

terms and conditions

*note – this is a draft template, intended to serve as a baseline for Other Transactions agreements awarded by the HEAL Initiative Program. Requests by applicant(s) to modify any of the terms and conditions language will be considered by the Government on a case-by-case basis and negotiated as deemed appropriate. Failure to reach an agreement within a timeframe identified by the NIH may result in the Government not making an award. Highlighted areas within will or may change based on scope and details of proposed work.

A. Background

The purpose of this Agreement is to implement and support activities in the role of the **HEAL Research Dissemination and Engagement Center (R-DEC)**. The awardee(s) will work closely with the NIH HEAL Initiative and with other awarded organizations, especially those under the HEAL Data Ecosystem, to meet the needs of the overall program. Given the urgency of the evolving opioid crisis, the results of HEAL research must reach affected people and communities as quickly as possible. HEAL intends to disseminate findings and data as broadly as possible, including to pain and addiction researchers, the broader research community, and various non-researchers and community groups. The evidence built upon decades of NIH efforts in community-engaged research supports the benefit of enabling a more robust focus on meaningful engagement within the NIH HEAL Initiative infrastructure. To successfully reach these audiences and engage them in meaningful ways, HEAL will fund the R-DEC to interface with the HEAL research community, key partner organizations, and the intended beneficiaries of HEAL research. The R-DEC will work closely with the existing HEAL Data Ecosystem that accelerates sharing of HEAL-generated data and enabling HEAL data to be searched, analyzed, and used to make new discoveries. Most importantly, this partner will understand and translate data and findings in ways meaningful at the community level, with input from the communities, to address needs and priorities of communities standing to benefit most from HEAL research. The R-DEC will generate, manage, and coordinate processes and products that connect the growing evidence base of HEAL research with communities, organizations, government entities, and other potential beneficiaries of HEAL research results.

B. Authorization

1. This award is made under the Other Transaction Authority (OTA) as authorized by section 402(n) of the Public Health Service Act, 42 U.S.C. 282(n). It is not intended to be, nor shall it be construed as a partnership (in the strict legal sense), corporation, or other business organization. This Agreement is not governed by the Federal Acquisition Regulation (FAR), 2 CFR 200 or the NIH Grants Policy Statement.
2. Research and Development (R&D)

Other Transaction awards issued by the National Institutes of Health (NIH) are deemed to 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).

C. Scope

1. The Awardee shall perform a coordinated research and development program resource (hereafter referred to as "Program") that shall be carried out in accordance with the "Statement of Work and Milestones and Deliverables" (SOM) hereby incorporated into this Agreement as Attachment 1 and Attachment 2.
2. Subject to the availability of funds, the Awardee shall be paid based on funds made available in accordance with the Statement of Budgetary Projections (SBP) Attachment 4 hereby incorporated in this Agreement.

D. Definitions

In this Agreement, the following definitions apply:

Agreement: This Agreement and any Attachments that are expressly incorporated in and made a part of the Agreement, including Attachment 1, Attachment 2, Attachment 3, and Attachment 4.

Agreement Officer (AO): Individual responsible for legally committing the government to an OT award and to the Agreement through which terms and conditions are established, and for the administrative and financial aspects of the award.

Agreement Officer Representative (AOR): A designee of the Agreement Officer that provides day-to-day programmatic oversight, working closely with the Agreements Officer and the Awardee.

Agreement Specialist: A designee of the Agreements Officer for administrative and financial aspects of the award.

Awardee: Renaissance Computing Institute at the University of North Carolina, the entity responsible for the administrative, financial, and programmatic activities described in the Agreement.

Awardee Business Official (ABO): A designee of the Awardee's institution who is responsible for legally committing the institution and is authorized to speak on behalf of the institution.

Data: Recorded information, regardless of form or method of recording, which includes but is not limited to, technical data, software, maskworks and trade secrets. The term does not include financial, administrative, cost, pricing or management information and does not include subject inventions.

Foreign Firm or Institution: A firm or institution organized or existing under the laws of a country other than the United States, its territories, or possessions. The term includes, for purposes of this Agreement, any agency or instrumentality of a foreign government; and firms, institutions or business organizations which are owned or substantially controlled by foreign governments, firms, institutions, or individuals.

NIH/HEAL: The United States of America, as represented by the National Institutes of Health (NIH), Helping to End Addiction Long-term (HEAL).

Invention: Any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.

Know-How: All information including, but not limited to discoveries, formulas, materials, inventions, processes, ideas, approaches, concepts, techniques, methods, software, programs, documentation, procedures, firmware, hardware, technical data, specifications, devices, apparatus, and machines.

Made: Relates to any invention means the conception or first actual reduction to practice of such invention.

Party: Includes the Government/NIH, or the Awardee, or both.

Practical application: To manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is capable of being utilized and that its benefits are, to the extent permitted by law or Federal regulations, available to the public on reasonable terms.

Program: Research and development being conducted by the Awardee, as set forth in Scope of Work.

The Program Director/Principal Investigator (PD/PI): Individual designated by the recipient to have the appropriate level of authority and responsibility to direct the project or program supported by the Other Transaction Agreement award.

Property: Any tangible personal property other than property actually consumed during the execution of work under this Agreement.

Subject Invention: Any invention conceived or first actually reduced to practice in the performance of work under this Agreement.

Technology: Discoveries, innovations, Know-How and inventions, whether patentable or not, including computer software, recognized under U.S. law as intellectual creations to which rights of ownership accrue, including, but not limited to, patents, trade secrets, maskworks and copyrights developed under this Agreement.

Unlimited Rights: The rights to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.

E. Goals/Objectives [to be refined based on work proposed by successful applicant(s)]

1. Build and maintain trusted partnerships with communities and individuals that are part of and affected by NIH HEAL Initiative research, including but not limited to clinicians and community care providers; advocacy groups with interest in pain, addiction and other research areas relevant to HEAL such as mental and behavioral health; patients and people with lived experience; and service organizations or community-based organizations in HEAL's focus areas;

2. Develop resources and provide services to support investigators in the dissemination of study results to the broader community. This includes distilling complex research findings into audience appropriate and culturally appropriate summaries, data visualizations, and other products.
3. Lead and manage the R-DEC, its partnerships and sub-awards using proven project management capabilities

F. Teaming Agreement

Teaming Collaboration with additional partners under HEAL Initiative's Research Dissemination and Engagement Center (R-DEC) Other Transaction Authority (OTA) Awards

Under this OTA award, it is expected that:

- HEAL R-DEC awardees are required to partner and collaborate to meet their milestones and deliverables
- Collaborative interactions are required amongst all R-DEC awardees and the HEAL Data Ecosystem awardees;
- HEAL Initiative and NIH staff will provide deep engagement and technical oversight of the project(s), milestones, and deliverables under each award;
- R-DEC awardees will maintain amenability and flexibility to grow, enhance, and change the product(s) developed based on the input and needs of community partners, and/or HEAL investigators as new, diverse projects are onboarded across the Initiative
- Additional partners may be added in the future who would contribute specific relationships and/or capabilities
- Flexible coordination of aligned awards and efforts within the ambit of the HEAL R-DEC, including coordination with the Data Ecosystem as needed, especially to disseminate products and communication materials developed with community partner input

Given the size and complexity of the HEAL Initiative and expected data to be generated by HEAL awardees, it is necessary to ensure alignment across activities conducted by the [INSERT R-DEC awardees] and the HEAL Data Ecosystem awardees (University of Chicago and the Renaissance Computing Institute at University of North Carolina, Chapel Hill and RTI, International (RENCI/RTI, the HEAL Stewards)), in addition to other awardees that may be onboarded in the future in support of the HEAL R-DEC and Data Ecosystem.

