FDP Fixed-Rate Clinical Trial Subaward Agreement

Pass-through Entity (PTE): National Coordinating Center ("NCC") University of Cincinnati on behalf of the Prime Recipient Beth Israel Deaconess Medical Center, Inc.		Subrecipient: County of San Bernardino dba Arrowhead Regional Medical Center	
PTE Principal Investigator (PI): Pooja Khatri MD on behalf of Magdy H. Selim MD, PhD		Subrecipient Principal Investigator (PI): Dan Miulli, DO, FACOS	
PTE Federal Award No: 1U01NS102289-01A1 REVISED	FAIN: U01NS102289		Federal Awarding Agency: DHHS National Institutes of Health
Federal Award Issue Date: 09/10/2019	Total Amount of Federal Award to PTE: $1,299,542	CFDA No: 93.853	CFDA Title: Extramural Research Programs in the Neurosciences and Neurological Disorders
Study Title: StATins Use in intRacerebral hemorrhage patieNts (SATURN) "Study"			

Subaward Estimated Project Period of Performance: Start: **09/01/2019** End: **05/31/2026**	**Amount Funded This Action:** Pre-determined fixed price unit basis as approved by NINDS. See Attachment **5**.	**Subaward No.: 012044-140000**

Estimated Project Period (if incrementally funded): 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:	By an Authorized Official of Subrecipient:
Name: Diane L. Sparks, RN, BS Title: Contracts Manager, Legal Liaison, NIH StrokeNet, National Coordinating Center Date:	Name: Curt Hagman Title: Chairman, Board of Supervisors Date: July 14, 2020

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.

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 ☒ ~~g~~rants / ☐ ~~sh~~all 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 Clinical Trial Agreement subaward.

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") – Beth Israel Deaconess Medical Center, Inc. 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 09/01/2019 End: 05/31/2026*. The CTA is dependent on continued funding of the 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.

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~~ **NDMC**s 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 theStudy 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, **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 AwardingAgency , 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 - N/A

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: 012044-140000
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:	Pooja Khatri, MD		
Address:	University of Cincinnati, College of Medicine Dept of Neurology and Rehabilitative Medicine, 260 Stetson Street		
City/State/Zip+4:	Cincinnati, OH 45267-0525		
Telephone:	Rose Beckman 513-559-3907		
E-Mail:	khatrip@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**: 012044-140000
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:	310-794-6379; 323-409-8552	E-mail:	JSaver@mednet.ucla.edu; gsung@usc.edu	
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: 012044- 140000

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: 012044- 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.

☐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
Below ☒or Attached ☐Click or tap here to enter text. pages
If award is FFATA eligible and SOW exceeds 4000 characters, include a *Subrecipient Federal Award Project Description*

Clinical Trial Performance Site Locations: 140 sites

Projected Enrollment: 1456 subjects
Once the subject enrollment accrual is achieved the Principal Investigator will receive notification from the trial database via an email message instructing the site to cease subject enrollment. Subjects cannot be randomized once the final subject is randomized and will not be considered eligible for payment under the terms of this agreement.

Sites will be retrained or placed on probation if:

- A site does not randomize within 6 months of activation or has 6 months pass without any randomizations at any point in the trial.
- A site enrolls less than 4 subjects per year.

Once a site is on probation the site may be replaced with a back-up site if:
No subject randomizations occurs within 3 months after being placed on probation.
There is non-adherence to the responsibilities listed below.

EACH CLINICAL TRIAL PERFORMANCE SITE WILL BE RESPONSIBLE FOR:

- Complying with the trial investigational plan as defined in the protocol and approved by the StrokeNet CIRB and the NINDS appointed DSMB
- Compliance with trial specific StrokeNet CIRB informed consent template
- Obtaining appropriate Central IRB and local IRB acknowledgement of CIRB review.
- Reporting of required adverse events to CIRB and to the WebDCU CTMS for central trial review in compliance with defined procedures
- Completion of internal logistics necessary to execute the trial
- Completion of Clinical Trial Agreement
- Documentation of qualified clinical and protocol trained site personnel
- Documentation of qualified human subject protection trained site personnel
- Documenting trial related financial conflict of interest for all site personnel
- Assurance that standard medical care and management of adverse events will be provided for all subjects randomized
- Receipt, storage and accountability of Study provided supplies in compliance with defined procedures
- Handling and administration of study supplies to subjects in compliance with defined procedures
- Complying with all local, and US federal requirements for the initiation and ongoing performance of a clinical trial per the principles of Good Clinical Practice as defined in ICH Consolidated Guidance (ICH E6) and Title 45 and part 46 Federal Policy for the Protections of Human Subjects “Common Rule”
- Assuring that the expenses for research related procedures are not billed to the subject
- Assurance of access to subject medical records for site monitoring visits per institutional and trial procedures.
- Providing a site representative to attend all required investigator meetings and trial conference calls
- Data collection entered into WebDCU in a time frame consistent with the MOP.
- Compliance with all SATURN policies and procedures published in the trial MOP. MOP will be available under Project Documents in the WebDCU™ CTMS as maintained by the NCC and on the StrokeNet website: http://www.nihstrokenet.org/
- Responsiveness of site PI or in his/her absence, another designated investigative team member, to email correspondence within 2 business days.

