- Termination of the protocol
- Temporary suspension of the protocol
- Changes in informed consent or IRB/EC approval status
- Temporary suspension or permanent termination of patient accrual
- Other problems or issues that could affect the human subjects in the studies

Notification of any of the above changes must be made **within three (3) working days** by e-mail, followed by a letter from the Principal Investigator, detailing the change of status notification to the local IRB/EC and a copy of any responses from the IRB/EC. Changes should not be implemented without written approval of the NINDS Program Official.

F. Funding

Funding support recommended for each year of the project is only an estimate and is contingent upon favorable review by NINDS staff of the progress of the project, sufficient subject accrual, and demonstrated need for the funds. Funds awarded for patient care costs may not be used for any other purpose without the prior written approval of the NINDS.

Personnel funds must be managed in a way that allocates personnel effort and salary charges in accordance with the work being carried out in this project. Specifically, if accrual is delayed or lags, or if the needs of the project do not require full personnel effort and salaries as awarded, proportionate reductions in effort and salary charges will be instituted both at the parent grant site and at participating sites. NINDS personnel will provide guidance for determining appropriate personnel charges and levels of effort.

NINDS staff will work with the Principal Investigators [including Steering Committee or Clinical Coordinating Center as applicable] to devise a plan to assess the performance of each clinical site with respect to recruitment and retention of participants, data quality and completeness, compliance with human subjects concerns, and other considerations. This assessment may be used to redistribute site funding so as to maximize the likelihood of successful study completion. In some cases, a site may be closed to further recruitment and may be funded only to complete follow-up of current study participants.

G. Clinicaltrials.gov Registration and Results Reporting

ClinicalTrials.gov is a database of federally and privately supported research trials to test the effect of treatments and procedures for a wide range of diseases and conditions. The NIH is committed to providing information to increase public awareness and access to clinical trials sponsored federally and by industry and foundations.

Awardee is required to comply with Public Law 110-85 (Food and Drug Amendments Act of 2007: FDAAA), as applicable, for required clinical trial registration and results reporting.

NIH encourages registration of all trials whether required under the law or not. For more information see the NIH Office of Extramural Research website, "What NIH Grantees Need to Know about ClinicalTrials.gov and FDAAA."

This award provides support for one or more clinical trials. NINDS is not the sponsor of any applicable clinical trial conducted under this award.

By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register Phase II-IV "applicable clinical trials" on the Clinicaltrials.gov website. Applicable clinical trials must be registered no later than 21 days after the first participant is enrolled. "Basic results" information for applicable clinical trials is to be submitted within one year after the "Primary Completion Date" of the trial.

Awardee must certify compliance with FDAAA in continuation progress report. Instructions on compliance certification are available on the NIH website.

H. Other Required Reporting During the Award Period

Awardees are required to notify the NINDS of any of the following circumstances:

- Plans to add or discontinue institutions in a multicenter study. The NINDS must receive a justification from the Awardee **at least thirty (30) days** in advance of making such a change, and must concur with the decision.
- A change in the Principal Investigator at a site. The CV of the new Principal Investigator must be submitted to the NINDS **thirty (30) days in advance** of the anticipated change. Documentation that the new Principal Investigator has completed NIH-required training in human subjects protection should also be provided.
- A change in the membership or operating procedures of any external advisory committees, including Safety Monitoring Committee (SMC), or a change of the Medical Monitor. The CV of any new Study Monitoring Committee (SMC) member or Medical Monitor must be submitted to the NINDS **thirty (30) days in advance** of the anticipated change.
- Any significant correspondence from the FDA concerning the trial. This applies to clinical trials funded in whole or in part by the NINDS and involving an IND/IDE (regardless of who the official sponsor is). Such correspondence includes warning letters, investigator disqualification notices, clinical holds, etc. This correspondence from the FDA must be submitted to the NINDS **within 72 hours** of the Awardee learning of it. For further details, consult the NIH policy.
- Any significant correspondence from the IRB concerning the study regarding human subjects and protocol approval/disapproval or suspension must be submitted to the NINDS **within 72 hours** of the Awardee receiving it.

I. Study Close-out

A study close-out plan should be formulated by the investigators to unmask and debrief site staff and study participants upon trial completion. Information on close-out procedures can be found in the Manual of Procedures (MOP) template. The study close-out plan should be reviewed and approved by the safety monitoring group (IMM, SMC or DSMB) for the trial.

J. Gender and Minority Data Analyses

Since a primary aim of research is to provide scientific evidence leading to a change in health policy or standard of care, it is imperative to determine whether the intervention or therapy being studied affects women or men or members of minority groups and their subpopulations differently. A description of plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups must be included in Phase III clinical trial protocols. Cumulative subject accrual and progress in conducting subset analyses must be reported to NIH in the annual Progress Reports. Final analyses of sex/gender and racial/ethnic differences must be reported in the required Final Progress Report or Competitive Renewal Applications, as stated in Section IIB of the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.

