



**Heluna Health**  
EMPOWERING POPULATION  
HEALTH INITIATIVES SINCE 1969

13300 Crossroads Parkway North, Suite 450 | City of Industry, CA | 91746  
Phone: 800.201.7320 | Fax: 562.205.2453 | [www.helunahealth.org](http://www.helunahealth.org)

## [SUBCONTRACT/SUBAWARD] AGREEMENT BETWEEN

**HELUNA HEALTH**

**AND**

**THE CITY AND COUNTY OF SAN FRANCISCO**

This [Subcontract/Sub-Award] Agreement (this "Agreement") is made and entered into as of April 1, 2020 by and between PUBLIC HEALTH FOUNDATION ENTERPRISES, INC., DBA Heluna Health, a 501(c)(3) California nonprofit corporation (hereinafter referred to as "HELUNA HEALTH"), and the party identified in Section 1 below (hereinafter be referred to as "Subcontractor/Subawardee").

### RECITALS

- A. HELUNA HEALTH has been granted an award by National Institutes of Mental Health (the "Funding Agency"), under contract number 1R01MH119956-02; Catalog of Federal Domestic Assistance (CFDA) number 93.242 under which HELUNA HEALTH and its subcontractors and subawardees will collaborate on the program.
- B. Subcontractor/Subawardee has expertise in the necessary area(s) which their expertise can assist HELUNA HEALTH to perform its obligations under the Funding Award Agreement; and
- C. HELUNA HEALTH desires to engage the services of Subcontractor/Subawardee to assist HELUNA HEALTH in the performance of certain of its obligations under the Funding Award Agreement as set forth herein.

### AGREEMENT

#### 1. IDENTITIES OF PARTIES.

##### SUBCONTRACTOR/SUBAWARDEE:

**Legal Name of Subcontractor/Subawardee:** City and County of San Francisco

**DBA of Subcontractor/Subawardee:** SFDPH

**Type of Entity:** ☐ Sole Proprietorship; ☐ Partnership; ☐ Corporation;

☐ Limited Liability Company; ☒ Government Institution

**State of Organization (if an entity):** California

**Address:** 101 Grove Street, Room 402

**City/State/Zip:** San Francisco, CA 94102

**Business Telephone:** (415) 554-2778

Social Security or Employer Identification Number: 94-60000417

License Number and Expiration Date, if any: N/A

Email Address: Sajid.shaikh@sfdph.org

Name of Principal Investigator/Project Coordinator: Susan Buchbinder

Phone Number of Principal Investigator/Project Coordinator: (415) 437-7479

Is Subcontractor/Subawardee required to file a Single Audit with the Federal Government? (Required for parties who receive Federal funds in the aggregate amount of \$500,000 or more):

☒ Yes ☐ No

If yes, has Subcontractor/Subawardee filed the required Single Audit? ☒ Yes ☐ No  
(If yes, submit copy to HELUNA HEALTH prior to signing this Agreement)

HELUNA HEALTH:

Heluna Health

Address and Phone #: 13300 Crossroads Parkway North, Suite 450, City of Industry, CA, 91746-3505; (562) 699-7320

Program Name: PrEP-3D

Program/CID #: 0597.0102

Project Director Name: Susan Buchbinder

Project Director Phone #: (415) 437-7479

Project Director Email Address: Susan.buchbinder@sfdph.org

Contracts Manager Name: Adam Abate

Contracts Manager Email Address: AAbate@helunahealth.org

## 2. SCOPE OF SERVICES

(a) Services. Subcontractor/Subawardee shall perform the services, duties and obligations set forth in the Statement of Work ("SOW") attached as Exhibit A hereto, which is made a part hereof and incorporated herein by reference (the "Services"). The Services relate to Section Exhibit C of the Funding Award Agreement. Subcontractor/Subawardee shall perform the Services in accordance with the specifications, timetables and requirements set forth in the SOW and this Agreement. HELUNA HEALTH may, in its discretion, provide to Subcontractor/Subawardee a copy of the Funding Award Agreement or the relevant sections thereof. If Subcontractor/Subawardee is provided with a copy of the Funding Award Agreement or the relevant sections thereof, Subcontractor/Subawardee shall carefully review them and shall perform the Services in accordance with the specifications, timetables and requirements set forth therein.