Indirect Information

Indirect Cost Rate (IDC) Applied Click or tap here to enter text. % ☐ 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/saturn-trial/resources

Attachment 6
Fixed-Rate Clinical Trial Subaward Agreement
Prime Award

RESEARCH PROJECT COOPERATIVE AGREEMENT (RCC)

Year 1 Award Issue Date: 09/10/2019

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

Grant Number:

1U01NS102289-01A1 REVISED

Beth Israel Deaconess Medical Center ("Prime Recipient")

Principal Investigator(S):

Magdy H Selim, MD

Project Title: StATins Use in intRacerebral hemorrhage patieNts (SATURN)

November 25, 2019 (date of FEO Subaward from BIDMC)

FDP Cost Reimbursement Research Subaward Agreement

Pass-through Entity (PTE): Beth Israel Deaconess Medical Center, Inc.	Subrecipient: University of Cincinnati
PTE Principal Investigator: Magdy Selim	Subrecipient Principal Investigator: Pooja Khatri
Federal Awarding Agency: NIH/NINDS	PTE Federal Award No: 1U01NS102289-01

Project Title: StATins Use in intRacerebral hemorrhage patieNts (SATURN)

Subaward Period of Performance:	Amount Funded This Action:	Subaward No.
Start: Sep 1, 2019 End: May 31, 2020	$ 1,299,542.00	01061832

Estimated Project Period (if incrementally funded):	Incrementally Estimated Total:	Is this Award R & D
Start: Sep 1, 2019 End: May 31, 2026	$ 7,093,003.00	☐ Yes or ■ No

Check all that apply: ☐ Subject to FFATA (Attachment 3B) ☑ Cost Sharing (Attachment 5)

Terms and Conditions

1. PTE hereby awards a cost reimbursable subaward, as described above, to Subrecipient. The statement of work and budget for this Subaward are (check one): ☐ as specified in Subrecipient's proposal dated 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 reimburse Subrecipient not more often than monthly for allowable costs. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), Subaward number, and certification, as 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 Administrative Contact, as shown in Attachment 3A.
3. A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Administrative Contact, as shown in Attachment 3A, NOT LATER THAN **60** days after Subaward end date. The final statement of costs shall constitute Subrecipient's final financial report.
4. All payments shall be considered provisional and 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. PTE reserves the right to reject an invoice, in accordance with 2 CFR 200.305.
5. 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.
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, shall be directed to the appropriate party's Authorized Official Contact, as shown in Attachments 3A and 3B. Any such change made to this Subaward agreement requires the written approval of each party's Authorized Official, as shown in Attachments 3A and 3B.
7. 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 with 30 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, as applicable.
10. No-cost extensions require the written approval of the PTE. Any requests for a no-cost extension shall be directed to the Administrative Contact, as shown in Attachment 3A, not less than 30 days prior to the desired effective date of the requested change.
11. By signing this Research Subaward Agreement Subrecipient certifies that it will perform the work under this agreement in accordance with the terms of this agreement, the applicable terms of the Prime Award, federal, state and local law, rules and regulations, including the research terms and conditions set forth in all attachments annexed hereto, which are expressly made a part of this Research Subaward Agreement and the Subrecipient's policies.

By an Authorized Official of Pass-through Entity:	By an Authorized Official of Subrecipient:
Name: Jennifer Sabbagh Date Nov 25, 2019	Name: David S. Gearring, Sr. MHA Date 11/21/19
Title: Sr. Research Administrative Director	Title: Director, Business Affairs, Sponsored Research Services

Subaward Number: 01061832

Attachment 2
Research Subaward Agreement
Federal Award Terms and Conditions

Sponsor Agency

NIH	NSF	USDA	EPA	NASA	AFOSR	ARO	ONR	AMRMC	AMRAA	Other Agency
◉	○	○	○	○	○	○	○	○	○	○

Clear Sponsor Selection

Required Data Elements

The data elements required by Uniform Guidance are incorporated as follows:
(Select One)

☑ Copy of Award Notice
☐ As Entered

Agency-Specific Certifications/Assurances

By signing this Research Subaward Agreement, Subrecipient makes the certifications and assurances required by Uniform Guidance: 2 CFR 200 et seq.