Expectations and Activities:

It is expected that awardee teams will meet regularly and synergize efforts to address joint challenges that may impede or slow any teams' deliverables for the HEAL R-DEC, as well as align efforts and prevent unnecessary duplication of efforts. This coordination will require timely sharing of project documentation related to joint activities, clear delegation of task ownership and timelines, regular progress updates, and documentation of risks and challenges. These items should be documented in a shared workspace that is also accessible to HEAL program staff. This teaming collaboration will continue throughout the entire funding period of all HEAL R-DEC awards. Relevant information must be shared and coordination and collaboration should also include HEAL Data Ecosystem awardees under appropriate circumstances. Examples of activities that will require alignment include but are not limited to:

- Final landscape analyses identifying ongoing engagement activities in HEAL and gaps where new activities are needed
- Sharing of materials relevant to understanding the data-related needs of the broad community base and partners
- Sharing of training products, communications, and data visualization-related products to be cross-promoted through Data Ecosystem venues

- Collection, sharing, and integration of community feedback into Data Ecosystem design, operations, user onboarding, training, and general use of Data Ecosystem products

Roles:

- **Joint Oversight and Leadership: to be identified upon award**
- **Joint Management and Facilitation: to be identified upon award**
- NIH program staff and HEAL leadership will provide support and guidance as necessary, for example, feedback regarding overall HEAL initiative strategy and mission, related scientific guidance, mitigation of disputes or disagreements, and contact points with the HEAL investigator community or partners when appropriate
- Appropriate subject matter experts and representatives of external partners should be included in discussions and decisions where relevant.

Documentation of Teaming Management:

- Shared documentation and tracking of action items, task owners, timelines, and expected products or outcomes
- Regular report out of joint progress, risks, and next steps. These report practices include sharing with NIH program staff joint meeting notes and action items by EOD after relevant meetings, creating and regularly updating a joint task tracker, and depositing related deliverables within a shared location accessible to NIH program staff and awardee team members.
- Progress, decisions, and/or outcomes included within monthly report/deliverable gantt chart and progress summary
- When required, share documentation with HEAL stakeholders beyond the immediate teams

The above components of the teaming terms are subject to change if future awardees are added as partners.

TERM

A. Term of this Agreement

The Program commences upon the date of the last signature hereon and continues for 60 months or for other such period as mutually agreed to by the Parties, subject to the availability of funds. Provisions of this Agreement, which, by their express terms or by necessary implication, apply for periods of time other than specified herein, shall be given effect, notwithstanding this Article. If all funds are expended prior to the project end date, the Parties have no obligation to continue performance and may elect to cease development at that point.

B. Funding

This award has been funded in the amount below.

FISCAL YEAR	NIH OBLIGATED FUNDING
TBD	TBD

The funds listed in the table above are available for use; however, outyear funding and extension of this agreement is based on the successful completion of the milestones as outlined in Attachment 2. Determination of the successful completion of the milestones will be at the sole discretion of the NIH.

No legal liability on the part of the Government for any payment may arise for performance under this agreement beyond the funding established in the Statement of Budgetary Projections as outlined in Attachment 4 unless the Awardee receives notice in writing from the Agreement Officer.

C. NIH Termination

If the NIH decides to terminate this award, the termination of the award will be considered a unilateral termination and the awardee will not have the right to appeal. Although a decision is made to terminate, the Awardee must continue to comply with the Financial Records and Reporting Section of this Agreement.

NIH and the Awardee shall negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination, which may include non-cancelable commitments.

D. Awardee Termination

The Awardee may terminate this Agreement by giving the NIH AO ninety (90) days written notification of their intent to do so, provided that such written notice is preceded by consultation between the Parties.

NIH and the Awardee shall negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination, which may include non-cancelable commitments.

E. Extending the Term

The Parties may extend by mutual written agreement the term of this Agreement as the Goals/Objectives reasonably warrant. Any extension shall be formalized through revision of the Agreement by the AO and the ABO and shall be subject to the availability of funds.

MANAGEMENT OF THE PROJECT

A. Management and Program Structure

The Awardee shall be responsible for the overall technical and program management of the Program, and technical planning and execution shall remain with the Awardee.

NIH Scientific Program Director shall provide recommendations to Awardee on developments and technical collaboration and be responsible for the review and verification of the milestone objectives and deliverables. In signing this Agreement, the ABO certifies that the Awardee will comply with all applicable assurances, and certifications referenced in the Agreement and accompanying award. The ABO's signature further certifies that the Awardee will be accountable both for the appropriate use of funds awarded and for the performance of the SOM. The ABO is the responsible individual for ensuring that the Awardee complies with applicable Federal laws and regulations, including required certifications and assurances, its application and terms and conditions of the Agreement and accompanying award.

B. Modifications

1. As a result of meeting(s), annual review(s), or at any time during the term of the Agreement, progress or results may indicate that a change in the Goals/Objectives and/or milestones would be beneficial to Program objectives, recommendations to modify the Goals/Objectives and/or milestones may be initiated by either party. The initiating party will document in writing and submit to the other party its recommendations for modifying the Goals/Objectives and/or

milestones, including justifications to support the change. NIH AO and the ABO shall approve any Agreement modification on a bilateral basis.

2. NIH is not obligated to pay for additional or revised future objectives and milestones until the Goals/Objectives and/or milestones is formally revised by the AO and made part of this Agreement.
3. The Scientific Program Director shall be responsible for the review and verification of any recommendations to revise or otherwise modify the Goals/Objectives and/or milestones, prospective milestones, or other proposed changes to the terms and conditions of this Agreement.
4. The AO will be responsible for all official approvals related to the award. This includes but is not exclusive of documenting, communicating, and securing any necessary NIH approvals related to modifications to this Agreement.

C. Monitoring

The Awardee is responsible for managing the day-to-day operations of Agreement activities using Awardee's established controls and policies. However, to fulfill the role in the stewardship of federal funds, the Scientific Program Director and the Scientific Program Lead will monitor and identify potential problems and areas where technical assistance might be necessary. This active monitoring can be accomplished through review of reports and correspondence, audit reports, site visits and other information, which may be requested of the Awardee. Monitoring of a project or activity will continue for as long as NIH retains a financial interest in the activity as a result of property accountability, audit, and other requirements that may continue for a period of time after the Agreement is administratively closed out and is no longer providing active Agreement support. Failure to adhere to this requirement shall constitute a material breach of this Agreement and may result in exercise of available enforcement remedies.