(b) Location(s) of Services. Subcontractor/Subawardee shall perform the Services at the following location(s):



25 Van Ness, Suite 100  
San Francisco, CA 94102

(c) Subcontractor/Subawardee Principal Investigator/Project Coordinator. Subcontractor/Subawardee shall appoint the Principal Investigator/Project Coordinator (the "PI") identified above to be primary point of contact with HELUNA HEALTH and the Funding Agency with respect to the Services and to have primary responsibility within Subcontractor's/Subawardee's organization for the performance of the (technical or programmatic) aspects of the Services. Subcontractor/Subawardee shall not replace or reassign the PI without HELUNA HEALTH's and the Funding Agency's prior written approval.

(d) HELUNA HEALTH Project Director. The HELUNA HEALTH Project Director identified above shall be primarily responsible on behalf of HELUNA HEALTH for the overall direction of the Services, including review and approval of Subcontractor's/Subawardee's performance of the Services. HELUNA HEALTH will notify Subcontractor/Subawardee if HELUNA HEALTH replaces or reassigns such Project Director.

(e) Performance Reporting. If requested by HELUNA HEALTH or the Funding Agency, Subcontractor/Subawardee shall submit a final technical or performance report, annual performance report, and quarterly performance reports. The final report shall be due 30 days after expiration or termination of this Agreement; annual reports and quarterly reports shall be due 30 days after the reporting period. Subcontractor/Subawardee shall also provide any other reports as may be requested by HELUNA HEALTH. Performance reports shall include a comparison of actual accomplishments with goals and objectives established for the period, findings of the PI, or both, as requested by HELUNA HEALTH. Where possible, quantitative output data should be related to cost data for computation of unit costs. Other pertinent information will include, when appropriate, the reasons why established goals were not met and an analysis. Subcontractor/Subawardee shall immediately notify HELUNA HEALTH of developments that have a significant impact on the performance of the Services hereunder and of any problems, delays, or adverse conditions that materially impair its ability to meet the objectives of the Services, including providing a statement of the action taken or contemplated and any assistance needed to resolve the situation.

### **3. COMPLIANCE WITH FUNDINGAWARD AGREEMENT AND LAWS AND REGULATIONS; FLOW DOWN PROVISIONS**

(a) Compliance with Funding Contract. Subcontractor/Subawardee shall comply with, and shall ensure that all of its personnel and lower-tier subcontractors comply with, all of the rules, requirements and restrictions set forth in the Funding Award Agreement that are applicable to Subcontractor/Subawardee and Subcontractor's/Subawardee's activities.

(b) Flow Down Provisions. Without limiting the generality of Section 3(a) above, Subcontractor/Subawardee shall comply with, and shall ensure that all of its personnel and lower-tier subcontractors comply with, all of the flow-down provisions of the Funding Award

Agreement applicable to Subcontractor/Subawardee set forth in Exhibit C attached hereto or otherwise made available to Subcontractor/Subawardee (including through links to website pages), which are made a part hereof and incorporated herein by reference (the "Flow Down Provisions"). Subcontractor/Subawardee represents and warrants that it has carefully reviewed all of the Flow Down Provisions and is able to comply with all of the Flow Down Provisions. In the event that the requirements set forth in the Flow Down Provisions are greater than the requirements set forth in this Agreement, or in the event of any conflict between the provisions of this Agreement and the Flow Down Provisions, the Flow Down Provisions shall control and Subcontractor/Subawardee shall comply with the requirements set forth in the Flow Down Provisions in accordance with Section 2(a).