General Terms and Conditions

1. Conditions on activities and restrictions on expenditure of federal funds in appropriations acts are applicable to this subaward to the extent those restrictions are pertinent. This includes any recent legislation noted on the Federal Awarding Agency's Award Conditions website:
   http://grants.nih.gov/policy/notices.htm
2. 2 CFR 200
3. The Grants Policy Statement, including addenda in effect as of the beginning date of the period of performance or as amended found at:
   http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf
4. Interim Research Terms and Conditions found at: https://www.nsf.gov/awards/managing/rtc.jsp
   and Agency Specific Requirements found at: http://grants.nih.gov/grants/policy/NIH%20Interim%20Grant%20General%20Conditions.pdf except for the following:
   a. If applicable, the right to initiate an automatic one-time extension of the end date is replaced by the need to obtain prior written approval from the Pass-through Entity;
   b. Any payment mechanisms and financial reporting requirements described in the applicable Agency Terms and Conditions and Agency-Specific Requirements are replaced with Terms and Conditions (1) through (4) of this Subaward Agreement; and
   c. Any prior approvals are to be sought from the Pass-through Entity and not the Federal Awarding Agency.
5. Title to equipment costing $5,000 or more that is purchased or fabricated with research funds or Subrecipient cost sharing funds, as direct costs of the project or program, shall unconditionally vest in the Subrecipient upon acquisition without further obligation to the Federal Awarding Agency subject to the conditions specified in 2 CFR 200.313 of the Uniform Guidance.
6. Treatment of Program Income:

○ Additive ○ Other, Pass-through Entity specify:

[NIH Only] Multiple PIs (MPIs) If the Federal Award includes MPIs

☑ This is not an MPI award
☐ This is an MPI award. Both parties will follow the finalized MPI Leadership Plan, and:

Special Terms and Conditions:

Copyrights (Select One)
☑ Subrecipient Grants
☐ Subrecipient Shall Grant

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.

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.

Automatic Carryforward (Select One)

☐ Yes ☑ No (Select carryforward contact below)

Contact for carryforward request (If carryforward is restricted, requests for carryforward must be sent to Pass-Through Entity's contact below, details in Attachment 3)

Administrative Contact

Attachment 1

Research Subaward Agreement

Certifications and Assurances

By signing the Subaward Agreement, the Authorized Official of Subrecipient certifies, to the best of his/her knowledge and belief, that:

Certification Regarding Lobbying (2 CFR 200.450)

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 (2 CFR 200.213 and 2 CFR 180)

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

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 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.

Use of Name

Neither party shall use the other party's name, trademarks, or other logos 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 Agreement 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.

Work Involving Human or Animal Subjects (Select Applicable Options)

☑ Human Subjects ☐ Animal Subjects ☐ No Human or Animal Subjects

Subrecipient agrees that any non-exempt human and/or animal subjects research protocol conducted under this Agreement 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 Agreement involving human and/or animal subjects 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 animal subjects 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

☑ Upon Request
☐ Prior to execution of this Agreement
☐ Prior to execution of this Agreement and annually thereafter
☐ Not required for the following reason:

Human Subjects Data (Select One)

☐ Not Applicable
☑ Applicable

Human Subjects Data will be exchanged under this Agreement (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):

☑ In the Additional Terms section below
☐ Via a separate Data Use Agreement

Promoting Objectivity in Research Applicable to Subrecipients (Financial Conflicts of Interest): Subrecipient must designate herein which entity's financial conflicts of interest policy will apply (Select One):

☐ PTE ☐ Subrecipient

If applying its own financial conflicts of interest policy, by execution of this Subaward Agreement, Subrecipient Institution certifies that its policy complies with the requirements of the relevant Federal Awarding Agency as identified herein: NIH - 42 CFR Part 50 Subpart F

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, when applicable, subsequently be reported to Federal Awarding Agency. Such report shall be made before expenditure of funds authorized in this Subaward Agreement and within 45 days of any subsequently identified financial conflict of interest.

Data Sharing and Public Access Policy:

(Check if Applicable)

☑ Subrecipient agrees to comply with the Federal Award Agency's data sharing and public access policy requirements and the Data Management/Sharing Plan submitted to the Federal Awarding Agency and incorporated herein as Attachment 7.

Pilot Program for Enhancement of Contractor Employee Protections (48 CFR 3.9080):

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.

Additional Terms (as required by the Federal Award or to cover Human Subjects Data):

In the performance of the Project, it is the intention of the PTE to provide Subrecipient with certain patient data and information ("Patient Data") which, to the best of PTE's knowledge, are (i) de-identified data as defined by Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, and implementing regulations, and (ii) non-identifiable in accordance with the standards of the federal research regulations at 45 C.F.R. Part 46. Each party certifies that it will use and disclose such Patient Data in compliance with the study protocol; the applicable informed consent form(s) (or relevant waivers, if applicable); and all applicable laws and regulations (each as amended from time to time). Without limiting the foregoing, each party agrees that it will use and disclose Patient Data received in the performance of the Project solely for the purposes of conducting the Project or as otherwise required by law. Each party agrees to use appropriate safeguards to ensure compliance with these obligations and will promptly inform the other party of any inappropriate use or disclosure of Patient Data. The Subrecipient will refrain from using the Patient Data to attempt to identify or contact individuals. The obligations in this paragraph will survive expiration or termination of this Agreement.