D. Management Systems and Procedures

The Awardee is expected to have in use clearly delineated roles and responsibilities for its organization's staff, both programmatic and administrative; written policies and procedures; training; management controls and other internal controls; performance assessment; administrative simplifications; and information sharing. The Awardee may use its existing systems to manage Agreement funds and activities, provided that policies and procedures are consistently applied across its business functions.

E. Notification of Claim Against Awardee

The Awardee shall give the AO immediate written notice of any action or suit filed and prompt notice of any claim made against the Awardee by any Sub-OT Awardee that, in the opinion of the Awardee, may result in litigation related in any way to this Agreement.

F. Lower Tier Agreement Costs

No funds awarded under this Agreement may be used by the Awardee to pay for costs associated with the management or administration of Lower Tier Agreements unless the Awardee has received the prior written approval of the AO.

Neither the approval nor the non-approval of a Lower Tier Agreement shall relieve the Awardee of responsibility to comply with the terms of this Agreement and perform work pursuant to the SOM.

G. Flow Down of Terms

Lower Tier Agreements must include the following Agreement terms, suitably modified to identify the Parties:

1. Obligation and Payment
2. Disputes
3. Patent Rights
4. Data Rights
5. Applicable Statutes and Regulations
6. Information Sharing

AGREEMENT ADMINISTRATION

Agreement Administration

Unless otherwise provided in this Agreement, approvals permitted or required to be made by the NIH may be made only by the AO. Administrative and contractual matters under this Agreement shall be referred to the following representatives of the parties:

Points of Contact

Agreements Officer (AO):

AO Name: Quintin Hackshaw

AO Email Address: quintin.hackshaw@nih.gov

AO Phone Number: 301-451-2710

Agreements Specialist (AS):

AS Name: Dianna Bailey

AS Email Address: dianna.bailey@nih.gov

AS Phone Number: 301-402-5546

Scientific Program Director (SPD):

SPD Name: Jessica Mazerik, PhD

SPD Email Address: jessica.mazerik@nih.gov

SPD Phone Number: 301-402-5935

Scientific Program Lead (SPL):

SPL Name: Erin Spaniol, MS, OTR, MPH

SPL Email Address: erin.spaniol@nih.gov

SPL Phone Number: 301-451-3765

Awardee Points of Contact

Awardee Business Official (ABO):

ABO Name:

ABO Email Address:

ABO Phone Number:

Principal Investigator (PI):

PI Name:

PI Email Address:

PI Phone Number:

Each party may change its representatives named in this Article by written notification to the other party.

OBLIGATION AND PAYMENT

A. Obligation

1. The NIH's liability to make payments to the Awardee is limited to only those funds obligated under the Agreement or by modification to the Agreement and is subject to availability of funds. The NIH may obligate funds to the Agreement incrementally.
2. If modification becomes necessary in performance of this Agreement, the NIH AO and the ABO shall execute a revised SOM and/or milestones.

B. Payments

Awardee has an established and agrees to maintain an established accounting system which complies with Generally Accepted Accounting Principles and the requirements of this Agreement and shall ensure that appropriate arrangements have been made for receiving, distributing, and accounting for Federal funds. An acceptable accounting system is one in which all cash receipts and disbursements are controlled and documented properly.

Payments shall be made in the amounts set forth in Attachment No. XX, provided the AOR and/or AO has verified the accomplishment of the Payable Milestones when applicable.

- 1.

C. Interest Earned on Advances

Awardees receiving advance payments are expected to maintain those advanced funds in an interest-bearing account and promptly return any funds not spent within three (3) business days. Interest earned on federal advance payments deposited in interest-bearing accounts must be remitted annually to the Department of Health and Human Services, Payment Management System, Rockville, MD 20852. Interest amounts up to \$500 per year may be retained by the Awardee for administrative expenses.

D. Limitation of Funds

In no case shall the NIH's financial liability exceed the amount obligated under this Agreement.

E. Obligation

The liability to make payments to the Awardee is limited to only those funds obligated under the Agreement or by modification to the Agreement and is subject to availability of funds. NIH may obligate funds to the Agreement incrementally.

If modification becomes necessary in performance of this Agreement, the NIH AO and the ABO shall execute a revised SOM.

F. Appropriation Mandates

This award must comply with NIH fiscal appropriation mandates.

G. Close out of Fixed Year Appropriations Accounts

Fixed year appropriation accounts have a five (5)-year availability span. Awardees must draw down all appropriated fiscal year award funds no later than June 30 of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit the NIH's ability to further extend the final budget period.

H. Unobligated Balances and Actual Expenditures

Using the principle of "first in-first-out," unobligated funds are expected to be used before newly awarded funds.

FINANCIAL RECORDS AND REPORTING

A. Financial Management System Standards

The Awardee must have in place accounting and internal control systems that provide for appropriate monitoring of award accounts to ensure that obligations and expenditures are reasonable, allocable, and allowable. In addition, the systems must be able to identify unobligated balances, accelerated expenditures, inappropriate cost transfers, and other inappropriate obligation and expenditure of funds, and awardees must notify NIH AO when problems are identified. The Awardee's failure to establish adequate control systems constitutes a material breach of this Agreement and may result in exercise of available enforcement remedies.

B. Financial Records and Reports

The Awardee shall maintain adequate records to account for all funding under this Agreement. Upon completion or termination of this Agreement, whichever occurs earlier, the Awardee shall furnish to the AO a copy of any final reports specified in the Goals/Objectives and/or milestones. The Awardee's relevant financial records are subject to examination or audit on behalf of the NIH by the NIH for a period not to exceed three (3) years after expiration of the term of this Agreement. The AO or designee shall have direct access to sufficient records and information of the Awardee, to ensure full accountability for all funding under this Agreement. Such audit, examination, or access shall be performed during business hours on business days upon prior written notice and shall be subject to the security requirements of the audited party.

If any litigation, claim, financial management review, or audit is started before the expiration of the three (3)-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken.

These record retention policies apply to both paper and electronic storage of applicable information, including electronic storage of faxes, copies of paper document, images, and other electronic media. Institutions that rely on an electronic storage system must be able to assure such a system is stable, reliable, and maintains the integrity of the information. When storing electronic images of paper documents, the system must also assure a full, complete, and accurate representation of the original, including all official approvals.

C. Final Reporting

Within 60 days of the end or termination of this Agreement, the Recipient shall provide to the NIH the following final reports:

Final Progress Report: Final progress report that includes a general synopsis of the research activity and any noteworthy accomplishments, milestones achieved summary and including

results disseminated to the community. At the request of the Government, this may include a summary of lessons learned.

Final Financial Report: Final Federal Financial Report (FFR), SF-425, for the entire award period. The SF-425 can be accessed at <https://www.grants.gov/forms/post-award-reporting-forms.html>. The FFR must be uploaded via eRA. Instructions for submitting the FFR can be accessed here:

https://era.nih.gov/erahelp/commons/FFR/Archive_FFR/ffr_submittingForm.htm.

Final Invention Statement: Final Invention Statement and Certification (Form HHS 568). The HHS 568 form can be located at <https://grants.nih.gov/grants/hhs568.pdf>. Form HHS 568 should be submitted via eRA. Instructions for submitting the HHS 568 can be accessed here:

<https://era.nih.gov/grantees/submit-final-inventionstatement>.