K. Publication of Data and Analyses

Timely publication of major findings is essential. Specifically, the primary study results should be submitted for publication in a peer-reviewed journal within one year of completion of the follow-up of subjects in the clinical trial. Any papers published under the auspices of this award must cite the funding support of all pertinent NIH Institutes. In accordance with PL. 110-161, compliance with the NIH Public Access Policy is mandatory. For more information, see NOT-OD-08-033 and the Public Access website.

L. Data Sharing

Because of the extensive effort that went into collecting data by investigators and study participants, it is important that datasets from completed studies be available for further research so that the full potential of the datasets is maximized. It is expected that investigators submit to NINDS Office of Clinical Research a complete, cleaned, and de-identified dataset and any supporting documentation (including but not limited to the study protocol, statistical analysis plan, and data dictionary) required for the analysis of the data within one year of the primary publication or within 18 months of the last study visit of the last subject, whichever occurs first. See the NIH guidelines on sharing research data.

M. Special terms and conditions for multicenter Phase III clinical trials

○ *Steering Committee*

The Principal Investigator, in consultation with the NINDS Project Scientist, will

establish a Steering Committee as the main governing body of the study that will include the NINDS Project Scientist (or his/her designee) as a voting member. The Steering Committee will be responsible for providing study oversight by monitoring safety procedures and on-site data quality, and evaluating the progress of the project using performance measures such as patient accrual/retention, data quality and scientific contributions. The Steering Committee will carry out these responsibilities with the assistance of various study subcommittees, *e.g.* recruitment/retention, conflict of interest, and publication; the NINDS Program Official will serve on subcommittees as he/she deems appropriate.

- *Reporting*

The study team will submit updated enrollment information by site electronically to the NINDS Recruitment Planning and Monitoring System (RPMS) (including startup, site activation and accrual and retention data) at least monthly during the study enrollment period.

- *Financial Status*

The PI is expected to be aware of the financial status of their grant and should inform NINDS of any concerns. Awardee must submit an estimate of funds expended and funds remaining to the program director annually. This does not replace the FFR submitted by the Institution on a yearly basis to the NINDS GMO, but serves to help the NINDS Program Official and the Steering Committee gauge expenditures relative to study progress.

Multi-Center Clinical Research Cooperative Agreement Terms

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism) in which substantial NIH programmatic involvement with the awardees is anticipated during performance of the activities.

Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility for the activity resides with the awardee(s) for the project as a whole, although specific tasks and activities in carrying out the studies will be shared among the awardees and the NIH as defined below.

1. The PI(s) will have primary responsibility for:

The Principal Investigator (PI) has primary authority and responsibility to define research objectives and approaches, and to plan, conduct, analyze, and publish results, interpretations, and conclusion of their studies and for providing overall scientific and administrative leadership for the Research Project.

The PI will oversee all aspects of the organization and execution of the studies outlined in the application and approved by NINDS after peer review.

Awardees have primary and lead responsibilities for the project as a whole, including any modification of study design, conduct of the study, quality control, data analysis and interpretation, preparation of publications, and collaboration with other investigators, unless otherwise provided for in these terms or by action of the primary leadership committee.

There will be a primary leadership committee, whose primary functions are to oversee scientific and policy issues, i.e. protocol amendments, publications policy, and ancillary studies. Voting membership on this committee shall consist of the Principal Investigator, the NINDS Project Scientist, and other key investigators. Meetings of the primary leadership committee will be held as needed, but not less than once a year.

Awardees will be required to accept and implement the common protocol and procedures approved by the primary leadership committee.

The awardee will manage and conduct the proposed clinical research in compliance with all established DHHS, NIH, NINDS policies and procedures. The awardee will be responsible for protecting participant safety and obtaining adequate recruitment to complete the study. It is the grantee institution's responsibility (1) 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 and (2) to retain documentation of compliance with the requirements of 45 CFR Part 46.

Awardees will retain custody of and have primary rights to their data developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and NIH policies.

If research findings result in inventions, grantees have the right to retain title to these inventions, Pursuant to the Bayh-Dole Act of 1980 as implemented in 37 CFR 401, for their utilization, commercialization, and public availability and Executive Order 12591.

In general, grantees own the data generated by or resulting from a grant-supported project. Except as provided in the terms and conditions of the award, the grantee is free to copyright without NINDS approval when publications, data, or other copyrightable works are developed under this grant.