Attachment 2
Research Subaward Agreement
PTE Additional Federal Award Terms and Conditions

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

1. Independent Parties.
   Subrecipient hereby acknowledges that all employees hired by it, under or as a result of this Agreement, shall during the term of this Agreement be deemed to be employees of the Subrecipient and will at no time be considered employees or agents of the PTE.
2. Health Insurance Portability and Accountability Act (HIPAA).
   Subrecipient acknowledges that it may receive protected health information (PHI), as defined by HIPAA regulations, regarding subjects involved in the Study. Subrecipient agrees that such information: (a) will be used only for purposes of conducting the study consistent with both the protocol and the subject consent form signed by study subjects; (b) may be disclosed to the U.S. F.D.A. and/or other regulatory agencies to gain regulatory approval; and (c) will not be disclosed or utilized for any other purpose. Additionally, Subrecipient agrees to cooperate with PTE to enter into any other agreements or provide additional documentation reasonably necessary to comply with HIPAA as applicable. Subrecipient will use appropriate safeguards to ensure conformance with these obligations and will promptly inform PTE of any inappropriate use or disclosure of such information. The obligations stated in this paragraph shall survive expiration or termination of this Subaward Agreement.
3. Liability.
   Liability of the Subrecipient of this Agreement shall be governed by Ohio Revised Code Chapters 2743 and 3345.40. Subrecipient will be responsible for the acts and omissions of its employees and agents. Subrecipient maintains a comprehensive program of self-insurance and commercially purchased insurance, covering property, casualty and liability exposures to the Subrecipient and its employees, agents and volunteers, while acting on the Subrecipient's behalf.
4. Human Subjects and Animal Research.
   Subrecipient shall not conduct any human subjects or animal research activities during a lapse in protocol approval. Subrecipient will monitor compliance with these requirements, and PTE reserves the right to review Subrecipient's human subjects research and/or animal care and use policies and procedures at any time. Subrecipient will supply to PTE a copy of its IRB or IACUC approval for each human subjects research and/or animal research protocol under this Subaward Agreement.
5. Human Subjects and Animal Research Reporting.
   Subrecipient agrees to promptly notify PTE (and provide supporting documentation and explanation, if applicable) of any of the following: (i) its IRB or IACUC's, as applicable, disapproval, termination, suspension, or recommendations for modification of the Project's study protocol or related documentation, including the informed consent form; (ii) determinations of the IRB or IACUC in regard to instances of noncompliance with any applicable law and regulation or the requirements of the IRB or IACUC, as applicable; and (iii) human subject complaints or unanticipated problems involving risks to subjects or deviations from the Project's protocol, including but not limited to any such events reported to the IRB by investigators and subject withdrawals. Subrecipient agrees to promptly notify PTE of all adverse events, serious adverse events, unexpected adverse events, as defined by applicable law and regulations, and safety information in accordance with the human subjects research protocol. If the adverse event is serious or unexpected, or requires action by PTE to prevent an unreasonable risk of substantial harm to public health, then notice will be given immediately, but in no event later than twenty-four (24) hours after learning of such event. Subrecipient will provide PTE with all associated documentation (e.g., lab reports, death summary, operative reports, etc.) for each serious adverse event in connection with the human subjects research protocol. Subrecipient will notify PTE of any significant deficiencies noted by Subrecipient regarding its animal facilities that directly affect the Project protocol or welfare of the study animals.
6. Insurance.
   In connection with this Agreement PTE and Subrecipient shall maintain a reasonable level of professional liability insurance and general liability insurance. Certificates evidencing such insurance will be made available for examination upon request.
7. Changes.
   This Agreement constitutes the entire agreement among the parties, and all prior negotiations, representations, agreements and understandings are superseded hereby. No agreements amending, altering or supplementing the terms hereof may be made except by means of a written document signed by the duly authorized representatives of the parties.
8. Dispute Resolution.
   Should a dispute arise under this contract, the parties agree to undertake a good faith effort to mediate the dispute for a period of ninety (90) days prior to taking any legal action.

9. Export Control.
   The Agreement is made subject to the laws and regulations concerning the export and re-export of products, services or technical information, and to the exclusions and exceptions thereunder, such as the exception for "fundamental research" from export controls in Part 734 of Title 15 of the U.S. Code of Federal Regulations ("Export Laws"). To this end, Subrecipient shall cooperate with PTE as reasonably necessary to permit PTE to comply with Export Laws. Subrecipient hereby represents and covenants the Subrecipient i) is neither a national of nor controlled by a national of any country to which the United States prohibits the export or re-export of goods, services, or technology; (ii) is not a person specifically designated as ineligible to export from the United States or deal in U.S. origin goods, services or technologies; (iii) will not export or re-export, directly or indirectly, any goods, services or technology, to any country or person (including juridical persons) in contravention of Export Laws; and (iv) in the event that a U.S. government license or authorization is required for an export or re-export of goods, services, or technology Subrecipient shall obtain any necessary U.S. government license or other authorization prior to undertaking the export or re-export.

   PTE hereby represents and covenants the same as Subrecipient and also represents and covenants that PTE:

   i. will notify Subrecipient before providing any export-controlled product, service or technical information to Subrecipient.
   ii. will label any export-controlled product, service or technical information provided to Subrecipient as such; and
   iii. will procure any U.S. government license or authorization necessary to provide any export-controlled product, service or technical information to Subrecipient.