AUDIT

A. Audit Requirements

For purposes of this Agreement, the Awardee is deemed to be subject to the audit requirements of OMB 2 CFR 200, Subpart F-Audit Requirements, as implemented by DHHS 45 CFR Subpart F: <https://www.ecfr.gov/cgi-bin/text-idx?SID=c92a1180439e91c819db8c5f87cf1f1f&node=2:1.1.2.2.1.6&rgn=div6>.

A non-Federal entity that expends \$750,000 or more during the non-Federal entity's fiscal year in Federal awards must have a single or program-specific audit conducted for that year in accordance with the provisions of this part.

1. A non-Federal entity that expends \$750,000 or more during the non-Federal entity's fiscal year in Federal awards must have a single audit conducted in accordance with §200.514 Scope of audit except when it elects to have a program-specific audit conducted in accordance with paragraph (2) of this section.
2. *Program-specific audit election.* When an auditee expends Federal awards under only one Federal program (excluding R&D) and the Federal program's statutes, regulations, or the terms and conditions of the Federal award do not require a financial statement audit of the auditee, the auditee may elect to have a program-specific audit conducted in accordance with §200.507 Program-specific audits. A program-specific audit may not be elected for R&D unless all of the Federal awards expended were received from the same Federal agency, or the same Federal agency and the same pass-through entity, and that Federal agency, or pass-through entity in the case of a subrecipient, approves in advance a program-specific audit.

B. Cost Principles

In general, this Agreement is subject to reimbursement of actual, allowable costs incurred and are expected to align with generally accepted and established federal costs principles for the entity receiving funding (e.g., academic, non-profit, for-profit).

DISPUTES

A. General

The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this agreement.

B. Dispute Resolution Procedures

1. Any disagreement claim or dispute between NIH and the Awardee concerning questions of fact or law arising from or in connection with this Agreement, and the Awardee, whether or not involving an alleged breach of this Agreement, may be raised only under this section.
2. Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable.

C. Limitation of Damages

Claims for damages of any nature whatsoever pursued under this Agreement shall be limited to direct damages only up to the aggregate amount of the NIH funding disbursed as of the time the dispute arises. SUBJECT TO APPLICABLE LAW IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR CLAIMS FOR CONSEQUENTIAL, PUNITIVE, SPECIAL OR INCIDENTAL DAMAGES, CLAIMS FOR LOST PROFITS, OR OTHER INDIRECT DAMAGES.

ROLES AND RESPONSIBILITIES

A. Collaborative Effort

The administrative and funding instrument used for this program is other transactions. Other transaction awards involve substantial NIH programmatic involvement with the Awardee during the period of performance. The NIH role is to support and stimulate the award activities by involvement in a collaborative partnership with the Awardee. All award recipients and partner organizations are required to effectively collaborate and cooperate with the HEAL Program, NIH and other NIH designees. Consistent with this concept, the dominant role and prime responsibility for decisions regarding task implementation and activities will be shared, with NIH having the final decision authority.

B. Principal Director/Principal Investigator

The PD(s)/PI(s) will have the primary responsibility for:

1. Proposing approaches, design, and implementation for task/milestone completion.
2. Ensuring all participating institutions are fully integrated into the project goals.
3. Implementing and maintaining an NIH approved data security plan for all participating institutions.
4. Completing of all tasks/milestones in a timely manner as defined in the terms and conditions of award.
5. Adhering to NIH requested needs for progress review including but not limited to technical/fiscal reports, program visits, conference calls, meetings, and external consultation.
6. Collaborating with additional NIH Program partners as designated by NIH.
7. PD(s)/PI(s) has the ultimate responsibility for implementing the activities as approved by NIH.

C. The NIH Program Manager and Scientific Program Director

The NIH Scientific Program Lead and Scientific Program Director will:

1. Provide substantial programmatic involvement that is above and beyond the normal stewardship role in awards.

2. Cooperation and coordination with, or assistance in coordinating access to other NIH collaborators and/or resources.
3. Scientific and technical discussions with awardees or actions to facilitate or expedite interactions between the awardee and the HEAL collaborators.
4. Participate on steering/advisory committees as developed by the award institution and/or NIH in order to guide the course of the project.
5. Approve awardee proposed tasks/milestones and timelines.
6. Determine the appropriate means for reviewing progress including but not limited to technical/fiscal reports, program visits, conference calls, meetings, and external consultation.
7. Evaluate the awardee's tasks/milestones progress and completion.
8. Provide technical assistance and final decisions for award directions and performance.
9. Enforce general statutory, regulatory or policy requirements.

PATENT RIGHTS

A. Allocation of Principal Rights

Unless the Awardee shall have notified NIH, in accordance with subparagraph 2 below, that the Awardee does not intend to retain title, the Awardee shall retain the entire right, title, and interest throughout the world to each Subject Invention consistent with the provisions of this Article.

1. With respect to any Subject Invention in which the Awardee retains title, the Government shall have a nonexclusive, nontransferable, irrevocable, royalty-free, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world.
2. With respect to any software developed, the Awardee will own the software and data developed under this award, subject to the Government's royalty-free, nonexclusive, irrevocable right to use, disclose, reproduce, post, link to, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so anywhere in the world. In addition, technical solutions and methods developed under this solicitation will remain the property of the Awardee, who may freely use them for their own commercial purposes, subject to a nonexclusive, nontransferable, irrevocable, royalty-free, paid-up license to the Government to practice, or have practiced for or on its behalf, the inventions, technical solutions and methods throughout the world.

B. Invention Disclosure, Election of Title, and Filing of Patent Application

1. The Awardee shall disclose each Subject Invention to NIH within four (4) months after the inventor discloses it in writing to his/her personnel responsible for patent matters. The disclosure to the NIH shall be in the form of a written report and shall identify the Agreement and circumstances under which the Invention was made and the identity of the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding, to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the Invention. The disclosure shall also identify any publication, sale, or public use of the invention and whether a manuscript describing the Invention has been submitted and/or accepted for publication at the time of disclosure.
2. If the Awardee determines that it does not intend to retain title to any such Invention, the Awardee shall notify NIH, in writing. However, in any case where publication, sale, or public use has initiated the one-year statutory period wherein valid patent protection can still be

obtained in the United States, the period for such notice may be shortened by NIH to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.

3. The Awardee shall file its initial patent application on a Subject Invention to which it elects to retain title within one (1) year after election of title or, if earlier, prior to the end of the statutory period wherein valid patent protection can be obtained in the United States after a publication, or sale, or public use. The Awardee may elect to file patent applications in additional countries, including the European Patent Office and the Patent Cooperation Treaty, within either ten (10) months of the corresponding initial patent application or six (6) months from the date permission is granted by the Commissioner for Patents to file foreign patent applications, where such filing has been prohibited by a Secrecy Order.
4. The Awardee shall notify the NIH of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent, in any country, not less than thirty (30) calendar days before the expiration of the response period required by the relevant patent office.
5. Requests for extension of the time for disclosure election, and filing under Article VII, may be granted at NIH's discretion after considering the circumstances of the Awardee and the overall effect of the extension.
6. The Awardee shall submit to the NIH annual listings of Subject Inventions. At the completion of the Agreement, the Awardee shall submit a comprehensive listing of all subject inventions identified during the course of the Agreement and the current status of each.