Rights to data, including software developed under the terms of this funding agreement resulting from this award, shall remain with the grantee except that any such copyrighted material shall be subject to a royalty-free, nonexclusive and irrevocable license to the Government to reproduce, publish or otherwise use the material, and to authorize others to do so for Federal purposes.

Support or other involvement of industry or any other third party in the study may be advantageous and appropriate. However, except for licensing of patents or copyrights, support or involvement of any third party will occur only following notification of and concurrence by the NINDS.

Awardees are encouraged to publish and to publicly release and disseminate results, data and other products of the study as determined in collaboration with the DSMB and the primary leadership committee and submit the cleaned and de-identified dataset to the NINDS Office of Clinical Research. It is the responsibility of the awardees to comply with any FDA policy and regulations as relevant to this project and as published at 21 CFR Parts 50 and 312.

2. NIH staff has substantial programmatic involvement that is above and beyond the normal stewardship role in awards as described below.

NINDS Program Director will be the Project Scientist and will have substantial scientific-programmatic involvement during conduct of the study, through technical assistance, advice, and/or other coordination above and beyond normal program stewardship for grants. The Project Scientist will function as one of several co-investigators, collaborating and interacting as necessary with the Principal Investigators in accomplishing the overall goals of the Research Program.

The NINDS Project Scientist will serve on the primary leadership committee. In addition, the Project Scientist, or other NINDS Program Official, may serve on other study committees regarding recruitment, intervention, follow-up, quality control, adherence to protocol, assessment of problems affecting the study and potential changes in the protocol, interim data and safety monitoring, final data analysis and interpretation, preparation of publications, and development of solutions to major problems such as insufficient participant enrollment. The NINDS Project Scientist will have voting membership on the primary leadership committee and its subcommittees. The Project Scientist should receive copies of all correspondence with the FDA and may attend any FDA meetings.

NINDS Program Director will be the Program Official for the study and will provide normal program stewardship as carried out for grants and will serve on the study committees as deemed appropriate. Members of the grants management staff and the Division of Extramural Research of the NINDS will assure prudent stewardship of funds in compliance with relevant policy and regulation.

The NINDS reserves the right to terminate or curtail the study (or an individual award) in the event of: (a) failure to develop or implement a mutually agreeable collaborative protocol; (b) substantial shortfall in participant recruitment, follow up, data reporting, quality control, or major breach of the protocol; (c) reaching a major study endpoint substantially before schedule with persuasive statistical significance; or (d) human subject or ethical issues that may dictate a premature termination.

3. Areas of Joint Responsibility include:

Primary Leadership Committee - The Committee will be the primary governing board of the study. The PI will chair the Committee, which includes other members of the study leadership, the NINDS Project Scientist and a subset of the Principal Investigators from the participating clinical sites.

The primary leadership committee is responsible for overseeing all aspects of the study, including implementation of the study protocol, oversight of recruitment, retention and enrollment, review of reports from the study committees, and preparing and publishing scientific reports. The Committee is made up of members with expertise in all the disciplines necessary for carrying out the proposed protocol and conducting the proposed research.

The primary leadership committee will develop the collaborative protocol and approve any modifications to the study design and ancillary protocols. Data will be submitted centrally to the Statistical Center. This Committee will define rules regarding access to data and will formulate the publication policy for the project.

The NINDS Project Scientist, on behalf of the NINDS, will have the same access, privileges and responsibilities regarding the collaborative data as the other members of the primary leadership committee. Subcommittees will be established by the Committee, as it deems appropriate; the NINDS Project Scientist will serve on subcommittees, as he/she deems appropriate.

A change in the Principal Investigator or key personnel at the awardee institution or at a clinical site participating in the study requires the prior approval of the NINDS Program Official. The NINDS must be sent the biographical sketch of the new investigator or key personnel 30 days prior to the changes along with confirmation that he/she has completed the NIH-required training in human subjects' protection.

Data and Safety Monitoring Board (DSMB) - An independent DSMB will be appointed by NINDS when needed according to Institute policy and procedures. The DSMB will review progress at least annually and report to NINDS through the Program Official.

The DSMB will be established by the NINDS for the purpose of monitoring the conduct of the clinical trial. The Principal Investigator, in conjunction with staff of the Data Coordinating Center, will provide any data requested by the DSMB for review. The DSMB will meet via teleconference and in person as necessary to: review the research protocol and plan for data and safety monitoring; evaluate the progress of the trial, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, and participant risk/benefit changes; oversee adherence to the protocol and maintenance of data confidentiality; review safety data, including adverse events and reportable events; make recommendations regarding the continuation or conclusion of the study; and assist in the development of monitoring guidelines. Proposed protocol changes and proposed ancillary studies must be approved by the DSMB.