10. Financial Conflict of Interest.
    Intentionally left blank.

11. Required Data Elements.
    The data elements that must be included in Federal Agency Subawards per the Uniform Guidance are included by combination of incorporation into this Subaward Agreement and in the attached Attachment 6, the PTE Federal Award.

12. Research Misconduct.
    Subrecipient represents that it has implemented policies and procedures for the identification, reporting, and investigation of research misconduct, including the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, consistent with all law or regulation applicable to the conduct of research under this Subaward Agreement. Any allegation or determination that research misconduct has occurred in connection with this Subaward Agreement must be promptly reported to PTE.

13. Audit and Record Retention.
    a. Subrecipient will maintain, and will cause any of its approved subrecipients to maintain, according to applicable accounting principles and sound financial practices, books, records, correspondence, instructions, plans, drawings, receipts, vouchers, memoranda, and other evidence, sufficient to accurately and properly reflect all costs and the disposition of any materials, tools, or equipment under this Subaward Agreement. PTE, the Federal Awarding Agency, Inspectors General, the U.S. Comptroller General, or their authorized representatives will have the right, with reasonable advance notice during normal business hours, to conduct site visits, meet with Subrecipient personnel, and view any materials, equipment, tools, or supplies purchased under this Subaward Agreement, and any books, documents, records, correspondence, instructions, plans, drawings, receipts, vouchers, and memoranda relating to performance of this Subaward Agreement, for the purpose of auditing and verifying costs under this Subaward Agreement, and evaluating and testing Subrecipient's systems of internal controls, practices, and procedures. PTE, the Federal Awarding Agency, or their authorized representatives will have the right to reproduce any such records. Subrecipient will ensure that PTE, the Federal Awarding Agency, or their authorized representatives are provided access to the facilities of any approved subrecipients on terms substantially identical to those set forth above.
    b. Subrecipient certifies that it meets and will continue to meet any applicable annual audit requirements under Federal Awarding Agency regulations (including but not limited to audits specified in 45 CFR Part 75 Subpart F) and undertake required audits. Subrecipient will, upon request, furnish a full and complete copy of any audit report to PTE. Subrecipient agrees that in the event of any adverse audit findings or deficiencies (as detected through audits, on-site reviews, and other means) that affect or may affect costs or other activities under this Subaward Agreement, Subrecipient will take timely and appropriate action on all deficiencies and notify PTE of same. Subrecipient further agrees that all records and reports prepared in accordance with any applicable audit requirements or regulations will be available for inspection by PTE and/or representatives of the Federal Awarding Agency during normal business hours.

PTE's and Subrecipient's rights and obligations with respect to PTE's management decisions (as defined in 45 CFR § 75.2) will be consistent with 45 CFR § 75.521.

c. PTE may, in its discretion, (i) provide Subrecipient with training and technical assistance on program-related matters; and (ii) perform on-site reviews of the Subrecipient's program operations; and (iii) arrange for agreed-upon-procedures engagements as described in 45 CFR § 75.352(e)(3) and § 75.425.
d. Without limiting the foregoing, at any time during or after termination or expiration of this Subaward Agreement and/or closeout, PTE reserves the right (a) to request Subrecipient to conduct an audit or other review by an independent Certified Public Accountant or other qualified entity; (b) to issue management decisions in response to any resulting finding(s); and/or (c) to require Subrecipient to adjust its records, in accordance with such decisions. PTE also reserves the right to take such other measures as it may deem necessary, in its sole discretion, as a result of such audits and audit findings.
e. Subrecipient agrees to refund to PTE any sum of money relating to costs charged to this Subaward Agreement that PTE or an auditor determines to be an unallowable, unallocable or unreasonable cost under applicable cost principles in 45 CFR Part 75. Notwithstanding any other provision of this Subaward Agreement, PTE's payments to Subrecipient will not affect PTE's right to a refund on the basis of a later audit or other review, nor does it affect Subrecipient's obligation to return funds that that PTE or an auditor determines to be inconsistent with applicable cost principles in 45 CFR Part 75.
f. Subrecipient will retain all records relating to this Subaward Agreement for a period of at least 3 years from the date of final expenditure report, or from the date of the submission of the quarterly or annual financial report, respectively, as reported to the PTE, with any extensions thereof, or for such longer period(s) as may otherwise be required by applicable law or by the Federal Awarding Agency regulations, consistent with 45 CFR § 75.361. If any such records are or may be required to resolve any then threatened or pending litigation, claim, audit or arbitration related to this Subaward Agreement and started before the expiration of the 3-year period, the period of retention will continue until all litigation, claims, or audit findings involving the records have been resolved and final action taken. Records for real property and equipment acquired with Federal funds must be retained for 3 years after final disposition.
g. Subrecipient will immediately disclose to PTE any and all misuse of funds under this Subaward Agreement.
h. No funds may be paid as profit to Subrecipient even if Subrecipient is a commercial organization. Profit is any amount in excess of allowable direct and indirect costs.