C. Conditions When the NIH May Obtain Title

1. Upon the NIH's written request, the Awardee shall convey title to any Subject Invention to the NIH under any of the following conditions:
 - a. If the Awardee fails to disclose or elects not to retain title to the Subject Invention within the times specified.
 - b. In those countries in which the Awardee fails to file patent applications within the times specified in Paragraph B of this Article; however, if the Awardee has filed a patent application in a country after the times specified in Paragraph B of this Article, but prior to its receipt of the written request by NIH, the Awardee shall continue to retain title in that country; or
 - c. In any country in which the Awardee decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceedings on, a patent on a Subject Invention.

D. Minimum Rights to the Awardee and Protection of the Awardee's Right to File

1. The Awardee shall retain a nonexclusive, royalty-free license throughout the world in each subject invention to which the NIH obtains title, except if the Awardee fails to disclose the Subject Invention within the times specified in Paragraph B of this Article. The Awardee's license extends to its domestic subsidiaries and affiliates, including Canada, if any, and includes the right to grant licenses of the same scope to the extent that the Awardee was legally obligated to do so at the time the Agreement was awarded. Any extension of the Awardee's license to its subsidiaries and affiliates that are based outside the United States must comply with all export control laws and other federal laws that may apply. The license is transferable only with the approval of the NIH, except when transferred to the successor of

that part of the business to which the Subject Invention pertains. The NIH approval for license transfer shall not be unreasonably withheld.

2. The Awardee's domestic license may be revoked or modified by the NIH to the extent necessary to achieve expeditious Practical Application of the Subject Invention pursuant to an application for an exclusive license submitted consistent with appropriate provisions at 37 C.F.R. Part 404.
3. This license shall not be revoked in that field of use or the geographical areas in which the Awardee has achieved Practical Application and continues to make the benefits of the Subject Invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of NIH to the extent the Awardee, its licensees, or the subsidiaries or affiliates have failed to achieve Practical Application in that foreign country.
4. Before revocation or modification of the license, the NIH shall furnish the Awardee a written notice of its intention to revoke or modify the license, and the Awardee shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

E. Action to Protect the NIH's Interest

1. The Awardee agrees to execute or to have executed and promptly deliver to NIH all instruments necessary to (i) establish or confirm the rights the NIH has throughout the world in those Subject Inventions to which the Awardee elects to retain title, and (ii) convey title to NIH when requested under Paragraph C of this Article and to enable the NIH to obtain patent protection throughout the world in that Subject Invention.
2. The Awardee agrees to require by written agreement with its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the Awardee each Subject Invention made under this Agreement in order that the Awardee can comply with the disclosure provisions of Paragraph B of this Article. The Awardee shall instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to United States or foreign statutory bars.
3. The Awardee shall include, within the specification of any United States patent application and any patent issuing thereon covering a subject invention, the following statement: his invention was made with NIH support under Agreement, awarded by NIH. The NIH has certain rights in the invention.

F. Reporting on Utilization of Subject Inventions

1. The Awardee agrees to submit, during the term of the Agreement, an annual report on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the Awardee or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Awardee. The Awardee also agrees to provide additional reports as may be requested by the NIH in connection with any march-in proceedings undertaken by the NIH in accordance with Paragraph I of this Article. The NIH agrees it shall not disclose such information to persons outside the NIH without permission of the Awardee, unless required by law.

2. All required reporting shall be accomplished, to the extent possible, using the i-Edison reporting website: <https://s-edison.info.nih.gov/iEdison/>. To the extent any such reporting cannot be carried out by use of i-Edison, reports and communications shall be submitted to the AO.

G. March-in Rights

The Awardee agrees that, with respect to any Subject Invention in which it has retained title, NIH has the right to require the Awardee, an assignee, or exclusive licensee of a Subject Invention to grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the Awardee, assignee, or exclusive licensee refuses such a request, NIH has the right to grant such a license itself if NIH determines that:

1. Such action is necessary because the Awardee or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve practical application of the Subject Invention;
2. Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the Awardee, assignee, or their licensees;
3. Such action is necessary to meet requirements for public use and such requirements are not reasonably satisfied by the Awardee, assignee, or licensees; or
4. Such action is necessary because the agreement has not been obtained or waived or because a licensee of the exclusive right to use or sell any Subject Invention in the United States is in breach of such Agreement.

DATA RIGHTS

A. Allocation of Principal Rights

1. The Parties agree that in consideration for NIH funding, the Awardee intends to reduce to Practical Application items, components and processes developed under this Agreement.
2. With respect to any Subject Invention in which the Awardee retains title, the Government shall have a nonexclusive, nontransferable, irrevocable, royalty-free, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world.
3. March -In Rights:
 - a) This article ensures that it obtains an unlimited rights license to all data developed under the OT Agreement and, perhaps crucially, obligates the Awardee to retain and upon request deliver that data. Although this language is flexible, the ability to obtain data and share it, in accordance with applicable controlled access protocols, is often an essential objective of any funded initiative.

B. Marking of Data

1. Pursuant to Paragraph A above, any Data delivered under this Agreement shall be marked with the following legend:

Use, duplication, or disclosure is subject to the restrictions as stated in Agreement XXXX between the Government and the Awardee.

2. The Government may use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly this Data, in any manner and for any purpose, and to have or permit others to do so.

C. Termination Data Rights

In the event of a termination of the Agreement, the NIH shall have paid-up rights in Data as described in Data Rights

TITLE TO AND DISPOSITION OF PROPERTY

A. Background Data

Background Data means any Data, Technology, or Know-How in which the Awardee holds rights of ownership as recognized by U.S. law as an intellectual creation which

1. was not reduced to Practical Application under this Agreement and
2. was developed at private expense, either exclusively or partially. The NIH recognizes that Background

Data may be vital to the Awardee's commercial success and business interests. At the same time, the NIH may need to obtain certain limited rights in Background Data in order to make effective use of work products delivered or otherwise made available to the Government under this Agreement. In order to balance these interests and distinguish between Background Data and Data generated or developed under this Agreement, the Parties agree to the following:

1. With respect to any Background Data incorporated into work products delivered under this Agreement, the NIH shall have a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for any Government purpose, and to authorize others to do so.
2. The Awardee has identified and asserted in good faith all Background Data to be furnished to the Government with restrictions on use, release, or disclosure.
3. Background Data to be Furnished with Restrictions. The Awardee should identify the Background Data or enter "none" when all Background Data will be submitted without restrictions.

B. Basis for Assertion.

Generally, development at private expense, either exclusively or partially, is the only basis for asserting restrictions. For technical data, other than computer software documentation, development refers to development of the item, component, or process to which the data pertain. The Government's rights in computer software documentation generally may not be restricted. For computer software, development refers to the software. Indicate whether development was accomplished exclusively or partially at private expense. If development was not accomplished at private expense, or for computer software documentation, the Awardee should enter the specific basis for asserting restrictions;

C. Asserted Rights Category.

Enter asserted rights category (e.g., government purpose license rights from a prior contract, rights in SBIR data generated under another contract, limited, restricted, or government purpose rights under this or a prior contract, or specially negotiated licenses);

1. Name of Person/Entity Asserting Restrictions. The Awardee should identify the corporation, individual, or other person, as appropriate.