(c) Laws and Regulations. Subcontractor/Subawardee shall also comply with all state and federal statutes and regulations applicable to Subcontractor/Subawardee, the Services or the Funding Award Agreement, in performing its obligations under this Agreement. Without limiting the generality of the foregoing, Subcontractor shall:

(i) unless exempt, comply with the requirements under 45 CFR Part 74, and the Public Health Service Grants Policy Statement;

(ii) unless exempt, comply with Executive Order 11246 entitled "Equal Employment Opportunity" as amended by Executive Order 11375 and as supplemental in Dept. of Labor regulations (41 CFR Part 60);

(iii) comply with (and not violate) all statutes, laws, rules and regulations relating to non-discrimination against any employees or applicants for employment, including, without limitation, Title VII of the Civil Rights Act of 1964, The Americans with Disabilities Act Amendments Act of 2008, and the California Fair Employment and Housing Act (if Subcontractor/Subawardee is located within California), and shall take affirmative action to ensure that all employment related decisions are made in conformance with all such statutes, laws, rules and regulations; and

(iv) unless it is exempt from doing so, comply with 45 CFR Part 76, Appendix B-Certification Regarding Debarment, Suspension, and Ineligibility, Voluntary Exclusion-Lower Tier Covered Transactions.

(d) HIPAA Business Associate Agreement. If the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA") is applicable to the Services, Subcontractor/Subawardee shall execute and deliver HELUNA HEALTH's standard Business Associate Agreement as required by HIPAA.

(e) Lower-tier Subcontractors/Subawardees. Subcontractor/Subawardee shall incorporate all of the terms and conditions of this Agreement into all lower-tier subcontracts that Subcontractor/Subawardee may enter into in connection with this Agreement, and shall ensure that all such lower-tier subcontractors/subawardees and their personnel comply with all



of the requirements of this Agreement applicable to Subcontractor/Subawardee, and all of the rules, requirements and restrictions set forth in the Funding Award Agreement, including the Flow Down Provisions, that are applicable to such lower-tier subcontractors'/subawardees' activities.

#### **4. PAYMENT FOR SERVICES**

(a) Budget. The total compensation and reimbursements payable to Subcontractor/Subawardee hereunder shall be as set forth in the detailed budget for the Services attached hereto as Exhibit B (the "Budget"), which is made a part hereof and incorporated herein by reference, which Budget is as set forth in the Funding Award Agreement. The maximum amount payable to Subcontractor/Subawardee hereunder shall not exceed the maximum amount set forth in the Budget.

(b) Must Stay Within Budget Time Periods. Subcontractor/Subawardee shall be compensated only for Services actually performed by Subcontractor/Subawardee and within the appropriate time period set forth in the Budget.

(c) Approval of Services by HELUNA HEALTH. All Services must be completed to the satisfaction of HELUNA HEALTH in order to be entitled to payment hereunder.

(d) Funds Available to HELUNA HEALTH. HELUNA HEALTH shall not be obligated to make payment under this Agreement unless the corresponding funds are disbursed to HELUNA HEALTH under the Funding Award Agreement. In the event that HELUNA HEALTH has made payment to Subcontractor/Subawardee under this Agreement and HELUNA HEALTH subsequently does not receive from the Funding Agency for any reason the corresponding payment for the Services performed by Subcontractor/Subawardee or expenses incurred by Subcontractor/Subawardee, then Subcontractor/Subawardee shall refund such payment to HELUNA HEALTH within ten (10) days after written notice from HELUNA HEALTH.

(e) Billing of Expenses and Costs. All expenses and costs shall be billed in accordance with the approved budget. Expenses incurred after the expiration or termination of this Agreement shall be disallowed. Subcontractor/Subawardee shall submit its final invoice no later than 30 days after the date of expiration of the term or termination of this Agreement.