14. Certification Required by 45 CFR § 75.415.
All invoices and financial reports submitted to PTE by Subrecipient under this Subaward Agreement shall include, and hereby does include, the following certification, made and signed by an official who is authorized to legally bind Subrecipient: "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)." If this Agreement is a fixed amount subaward as described in 45 CFR § 75.353, then consistent with 45 CFR § 75.201(b)(3), Subrecipient shall further submit a certification, and hereby certifies, upon closeout of the Study, that the project or activity was completed or the level of effort was expended.

15. Additional Flow-down.
PTE may administratively flow down to Subrecipient those new or updated terms and policies that the Federal Awarding Agency requests or requires PTE to apply to Subrecipient, and such terms and policies automatically become a part of this Subaward Agreement.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

Attachment 3A
Research Subaward Agreement
Pass-Through Entity (PTE) Contacts

Subaward Number: 01061832

Pass-Through Entity (PTE)

PTE Name: Beth Israel Deaconess Medical Center, Inc.

Address: 330 Brookline Avenue

City: Boston State: MA Zip Code+4: 02215-5491 Zip Code Look-up

PTE Administrative Contact

Name: Kristin Cook

Address: Beth Israel Deaconess Medical Center, 330 Brookline Avenue

City: Boston State: MA Zip Code: 02215-5491

Telephone: 617-975-8544 Email: kcook2@bidmc.harvard.edu

COI Contact email (if different to above): regreen@bidmc.harvard.edu

PTE Principal Investigator

Name: Magdy Selim

Address: Beth Israel Deaconess Medical Center, 330 Brookline Avenue

City: Boston State: MA Zip Code: 02215-5491

Telephone: 617-632-8913 Email: mselim@bidmc.harvard.edu

PTE Financial Contact

Name: Russel LeRoy

Address: Beth Israel Deaconess Medical Center, 330 Brookline Avenue, BR 259

City: Boston State: MA Zip Code: 02215-5491

Telephone: 617-667-4136 Email: rleroy@bidmc.harvard.edu

Email invoices? (•) Yes ( ) No Invoice email (if different): Send invoices to PTE's Administrative Contact email listed above.

Invoice Address (if different): Send invoices to PTE's Administrative Contact address listed above.

PTE Authorized Official

Name: Jennifer Sabbagh

Address: Beth Israel Deaconess Medical Center, 330 Brookline Avenue, BR 264

City: Boston State: MA Zip Code: 02215-5491

Telephone: 617-975-8545 Email: jsabbagh@bidmc.harvard.edu

Central email: resadmin@bidmc.harvard.edu

Attachment 3B

Research Subaward Agreement

Subrecipient Contacts

Subaward Number: 01061832

Subrecipient Place of Performancefor 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. Gearring, 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

Central email: ospaward@uc.edu

Attachment 3B Page 2
Research Subaward Agreement
Highest Compensated Officers

Subaward Number: 01061832

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
Research Subaward Agreement
Reporting Requirements

Subaward Number: 01061832

Subrecipient agrees to the following:

☑ A Final technical/progress report will be submitted to the PTE's Principal Investigator identified in Attachment 3 within 60 days after the end of the period of performance.

☐ Monthly technical/progress reports will be submitted to the PTE's Principal Investigator identified in Attachment 3, within 60 days of the end of the month.

☐ Quarterly technical/progress reports will be submitted within thirty (30) days after the end of each project quarter to the PTE's Principal Investigator identified in Attachment 3.

☑ Technical/progress reports on the project as may be required by PTE's Administrative Contact in order that PTE may be able to satisfy its reporting obligations to the Federal Awarding Agency.

☑ Annual technical /progress reports will be submitted within 90 days prior to the end of each project period to the PTE's Administrative Contact identified in Attachment 3. 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.

☑ In accordance with 37 CFR 401.14, Subrecipient agrees to notify PTE's Administrative Contact identified in Attachment 3A 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 Awarding Agency specific forms to the PTE's Administrative Contact identified in Attachment 3A within 60 days 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 90 days after the end of the project period to the PTE's Administrative Contact identified in Attachment 3A (for Fixed Price subawards only.)

☐ Property Inventory Report; frequency, type, and submission instructions listed here and only to be used when required by PTE Federal Award:

Other Special Reporting Requirements:

Attachment 5

Cost Reimbursement Research Subaward Agreement

Statement of Work, Cost Sharing, Indirects & Budget

Subaward Number: 01061832

Statement of Work

Below ☑ or ☐ Attached ☐ pages

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

SCOPE OF WORK – NIH StrokeNet National Clinical Coordinating Center, University of Cincinnati – SATURN
The coordination of SATURN trial operations will be conducted through the NIH StrokeNet National Clinical Coordinating Center (NCC) at the University of Cincinnati led by Dr. Pooja Khatri, StrokeNet NCC Principal Investigator. The StrokeNet infrastructure funds experienced individuals who can perform and delegate to support staff, as needed, the activities required for efficient trial inception and execution on behalf of the SATURN trial.

A Project Manager at the NCC will perform, in coordination with the SATURN Principal Investigator and the National Data Management Center (NDMC), site management tasks for 140 StrokeNet clinical performance sites. These tasks include but are not limited to trial-wide communication, orchestration of required training activities, coordination of and assistance with site assessment and/or initiation visits if needed, collection and review of trial related regulatory documents, site authorization for enrollment, recruitment performance tracking and site performance analysis. This individual will be one of the primary contacts for sites for non-data entry issues and will work closely with the trial Principal Investigator and SATURN leadership team.