The Government shall have Unlimited Rights in any Data, Technology, or Know-How arising under this Agreement or incorporated into work products delivered or otherwise made available to the Government under this Agreement unless the Awardee has identified and asserted the Data, Technology, or Know-How as Background Data.

In addition to the assertions made at the time of the execution of this Agreement, other asserted Background Data may be identified and added after award via mutual agreement of the Parties when based on new information or inadvertent omissions, unless the inadvertent omissions would have materially affected the NIH's decision to execute this Agreement.

INFORMATION SHARING

A. Public Release or Dissemination of Information

There shall be no dissemination or publication, except within and between the Awardee and any subcontractors, of information developed under this Agreement or contained in the reports to be furnished pursuant to this Agreement without review and comment by the AOR, which shall be completed within 30 days of submission of a publication to AOR. All technical reports will be given proper review by appropriate authority to determine which Distribution Statement is to be applied prior to the initial distribution of these reports by the Awardee. Unclassified patent related documents are exempt from prepublication controls and this review requirement. There shall be no dissemination or publication, except within and between the Awardee and any subcontractor(s), of information developed under this effort without review and comment by the AOR, which shall be completed within 30 days of submission of a publication to AOR. Papers prepared in response to academic requirements which are not intended for public release outside the academic institution are exempt from prepublication controls.

The Awardee shall submit all proposed public releases for review and comment. The NIH shall coordinate with the Awardee prior to any public release. Public releases include press releases, specific publicity or advertisement, and publication or presentation, but exclude those relating to the open sourcing or licensing, sales or other commercial exploitation of products, services or technologies. In addition, articles for publication or presentation will contain a statement on the title page worded substantially as follows:

This research was, in part, funded by the NIH. The views and conclusions contained in this document are those of the authors and should not be interpreted as representing the official policies, either expressed or implied, of the NIH.

B. NIH Public Access Policy

Awardees are expected to fully comply with the NIH Public Access Policy, which ensures that the public has access to the published results of NIH-funded research at the NIH National Library of Medicine PubMed Central (PMC; <http://www.pubmedcentral.nih.gov/>). Awardees must submit (or have submitted for them) to PMC an electronic version of the final, peer-reviewed manuscript upon acceptance for publication. In line with the HEAL public access and data sharing policy <https://heal.nih.gov/about/public-access-data>, publications are to be made publicly available immediately upon publication.

C. Sharing Research Resources

NIH considers the sharing of research resources an important means to enhance the value of NIH-sponsored research. Restricting the availability of unique resources can impede the advancement of further research. Therefore, when these resources are developed with NIH funds and the associated research findings have been accepted for publication, or after they have been provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community and the public. Program staff is responsible for overseeing resource sharing policies and for assessing the appropriateness and adequacy of any proposed resource sharing plans.

D. Data Sharing Policy

Sharing research data supports the NIH mission and facilitates the translation of research results into knowledge, products, and procedures that improve human health. NIH endorses the sharing of final research data to serve these and other important scientific goals and expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers. All data and publications are to be shared in line with the HEAL public access and data sharing policy <https://heal.nih.gov/about/public-access-data>. "Timely release and sharing" is defined as no later than the acceptance for publication of the main findings from the final data set. **All relevant data and products generated through this agreement should be disseminated through the HEAL Data Ecosystem, aligning with the HEAL data sharing strategy.**

E. Human Subject Data Sharing

NIH recognizes that data sharing may be complicated or limited, in some cases, by organizational policies, and local, state and federal laws and regulations, including the HIPAA Privacy Rule. The rights and privacy of individuals who participate in NIH-sponsored research must be protected at all times.

Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. When data-sharing is limited, applicants should explain such limitations in their data-sharing plans. Awardees must exercise great care to ensure that resources involving human cells or tissues do not identify original donors or subjects, directly or through identifiers such as codes linked to the donors or subjects.

Organizations that believe they will be unable to meet these data sharing expectations should promptly contact the AO to discuss the circumstances, obtain information that might enable them to share data, and reach an understanding in advance of an award.

F. Protection of Information

The Parties agree that they shall take appropriate measures to protect proprietary, privileged, or otherwise confidential information that may come into their possession as a result of this Agreement. The Parties agree to use commercially reasonable efforts (or for the Government, the equivalent level of care) to safeguard the confidentiality of each other's or a Participant's confidential, proprietary, or commercially sensitive information if clearly identified as such when received pursuant to this Agreement. The recipient party agrees not to disclose confidential, proprietary, or commercially sensitive information to anyone, nor to use it for any purpose other than to carry out his/her designated role in pursuant to this Agreement, except as required by law or a court of competent jurisdiction.

This restriction on disclosure and use of confidential information survives the recipient Party's withdrawal or termination from this Agreement for five (5) years, unless required by law to be protected for a longer period. The previously stated obligations of confidentiality do not apply to any information that:

- a. becomes a matter of public knowledge by means other than a wrongful act, omission or fault of the recipient party, its employees, or agents; is rightfully received from a third party without restriction; is approved for release by the submitting party; or is disclosed pursuant to a court order or as required by law.

Disclosure in breach of this Article may result in irreparable harm to the party whose confidential information has been disclosed, for which monetary damages alone may not be an adequate remedy. An aggrieved party shall have the right to seek an immediate injunction enjoining breach of this provision, in addition to all other remedies to which it may also be entitled.

APPLICABLE STATUTES AND REGULATIONS

A. Pre-Award Risk Assessment

NIH reserves the right to modify the status of the Awardee, if upon conducting a pre-award risk assessment, it is determined that the Awardee is no longer eligible to receive NIH funds. At a minimum, NIH will review Awardee eligibility on an annual basis.

B. Civil Rights Act

This Agreement is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964 as amended (42 U.S.C. § 2000d) relating to nondiscrimination in Federally assisted programs. The Awardee has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act.

C. Certificates of Confidentiality

This program will not override the requirements noted in Section 301(d) of the PHS Act, as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 and by doing so, this program expects that all applicable regulations have been or will be followed by all respective entities. For more information please see the following link:

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/certificates-of-confidentiality/index.html>.

D. Technical Oversight

The NIH may conduct technical oversight for which relevant third-party technical teams will be permitted full access to the Awardee's work performed under this award for the expressed purpose of determining progress in reaching strategic goals and objectives, the degree of compliance with regulatory requirements, and other criteria as determined by the NIH. NIH will determine the frequency, scope, and timing of these oversight activities. NIH assumes all related costs.

E. Unallowable Costs

Awarded funds may not be used for entertainment costs, alcoholic beverages, alteration and renovation costs, bad debts, bonding costs, building acquisition costs, dues or membership fees, promotional items, for the purchase of laptops or other equipment including costs of computing

devices, fines, penalties, damages, or other settlements, tuition costs, legal services, maintenance and repair costs, meals, subscription costs, professional activity costs, proposal costs, publication costs, service charges, stipends, trainee costs, and any out-year direct cost escalations without the express written approval of the NIH. All other costs are subject to negotiations.