(f) Budget Modifications. The Budget may be modified only by written agreement of HELUNA HEALTH and Subcontractor/Subawardee and the prior written approval of the Funding Agency.

#### **5. INVOICING PROCEDURES**

(a) Approval by Funding Agency. If required under the Funding Award Agreement, Subcontractor/Subawardee must first submit all timesheets and invoices to the Funding Agency for approval by the Funding Agency. After the Funding Agency has approved a timesheet and

invoice submitted by Subcontractor/Subawardee, Subcontractor/Subawardee shall submit the same to HELUNA HEALTH.

(b) Address for Invoices. Subcontractor/Subawardee shall send all timesheets and invoices to the attention of the HELUNA HEALTH Project Director at the address set forth in Section 1 above.

(c) Invoicing Period. All invoices shall be submitted not more frequently than monthly, in arrears and must be submitted to HELUNA HEALTH within 30 days after the end of the applicable month or within 15 days after approval by the Funding Agency (if applicable), whichever is later. All final invoices must be received within 30 days of the expiration or termination of this Agreement or within such earlier time period as HELUNA HEALTH may require. If any invoices are not submitted within such time periods, Subcontractor/Subawardee waives (in HELUNA HEALTH's discretion) all rights to payment under such invoices.

(d) Formatting and Requirements of Invoices. All invoices shall be submitted in the form attached hereto as Exhibit D, as it may be modified by HELUNA HEALTH from time to time.

## **6. TERM AND TERMINATION**

(a) Term. Unless earlier terminated as provided herein, the term of this Agreement shall be from April 1, 2020 to March 31, 2021 (the "Term").

(b) Termination Without Cause. Without cause, HELUNA HEALTH may terminate this Agreement by giving 30 days prior written notice to Subcontractor/Subawardee of its intent to terminate this Agreement without cause.

(c) Termination for Cause. With reasonable cause, either party may terminate this Agreement effective immediately upon the giving of written notice of termination for cause. Reasonable cause shall include:

- i. A material violation or breach of this Agreement by the other party which is not cured within 15 days after written notice from the terminating party;
- ii. Any act of the other party that exposes the terminating party to liability to others for personal injury or property damage or any other harm, damage or injury; or
- iii. If either party receives notice from the Funding Agency of the cancellation or termination of, or reduction of funding under, the Funding Award Agreement affecting the Services.



(d) Termination for Lack of Funding. HELUNA HEALTH may terminate this Agreement if for any reason the funding available under the Funding Award Agreement is withdrawn, limited, or impaired.

(e) Cessation Upon Termination. On the effective date of termination, Subcontractor/Subawardee shall cease all further Services under this Agreement, and Subcontractor/Subawardee shall cancel as many outstanding obligations as possible and not incur any additional obligations.

(f) Payment After Termination. Subject to the terms and conditions set forth in this Agreement, upon termination of this Agreement, provided, that HELUNA HEALTH has received the corresponding funds from the Funding Agency under the Funding Award Agreement, HELUNA HEALTH shall pay for any reasonable non-cancellable obligations properly incurred by Subcontractor/Subawardee under this Agreement and in accordance with the Budget prior to termination, and shall pay any amounts due to Subcontractor/Subawardee and properly invoiced under this Agreement for Services performed prior to termination; provided, that if HELUNA HEALTH has terminated this Agreement for reasonable cause under Section 6(c) above, then HELUNA HEALTH shall have the right to offset and deduct from any payments due to Subcontractor/Subawardee hereunder any damages or losses incurred by HELUNA HEALTH as a result of such violation or breach.

(g) Return of Materials. Upon the expiration or termination of this Agreement, Subcontractor/Subawardee shall immediately promptly return to HELUNA HEALTH all computers, cell phones, smart phones, computer programs, files, documentation, user data, media, related material and any and all other Confidential Information (as defined in below) of HELUNA HEALTH and all Work Product (as defined below). HELUNA HEALTH shall have the right to withhold final payment to Subcontractor/Subawardee until all such items are returned to HELUNA HEALTH.