The Contracts Manager with assistance from contracts staff at the NCC will develop and execute a SATURN Clinical Trial Agreement (CTA) for all performance sites stipulating the amount of money participating institutions will receive for both subject care and non-subject care costs. These agreements will serve as the binding agreements between the NCC and all performance sites. The NCC finance team will oversee and facilitate distribution of site payments. The StrokeNet Central IRB and CIRB staff will be solely responsible for the review of this project and regulatory oversight of the SATURN trial protocol. Finally, available within the infrastructure is hosted webinar platform technology and website management, along with an Educational/Training Coordinator, for use by SATURN investigators and site coordinators, as needed.

Indirect Information Indirect Cost Rate (IDC) Applied 60.50 %

☐ TDC ☑ MTDC ☐ OTHER ☐ de minimus rate of 10%

Cost Sharing ☐ Yes ☑ No

If Yes, include Amount: $

Budget Information ☐ Below ☑ Attached, 1 pages

Direct Costs	$ 1,059,939
Indirect Costs	$ 239,603
Total Costs	$ 1,299,542

All amounts are in United States Dollars

Attachment 6
Research Subaward Agreement
PTE Notice of Award

See Attached

Grant Number: 1U01NS102289-01A1 REVISED
FAIN: U01NS102289

Principal Investigator(s):
Magdy H Selim, MD

Project Title: StATins Use in intRacerebral hemorrhage patieNts (SATURN)

Mrs. Heisey, Sabrina
Research Administrative Supervisor
330 Brookline Avenue
CLS-750
Boston, MA 022155491

Award e-mailed to: resadmin@bidmc.harvard.edu

Period Of Performance:
Budget Period: 09/01/2019 – 05/31/2020
Project Period: 09/01/2019 – 05/31/2026

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 BETH ISRAEL DEACONESS MEDICAL CENTER 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 U01NS102289. 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,

Elizabeth E Conklin
Grants Management Officer
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Additional information follows

SECTION I – AWARD DATA – 1U01NS102289-01A1 REVISED

Award Calculation (U.S. Dollars)

Salaries and Wages	$210,087
Fringe Benefits	$61,716
Personnel Costs (Subtotal)	$271,803
Materials & Supplies	$2,000
Travel	$55,000
Subawards/Consortium/Contractual Costs	$2,347,259
Publication Costs	$500
Federal Direct Costs	$2,676,562
Federal F&A Costs	$338,088
Approved Budget	$3,014,650
Total Amount of Federal Funds Obligated (Federal Share)	$3,014,650
TOTAL FEDERAL AWARD AMOUNT	$3,014,650
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$3,014,650	$3,014,650
2	$3,398,290	$3,398,290
3	$3,150,398	$3,150,398
4	$3,011,781	$3,011,781
5	$1	$1
6	$1	$1
7	$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:	1042103881A1
Document Number:	UNS102289A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2019

IC	CAN	2019	2020	2021	2022	2023	2024	2025
NS	8472428	$3,014,650	$3,398,290	$3,150,398	$3,011,781	$1	$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**: CONKLINE 09/09/2019
Award Processed: 09/10/2019 12:05:22 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1U01NS102289-01A1 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 – 1U01NS102289-01A1 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:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. 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).

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) U01NS102289. 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 – 1U01NS102289-01A1 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.

This revision rescinds the restriction for the foreign components Canadian sites listed below. Funds awarded are now available.

UNIVERSITY OF ALBERTA
UNIVERSITY OF OTTAWA
LONDON HEALTH SCIENCES CENTER
NOVA SCOTIA HEALTH AUTHORITY
MCMASTER UNIVERSITY
LAVAL UNIVERSITY
UNIVERSITY OF SASKATCHEWAN
MCGILL UNIVERSITY HEALTH CTR RES INST
THUNDER BAY REGIONAL RESEARCH INSTITUTE
UNIVERSITY OF MANITOBA
UNIVERSITY OF LETHBRIDGE
UNIVERSITY OF CALGARY
UNIVERSITY OF SHERBROOKE
UNIVERSITY OF MONTREAL HOSPITAL
UNIVERSITY HEALTH NETWORK

THE PREVIOUS TERMS AND CONDITIONS STATED BELOW REMAIN IN EFFECT EXCLUDING THE RESTRICTIVE FOREIGN CLEARACNE TERM.

****

Of the **$3,014,650** awarded in Year 1, a total of **(50%) $1,507,325** is currently available for expenditures necessary for planned start-up activities and to begin enrollment in the trial. The balance of funds for Year 1 **(50%) $1,507,325** 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
- Clinical Trial Agreements executed for at least 40 participating centers; and

- At least 15 centers initiated and open for subject enrollment.
- At least 5 participants randomized into the study.

The initial award will be committed for four years in order to demonstrate feasibility. During the fourth 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, 2022:

- 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.