F. Lobbying Prohibition

1. No part of any appropriation contained in the Consolidated and Further Continuing Appropriations Act, 2015, or transferred pursuant to section 4002 of Public Law 111-148 shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any state or local legislature or legislative body, except in presentation to the Congress or any state or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any state or local government, except in presentation to the executive branch of any state or local government itself.
2. No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used to pay the salary or expenses of any grant or contract awardee, or agent acting for such awardee, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive Order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local or tribal government in policymaking and administrative processes within the executive branch of that government.
3. The prohibitions in subsections (1) and (2) shall include any activity to advocate or promote any proposed, pending or future federal, state or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control.

G. Promotion or Legalization of Controlled Substances

Awardees are prohibited from knowingly using appropriated funds to support activities that promote the legalization of any drug or other substance included in Schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act, 21 U.S.C. 812 except for normal and recognized executive-congressional communications. This limitation does not apply if the awardee notifies the AO that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

H. Dissemination of False or Deliberately Misleading Information

None of the funds made available in the governing appropriations Act may be used to disseminate information that is deliberately false or misleading.

I. Restriction of Pornography on Computer Networks

The Consolidated and Further Continuing Appropriations Act, 2015 (P.L. 113-235) includes the following restriction:

1. None of the funds made available in this Act may be used to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.
2. Nothing in subsection (1) shall limit the use of funds necessary for any federal, state, tribal, or local law enforcement agency or any other entity carrying out criminal investigations, prosecution, or adjudication activities.

J. Communications Review

NIH would like to coordinate the announcement of NIH HEAL Initiative awards with awardees. Prior to publicly communicating about your award, including in a press release, web content, social media, etc., the award recipient will coordinate with NIH by providing the name and contact information for the Public Information Officer (PIO) at the awardee institution to renate.myles@nih.gov and emma.wojtowicz@nih.gov at the NIH Office of Communications and Public Liaison, and diana.morales@nih.gov at the HEAL Initiative, who will work with the PIO to coordinate the timing of announcements.

K. Partners

The following partners are included by the contractor for the success of the project.

- TBD

Written prior approval is required if any of the partners named above withdraws from the project entirely, is absent from the project during any continuous period, or significantly reduces time devoted to the project.

L. Appointments/Foreign Affiliation

List all positions and scientific appointments both domestic and foreign held by senior/key personnel that are relevant to an application including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).

Report all resources and other support for all individuals designated in an application as senior/key personnel – including for the program director/principal investigator (PD/PI) and for other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation. Information must be provided about all current support for ongoing projects, irrespective of whether such support is provided through the applicant organization, through another domestic or foreign organization, or is provided directly to an individual that supports the senior/key personnel's research efforts.

Report all current projects and activities that involve senior/key personnel, even if the support received is only in-kind (e.g. office/laboratory space, equipment, supplies, employees). All research resources including, but not limited to, foreign financial support, research or laboratory personnel, lab space, scientific materials, selection to a foreign "talents" or similar-type program, or other foreign or domestic support must be reported.

M. Preference for American Industry

Notwithstanding any other provision of this clause, the Awardee agrees that it shall not grant to any person the exclusive right to use or sell any Subject Invention in the United States unless

such person agrees that any product embodying the Subject Invention or produced through the use of the subject invention shall be manufactured substantially in the United States. However, in individual cases, the requirements for such an agreement may be waived by the NIH upon a showing by the Awardee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible.

N. Fly America Act

1. The Fly America Act (49 U.S.C. 40118) generally provides that foreign air travel funded by Federal Government money may only be conducted on U.S. flag air carriers. A "U.S. flag air carrier" is an air carrier that holds a certificate under 49 U.S.C. 41102 but does not include a foreign air carrier operating under a permit. There are limited circumstances under which use of a foreign-flag air carrier is permissible. These circumstances are outlined below:
2. Airline "Open Skies" Agreement. A foreign flag air carrier may be used if the transportation is provided under an air transportation agreement between the United States and a foreign government, which the Department of Transportation has determined meets the requirements of the Fly America Act. For example, in 2008, the U.S. entered into an "Open Skies" Agreement with the European Union (EU). This Agreement gives European Community airlines (airlines of Member States) the right to transport passengers and cargo on flights funded by the U.S. Government, when the transportation is between a point in the United States and any point in a Member State or between any two points outside the United States. The U.S.-EU Open Skies Agreement was amended effective June 24, 2010. GSA issued Guidance October 6, 2010. Pursuant to the amendment, federal contractors and awardees (not U.S. Government employees) need not be concerned about city-pair contract fares. However, contractors and awardees must check with the airline to ensure that the airline is covered by the U.S.-EU Open Skies agreement which may change periodically. Additionally, pursuant to the amendment, EU airlines are no longer limited to flying passengers between points in the United States and points in the EU. Instead, EU airlines are authorized to transport passengers between points in the United States and points outside the EU if the EU airline is authorized to serve the route under the U.S.-EU Open Skies Agreement. This includes flights that originate, arrive, or stop in the EU. For additional information, please see the text of the Amendment and GSA Bulletin FTR 11-2. For information on other "open skies" agreements in which the United States has entered, refer to GSA's website: <http://www.gsa.gov/portal/content/103191>.
3. Involuntary Rerouting. Travel on a foreign-flag carrier is permitted if a U.S.-flag air carrier involuntarily reroutes the traveler via a foreign-flag air carrier, notwithstanding the availability of alternative U.S.-flag air carrier service
4. Travel To and From the U.S. Use of a foreign-flag air carrier is permissible if the airport abroad is: (a) the traveler's origin or destination airport, and use of U.S.-flag air carrier service would extend the time in a travel status by at least 24 hours more than travel by a foreign-flag air carrier; or (b) an interchange point, and use of U.S.-flag air carrier service would increase the number of aircraft changes the traveler must make outside of the U.S. by two or more, would require the traveler to wait four hours or more to make connections at that point, or would extend the time in a travel status by at least six hours more than travel by a foreign-flag air carrier.
5. Travel Between Points Outside the U.S. Use of a foreign-flag air carrier is permissible if: (a) travel by a foreign-flag air carrier would eliminate two or more aircraft changes en route; (b) travel by a U.S.-flag air carrier would require a connecting time of four hours or more at an overseas interchange point; or (c) the travel is not part of the trip to or from the U.S., and use

of a U.S.-flag air carrier would extend the time in a travel status by at least six hours more than travel by a foreign-flag air carrier.

6. Short Distance Travel. For all short distance travel, regardless of origin and destination, use of a foreign-flag air carrier is permissible if the elapsed travel time on a scheduled flight from origin to destination airport by a foreign-flag air carrier is three hours or less and service by a U.S.-flag air carrier would double the travel time.