(h) Surviving Provisions. The provisions of Sections 7 through 16, and any other sections that by their nature should or are intended to survive the expiration or termination of this Agreement shall survive and the parties shall continue to comply with the provisions of this Agreement that survive.

**7. REPRESENTATIONS AND WARRANTIES.** Subcontractor/Subawardee represents, warrants and covenants to HELUNA HEALTH as follows:

(a) Licenses and Permits. Subcontractor/Subawardee maintains and shall maintain during all relevant times under this Agreement all applicable federal, state and local business and other licenses, including any professional licenses or certificates, industrial permits and/or licenses, industry specific licenses, licenses required by the state(s) and/or locality(s) in which it does business, fictitious business names, federal tax identification numbers, insurance, and anything else required of Subcontractor/Subawardee as a business operator.

(b) Qualifications and Performance. Subcontractor/Subawardee (i) has the experience and skill to perform the Services hereunder, (ii) shall perform the Services in a good and workman like manner and in accordance with generally accepted professional standards and in an expeditious and economical manner consistent with sound professional practices, and (iii) is adequately financed to meet any financial obligation it may be required to incur hereunder.

(c) Not Debarred. Neither Subcontractor/Subawardee nor its principals or personnel are presently, nor will any of them be during the term of this Agreement, debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or funding agency.

## **8. INDEPENDENT CONTRACTOR STATUS**

(a) Independent Contractor. Nothing in this Agreement is intended to place the parties in the relationship of employer-employee, partners, joint venturers, or in anything other than an independent contractor relationship. It is the parties' intention that Subcontractor/Subawardee shall be an independent contractor and not HELUNA HEALTH's employee or agent, and in conformity therewith, that Subcontractor/Subawardee shall retain sole and absolute discretion and judgment in the manner and means of carrying out Subcontractor/Subawardee's Services hereunder. Subcontractor/Subawardee is under the control of HELUNA HEALTH as to the results of Subcontractor/Subawardee's Services only, and not as to the means by which such results are accomplished.

(b) No Power to Bind HELUNA HEALTH. Without limiting the generality of the foregoing paragraph, this Agreement does not designate Subcontractor/Subawardee as the agent or legal representative of HELUNA HEALTH for any purpose whatsoever. Subcontractor/Subawardee is not granted any right or authority to assume or create any obligation or responsibility, or to make any promise or commitment regarding any work, on behalf of or in the name of HELUNA HEALTH or to bind it in any manner, or to make any contract or agreement on behalf of or in the name of HELUNA HEALTH, without the prior written consent from HELUNA HEALTH management. No sales, invoices nor orders for goods or services shall be valid and binding upon HELUNA HEALTH (whether as the provider or the recipient) unless and until accepted by HELUNA HEALTH, at its sole and absolute discretion, through its established channels. HELUNA HEALTH shall not be liable for any obligation incurred by Subcontractor/Subawardee.

(c) No Withholding. Except for tax withholdings that are required by law, neither federal, nor state, nor local income tax nor payroll taxes of any kind shall be withheld or paid by HELUNA HEALTH on behalf of Subcontractor/Subawardee or the employees of Subcontractor/Subawardee. Subcontractor/Subawardee and its personnel shall not be treated as employees of HELUNA HEALTH with respect to the Services performed hereunder for federal or state tax purposes or for any other purposes.



(d) No Employee Benefits. Neither Subcontractor/Subawardee nor its personnel shall be eligible for, and shall not participate in, any of HELUNA HEALTH's retirement, health, or other fringe benefit plans.

(e) Workers' Compensation. No workers' compensation insurance shall be obtained by HELUNA HEALTH concerning Subcontractor/Subawardee or Subcontractor's/Subawardee's personnel. Subcontractor/Subawardee shall comply with all workers' compensation laws concerning Subcontractor/Subawardee and its personnel.