NIH requires oversight and monitoring of all human intervention studies to ensure the safety of participants and the validity and integrity of the data. This policy is in addition to any monitoring requirements imposed by 45 CFR Part 46, FDA, or the NIH Guidelines for Research Involving Recombinant DNA Activities. The DSMB monitoring function is above and beyond that traditionally provided by IRBs; however, the IRB must be cognizant of the procedures used by DSMBs. The DSMBs will provide periodic reports to investigators for transmittal to the local IRBs. (Refer to <http://grants.nih.gov/grants/guide/notice-files/not98-084.html> and <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>.)

The Grantee Institution and Principal Investigator are responsible for ensuring that Clinical Sites follow approved protocols and maintain quality control of data in accordance with the DSMB guidance and recommendations. Any problems concerning the compliance of clinical sites in the protocol or quality control of data should be reported immediately by the awardee to the NINDS Program Official.

The addition or deletion of Clinical Sites is a prior approval authority retained by the awarding office; therefore, all changes in clinical sites must be approved in writing by NINDS. For additional sites, the awardee should provide NINDS with countersigned documentation of agreements between the two parties, proposed budget, justification for addition, and the appropriate human assurances. Requests for deletion of sites should be accompanied by a justification and budgetary changes.

Funding provided by the NINDS for the entire project will be expended in proportion to the rate of accrual of participants. Furthermore, the NINDS requires that the study have an enrollment plan, which includes periodic evaluations of the likelihood of successfully completing study accrual on time. If the NINDS, in consultation with the primary leadership committee, determines that the accrual rate falls substantially below that which is necessary for the timely completion of the project, the NINDS may require that the study be terminated.

4. Dispute Resolution

Any disagreement that may arise on scientific/programmatic matters (within the scope of the award), between award recipients and the NINDS may be brought to arbitration. An arbitration panel will be composed of three members: one selected by the primary leadership committee, with the NINDS member not voting or by the individual awardee in the event of an individual disagreement; a second member selected by NINDS, and the third member selected by the two prior selected members.

This special arbitration procedure in no way affects the awardee's right to appeal an adverse action that is otherwise appealable in accordance with the PHS regulations at 42 CFR Part 50, Subpart D and DHHS regulation at 45 Part 16 or the rights of NINDS under applicable statutes, regulations and terms of the award.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Cassandra L Fields
Email: fieldscass@mail.nih.gov **Phone:** 301-402-1620

Program Official: Joanna Vivalda
Email: joanna.vivalda@nih.gov **Phone:** 301-496-9135

SPREADSHEET SUMMARY
GRANT NUMBER: 1U01NS106513-01A1 REVISED

INSTITUTION: YALE UNIVERSITY

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	\$188,243	\$188,243	\$188,243		
Fringe Benefits	\$60,802	\$60,802	\$60,802		
Personnel Costs (Subtotal)	\$249,045	\$249,045	\$249,045		
Consultant Services	\$23,500	\$23,500	\$23,500		
Materials & Supplies	\$7,500	\$7,500	\$7,500		
Travel	\$342,507	\$5,500	\$5,500		
Other				\$1	\$1
Subawards/Consortium/Contractual Costs	\$2,926,447	\$2,763,432	\$3,791,978		
TOTAL FEDERAL DC	\$3,548,999	\$3,048,977	\$4,077,523	\$1	\$1
TOTAL FEDERAL F&A	\$483,210	\$197,256	\$192,743	\$0	\$0
TOTAL COST	\$4,032,209	\$3,246,233	\$4,270,266	\$1	\$1

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	67.5%	67.5%	67.5%		
F&A Cost Base 1	\$715,866	\$292,231	\$285,545		
F&A Costs 1	\$483,210	\$197,256	\$192,743		

Attachment 7
Fixed-Rate Clinical Trial Subaward Agreement Prime Award
Form of Transfer Record

This Record is to document shipment of Subject Material from Subrecipient to PTE, under the terms of a Fixed-Rate Clinical Trials Subaward Agreement entered by and between the parties effective _____. The Subject Material is provided as part of the Study defined in that Subaward Agreement, and all use of these Subject Material shall be subject to the provisions of that Subaward Agreement.

List and Description of Subject Material included in this shipment:

Blood Sample

Human-derived materials, such as this Subject Material, may pose known, or unknown, health or safety risks and must be handled accordingly, and in compliance with all applicable laws and regulations, including, but not limited to current EPA, FDA, USDA and NIH guidelines.

Shipping Authorization
(to be completed at time of shipment)

Date Shipped: _____

Signature

Printed Name

Receipt Acknowledgement
(to be completed upon receipt)

Date Received: _____

Signature

Printed Name