O. USA Patriot Act

The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act (USA PATRIOT Act) (P.L. 107-56) amends 18 U.S.C. Chapter 10 and provides criminal penalties for possession of any biological agent, toxin, or delivery system of a type or in a quantity that is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose. The Act also establishes restrictions on access to specified materials. "Restricted persons," as defined by the Act, may not possess, ship, transport, or receive any biological agent or toxin that is listed as a select agent.

P. Salary Cap

None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. See current salary cap levels at the following URL: http://grants.nih.gov/grants/policy/salcap_summary.htm.

Q. Debarment and Suspension

The Awardee is responsible for ensuring that no individuals or entities participating on this award are presently debarred, suspended or otherwise excluded from participating in or receiving Federal funds.

R. Other Support Restrictions

Commitment overlap occurs when any project-supported personnel (including support staff and key personnel) has time commitments exceeding 100 percent, regardless of how the effort/salary is being supported or funded. Therefore, no individual may reflect over 100 percent in the total effort he/she spends on research and other institutional responsibilities. An investigator may be affiliated with a number of organizations; however, the combination of appointments cannot exceed 100 percent. (Reporting zero percent of effort is not acceptable). Effort reporting is not required under other transaction awards therefore the award institution is responsible for ensuring no individual supported by this award exceeds 100 percent committed effort.

S. Key Personnel

In addition to the PI(s), the following individuals are named as key personnel:

- TBD based on awardee

Written prior approval is required if any of the individuals named above withdraws from the project entirely, is absent from the project during any continuous period, or significantly reduces time devoted to the project.

T. FedRAMP, Cloud Security, Operations, and Compliance Direct Costs

All FedRAMP, cloud security, operations, and compliance direct cost expenditures disbursed under this award, must directly support the scope of work as defined in Attachment A of this

Agreement. Any direct cost expenditures, related to these costs, cannot be used to benefit, or support any other projects, awards, or related work.

U. Programmatic, Meeting, and Financial Reporting Requirements

This award will be subject to the reporting requirements as defined in Attachment 3 of this Agreement.

V. Rehabilitation Act of 1973

The Awardee will ensure compliance with Section 508 of the Rehabilitation Act of 1973, codified at section 29 USC 794d, as amended, ensures those with disabilities have equal access to government information as contained on information and communications technology (ICT), and thereby to the government employment, programs and services to which all citizens are entitled.

W. Federal Information Security Management Act (FISMA)

The Awardee will comply with the regulations pursuant to the Federal Information Security Management Act (FISMA), 44 U.S.C. 3541 et seq.

The Awardee's information systems, electronic or hard copy, which contain Federal Data need to be protected from unauthorized access consistent with the Federal Information Security Management at the moderate level.

ORDER OF PRECEDENCE

In the event of any inconsistency between the terms of this Agreement and language set forth in the Attachments, the inconsistency shall be resolved by giving precedence in the following order: (1) The Agreement, and (2) all Attachments to the Agreement.

EXECUTION

This Agreement constitutes the entire agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This Agreement may be revised only by written consent of the Awardee and the NIH AO. This Agreement, or modifications thereto, may be executed in counterparts each of which shall be deemed as original, but all of which taken together shall constitute one and the same instrument.

ATTACHMENT 1 SCOPE OF WORK

Scope of Work will be defined by the parameters identified below. The awardee is expected to work with other components of the HEAL R-DEC and Data Ecosystem, HEAL investigators, and the HEAL program office. The amongst R-DEC awardees is especially critical for the successful progression of the SOW. The requirements are subject to change and are expected to evolve with the needs of the HEAL Program.

TBD

ATTACHMENT 2: MILESTONES AND DELIVERABLES

TBD

ATTACHMENT 3: PROGRAMMATIC, FINANCIAL REPORTING AND MEETINGS

All financial, programmatic, and/or other official reports, will be submitted by the Awardee Business Official to the Agreements Officer, Agreements Specialist, Scientific Program Director, and the Scientific Program Lead. Submissions by the Principal Investigator, scientific team, or other non-official team members will be considered unofficial.

A. Programmatic Reporting

This report shall include a brief description of the activities during the reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month. This report is due within 10 calendar days following each reporting period.

The Monthly Progress Report shall include the following information:

- The status of activities in the project plan for the period and milestones completed.
- Meetings held with the stakeholders.
- Project challenges and risks/issues.
- When applicable, recommendations developed through activities not specified in milestones (e.g., through engagements with other HEAL awardees)

When applicable, updates to previously submitted deliverables. Updated deliverables shall be submitted with Monthly Progress Report under a separate cover.

B. Financial Reporting

By the twenty-fifth of each month, the Awardee will report the cumulative amount of total funds spent and the remaining unobligated balance amount. For reporting purposes, the unobligated balance is defined as the amount of funds authorized under this award that the Awardee has not obligated.

1. The unobligated balance amount is computed by subtracting the cumulative amount of the Awardee's unliquidated obligations and expenditures of funds under this award from the cumulative amount of the funds that the have been released for use. For the purposes of this Award, do not include any funds that remain restricted.

The Awardee will categorize the monthly spending report that breaks the total amount of funds spent down by the following tasks below:

1. TBD based on SOW

C. Meeting Schedule

1. OT Initiation Meeting

- a. Within ten (10) days after the effective date of the award, the Principal Investigator(s) (PI) and relevant contractor and sub-contractor staff shall attend an OT Initiation Virtual Meeting with the Program staff and OT Officers.

2. Monthly Meeting

- a. The PI(s) and relevant functional team members will report monthly to the Program and OT staff. The purpose of the meeting shall be to review the submitted monthly progress report, demonstrate prototypes, share other accomplishments as well as discuss hurdles related to the objectives and issues/challenges/risks relevant to scientific and financial administration of the program and related activities reported.
- b. The meeting will be scheduled in coordination with the program and OT staff and agenda circulated to attendees no less than two (2) calendar days in advance. Within seven (7) calendar days following the meeting, meeting minutes and action items shall be prepared by the awardee and circulated to all participants.

3. Annual Meeting

The relevant PI(s) and team members shall attend the Annual HEAL Program Meeting. The objective of the attendance is to engage with the HEAL investigators to share progress, updates, identify potential areas for further partnerships, and showcase successful trans-program collaborative projects that have leveraged and benefited from provided resources/services, and gather input to provide better service as well as review/discuss management of the OT with program staff.

ATTACHMENT 4 STATEMENT OF BUDGETARY PROJECTIONS

The Awardee is authorized to expend funds up to the amounts reflected in the "Funds Authorized" section. It is the responsibility of the Awardee to manage within this level of obligated resources consistent with the overall goals of the HEAL data coordination and research platform (Data Corp, which includes the HEAL Data Ecosystem and R-DEC) and the Statement of Work and the Milestones.

FUNDING ACTION	DATE	FUNDS AWARDED	FUNDS AUTHORIZED	FUNDS RESTRICTED	PERIOD OF PERFORMANCE	AUTHORIZATION DESCRIPTION
Year 1 Awarded						

POSSIBLE OUTYEAR FUNDING

	POSSIBLE FUNDING AMOUNT	PERIOD OF PERFORMANCE
OPTION YEAR 1		
OPTION YEAR 2		
OPTION YEAR 3		
OPTION YEAR 4		

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