(f) Taxes. Subcontractor/Subawardee understands that Subcontractor/Subawardee is responsible to pay, according to law, Subcontractor's/Subawardee's income taxes. If Subcontractor/Subawardee is not an entity, Subcontractor/Subawardee further understands that Subcontractor/Subawardee may be liable for self-employment (social security) tax, to be paid by Subcontractor/Subawardee according to law. Subcontractor/Subawardee shall be solely responsible for the payment of all federal, state and local income taxes, social security taxes, federal and state unemployment insurance and similar taxes and all other assessments, taxes, contributions or sums payable with respect to Subcontractor/Subawardee or its employees as a result of or in connection with the Services performed by Subcontractor/Subawardee hereunder. Subcontractor/Subawardee represents and warrants and covenants that it shall report all income earned as a result of this Agreement and pay all federal, state and local income and self-employment taxes and other assessments required to be paid under applicable law. Subcontractor/Subawardee agrees to defend, indemnify and hold HELUNA HEALTH harmless from any and all claims made by federal, state and local taxing authorities on account of Subcontractor's/Subawardee's failure to pay any such federal, state or local income and self-employment taxes or other assessments due as a result of Subcontractor's/Subawardee's Services hereunder.

(g) Sub-Tier Subcontractors/Subawardees. Subcontractor/Subawardee shall have control over the manner and means of Subcontractor/Subawardee's performance under this Agreement. However, HELUNA HEALTH is engaging Subcontractor/Subawardee for Subcontractor's/Subawardee's unique skills, knowledge, abilities and other attributes. Accordingly, Subcontractors/Subawardees may not use any lower-tier subcontractors/subawardees in the performance of its services hereunder without HELUNA HEALTH's prior written approval. Any lower-tier subcontractors/subawardees who are approved by HELUNA HEALTH must execute all agreements and documents required by HELUNA HEALTH prior to performing any work. Subcontractor/Subawardee shall ensure that all lower-tier subcontractors/subawardees comply with all of the terms and provisions of this Agreement and shall be responsible and liable for all acts and omissions of all lower-tier subcontractors/subawardees as if they were the acts or omissions of Subcontractor/Subawardee.



## 9. ASSIGNMENT OF WORK PRODUCT

(a) Ownership of Work Product. Subcontractor/Subawardee agrees that, as between HELUNA HEALTH and Subcontractor/Subawardee, all discoveries, ideas, inventions, and information that Subcontractor/Subawardee may develop (either alone or in conjunction with others), information or work product developed wholly or partially by Subcontractor/Subawardee as part of or related to Subcontractor's/subawardee's retention by HELUNA HEALTH hereunder (including all intermediate and partial versions thereof) or the performance of the services hereunder or which existence Subcontractor/Subawardee may discover while retained by HELUNA HEALTH, including any software, platforms, all ideas, designs, marks, logos, and content relating thereto, whether or not subject to patent, copyright or trademark or other intellectual property protections including without limitation, any scripts, prototypes, other components (collectively the "Work Product"), shall be the sole property of HELUNA HEALTH upon its creation and (in the case of copyrightable works) upon its fixation in a tangible medium of expression.