NOTE: Claudia Moy, PhD is the Project Scientist, and Joanna Vivalda, PhD is the Program Official.

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 **June 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

RESTRICTION: This award is being made without foreign clearance for the following Canadian sites listed below. Funds awarded, $877,139 total cost re restricted and may not be used for any other purpose without foreign clearance approval and notification by NINDS staff. Consortia 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:

UNIVERSITY OF ALBERTA
UNIVERSITY OF OTTAWA
LONDON HEALTH SCIENCES CENTER
NOVA SCOTIA HEALTH AUTHORITY
MCMASTER UNIVERSITY
LAVAL UNIVERSITY
UNIVERSITY OF SASKATCHEWAN
MCGILL UNIVERSITY HEALTH CTR RES INST
THUNDER BAY REGIONAL RESEARCH INSTITUTE
UNIVERSITY OF MANITOBA
UNIVERSITY OF LETHBRIDGE
UNIVERSITY OF CALGARY
UNIVERSITY OF SHERBROOKE
UNIVERSITY OF MONTREAL HOSPITAL
UNIVERSITY HEALTH NETWORK

Standard Terms

This competing award has been made at the council-recommended direct cost level. See NINDS funding strategy: http://www.ninds.nih.gov/funding/ninds_funding_strategy.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

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 April 17, 2019. 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.

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 (DBMB) 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 Study 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

o 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.

o 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.

o 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

For additional information on study documentation needed for NINDS -supported clinical trials, refer to the Clinical Trials Checklist [**MS Word Version**] [**PDF Version**]

See All NINDS Terms of Award for Clinical Research

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.

See All NINDS Terms of Award for Clinical Research

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: Yvonne C. Talley
Email: talleyy@mail.nih.gov **Phone**: 301-496-7432 **Fax**: 301-451-5635

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

SPREADSHEET SUMMARY
GRANT NUMBER: 1U01NS102289-01A1 REVISED

INSTITUTION: BETH ISRAEL DEACONESS MEDICAL CENTER

Budget	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Salaries and Wages	$210,087	$297,984	$297,984	$297,984			
Fringe Benefits	$61,716	$88,350	$88,350	$88,350			
Personnel Costs (Subtotal)	$271,803	$386,334	$386,334	$386,334			
Materials & Supplies	$2,000	$2,000	$2,000	$2,000			
Travel	$55,000	$55,000	$55,000	$55,000			
Other					$1	$1	$1
Subawards/Consortium/Contractual Costs	$2,347,259	$2,614,081	$2,371,258	$2,232,641			
Publication Costs	$500	$500	$500	$500			
TOTAL FEDERAL DC	$2,676,562	$3,057,915	$2,815,092	$2,676,475	$1	$1	$1
TOTAL FEDERAL F&A	$338,088	$340,375	$335,306	$335,306	$0	$0	$0
TOTAL COST	$3,014,650	$3,398,290	$3,150,398	$3,011,781	$1	$1	$1

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
F&A Cost Rate 1	75%	75%	75%	75%			
F&A Cost Base 1	$450,784	$453,833	$447,074	$447,074			
F&A Costs 1	$338,088	$340,375	$335,306	$335,306			

RESOURCE SHARING:

Publications and presentations of the results of this study will be governed by the policies developed by the Executive Committee in conjunction with the NINDS. The Publication Policy will be fully compliant with the voluntary NIH Public Access Policy mandated by the Consolidated Appropriations Act of 2008 (Division G, Title II, Section 218 of PL 110-161). The Executive Committee will follow NIH policies on data sharing (as described at: http://grants2.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm and any updates thereto). Any manuscript(s) will be made available for review by the NINDS prior to submission. The genetic information, derived from this study, will be deposited in the US NIH genomic database (dbGAP) and used for future research. We will follow the NIH policies on data sharing. Sharing of the data generated by this study will be carried out in several different ways. We would wish to make our results available to the scientific community interested in stroke and ICH to avoid unintentional duplication of research. We would also welcome collaboration with others who could make use of the data generated by our study. Our plan for data sharing will include: 1) Presentations at national and international scientific meetings: We expect 3-4 presentations from this proposal at national and international meetings, including the International Stroke Conference, the Annual meeting of the American Academy of Neurology, the European Stroke Organization Conference, and the World Intracranial Hemorrhage conference. These meetings of professionals interested in stroke present new information on a variety of topics related to cerebrovascular diseases, including ICH. It is expected that the investigators from this proposed project will be active participants in these scientific meetings; 2) Web site: The Principal Investigator's institution, BIDMC, currently maintains a Web site link highlighting the research interests of various members of the division for cerebrovascular diseases, and posting information about stroke and ICH written primarily for a general audience. We plan to post the results from our study on our Web site; 3) Lectureship: Investigators on this project are frequently invited to give grand rounds and lectures at various institutions. The audience is largely interested in stroke and ICH; and 4) Generation of public use dataset after the completion of the trial.

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

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: _____

_____
Printed Name

_____
Signature

Receipt Acknowledgement (to be completed upon receipt)

Date Received: _____

_____
Printed Name

_____
Signature