(b) Assignment. Subcontractor/Subawardee hereby forever assigns to HELUNA HEALTH all right, title and interest in any Work Product designed and/or developed by Subcontractor/Subawardee or otherwise delivered to HELUNA HEALTH as part of or related to Subcontractor's/Subawardee's retention with HELUNA HEALTH. The Work Product shall be the sole property of HELUNA HEALTH, and all copyrightable and patentable aspects of the Work Product are to be considered "works made for hire" within the meaning of the Copyright Act of 1976, as amended (the "Act"), of which HELUNA HEALTH is to be the "author" within the meaning of such Act. All such copyrightable and patentable works, as well as all copies of such works in whatever medium fixed or embodied, shall be owned exclusively by HELUNA HEALTH on their creation, and Subcontractor/Subawardee hereby expressly disclaims any interest in any of them. In the event (and to the extent) that any Work Product or any part or element of them, is found as a matter of law not to be a "Work Made For Hire" within the meaning of the Act, Subcontractor/Subawardee hereby assigns to HELUNA HEALTH the sole and exclusive right, title and interest in and to all such works, and all copies of any of them, without further consideration, and, if such assignment is invalid, Subcontractor/Subawardee hereby grants HELUNA HEALTH a non-exclusive, worldwide, perpetual, fully paid-up, irrevocable, right and license to use, reproduce, make, sell, perform and display (publicly or otherwise), and distribute, and modify and otherwise make derivative works of Subcontractor/Subawardee's Work Product and to authorize third parties to perform any or all of the foregoing, including through multiple tiers of sublicenses.

(c) Moral Rights Waiver. For purposes of this subsection, "Moral Rights" means any rights of paternity or integrity, any right to claim authorship of the Work Product, to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, the Work Product, whether or not such would be prejudicial to Subcontractor's/Subawardee's honor or reputation, and any similar right, existing under judicial or statutory law of any country in the world, or under any treaty, regardless whether or not such right is denominated or generally referred to as a "Moral" right. Subcontractor/Subawardee hereby irrevocably



transfers and assigns to HELUNA HEALTH any and all Moral Rights that Subcontractor/Subawardee may have in the Work Product. Subcontractor/Subawardee also hereby forever waives and agrees never to assert any and all Moral Rights it may have in the Work Product, even after termination of Subcontractor's/Subawardee's work on behalf of HELUNA HEALTH as part of or related to Subcontractor's/Subawardee's retention with HELUNA HEALTH.

(d) No Liens. Subcontractor/Subawardee shall deliver all Work Product to HELUNA HEALTH free and clear of any and all claims, rights and encumbrances of third parties.

(e) Assignment Documents. Subcontractor/Subawardee will cooperate with HELUNA HEALTH, with HELUNA HEALTH's approval and at HELUNA HEALTH's expense, in obtaining patent, copyright, trademark or other statutory protections for the Work Product in each country in which one or more is sold, distributed or licensed, and in taking any enforcement action, including any public or private prosecution, to protect HELUNA HEALTH's intellectual property rights in or to the Work Product. Subcontractor/Subawardee hereby grants HELUNA HEALTH the exclusive right, and appoints HELUNA HEALTH as attorney-in-fact, to execute and prosecute in Subcontractor's/Subawardee's name as author or inventor or in HELUNA HEALTH's name as assignee, any application for registration or recordation of any copyright, trademark, patent or other right in or to the Work Product, and to undertake any enforcement action with respect to any Work Product. With HELUNA HEALTH's approval and at HELUNA HEALTH's expense, Subcontractor/Subawardee will execute such other documents of registration and recordation as may be necessary to perfect in HELUNA HEALTH, or protect, the rights assigned to HELUNA HEALTH hereunder in each country in which HELUNA HEALTH reasonably determines to be prudent.

(f) No Infringement. Subcontractor/Subawardee represents and warrants that any Work Product delivered to HELUNA HEALTH hereunder will be developed by Subcontractor/Subawardee and shall not infringe or violate any patents, copyrights, trademarks, trade secrets or other proprietary rights of any third party.

(g) No Harmful Code. With respect to the website and any computer programs or software code ("Software") included in the Services hereunder, Subcontractor/Subawardee represents and warrants that: (i) the Software and its media shall contain no computer instructions or inappropriate functions whose purpose or result is to disrupt, damage or interfere with HELUNA HEALTH's or its affiliates' or their customers' use of or access to the Software or any of their data, programs or computer or telecommunications facilities and (ii) unless expressly authorized in writing by HELUNA HEALTH, such Software shall not contain any mechanism which electronically notifies Subcontractor/Subawardee of any fact or event, nor contain any key, node lock, time-out, logic bomb or other function, implemented by any means, which may restrict HELUNA HEALTH's or its affiliates' or customers' use of or access to the Software or any other programs, data or equipment.

(h) Rights of Funding Agency and Federal Government. All rights to the Work Product assigned or granted to HELUNA HEALTH hereunder shall be subject to any rights of the Funding Agency under the Funding Award Agreement and any rights of the United States Federal Government under applicable laws and regulations.

## 10. PUBLICATIONS

(a) Right to Publish Works. Subcontractor/Subawardee may, with HELUNA HEALTH's and the Funding Agency's prior written consent, publish articles written by Subcontractor/Subawardee in connection with the Services performed by Subcontractor/Subawardee hereunder. Subcontractor/Subawardee shall submit all such articles for review by HELUNA HEALTH and the Funding Agency at least 60 days prior to the proposed publication date.

(b) Acknowledgment in Publications. On any publication approved by HELUNA HEALTH and the Funding Agency as described above, Subcontractor/Subawardee shall place an acknowledgment of federal government support, and shall include a disclaimer, as appropriate, as follows: "The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of Heluna Health. or **[Name of Funding Agency]**".

(c) Use of HELUNA HEALTH's or Funding Agency's Name. Subcontractor/Subawardee shall not use in any manner HELUNA HEALTH's name, logo or trademarks without HELUNA HEALTH's prior written consent. Subcontractor/Subawardee shall not use in any manner the Funding Agency's name, logo or trademarks without the Funding Agency's prior written consent.

## 11. INDEMNIFICATION

(a) By Subcontractor/Subawardee. Subcontractor/Subawardee hereby agrees to indemnify, hold harmless and defend HELUNA HEALTH, its board of trustees, officers, directors, agents, contractors and employees from any and all claims, causes of action, costs, demands, expenses (including attorney's fees and costs), losses, damages, injuries, and liabilities arising from (i) any accident, death, or injury whatsoever or however caused to any person or property arising out of the intentional action or negligence of Subcontractor/Subawardee (or its agents, subcontractors or employees), (ii) Subcontractor's/Subawardee's (or its agents', subcontractors' or employees') violation of any federal, state or local law or regulation, (iii) the breach by Subcontractor/Subawardee (or its agents, subcontractors or employees) of any its representations, warranties or agreements under this Agreement or (iv) any claims that the Work Product, or any element thereof, infringes the intellectual, privacy or other rights of any party.

(b) By HELUNA HEALTH. HELUNA HEALTH hereby agrees to indemnify, hold harmless and defend Subcontractor/Subawardee, its officers, directors, agents, contractors and employees from any and all claims, causes of action, costs, demands, expenses (including



attorney's fees and costs), losses, damages, injuries, and liabilities arising from (i) any accident, death, or injury whatsoever or however caused to any person or property arising out of the intentional action or negligence of HELUNA HEALTH, (ii) HELUNA HEALTH's violation of any federal, state or local law or regulation or (iii) the breach by HELUNA HEALTH of any its representations, warranties or agreements under this Agreement.

## **12. INSURANCE**

(a) Required Coverages. Subcontractor/Subawardee shall, unless otherwise agreed in writing by HELUNA HEALTH, maintain: (i) Workers' Compensation insurance, (ii) Professional Liability Insurance and Commercial General Liability Insurance (including broad form contractual and automobile liability coverage), with minimum limits of ONE MILLION DOLLARS (\$1,000,000) combined single limit per occurrence, and (iii) Automobile Liability on each automobile owned by him/her/it or his/her/its agents, subcontractors/subawardees or employees, which is used at any time to carry out Subcontractor's/Subawardee's duties hereunder, with minimum limits of \$100,000 per person and \$300,000 per occurrence for bodily injury. If higher or additional coverages are required under the Flow Down Provisions, Subcontractor/Subawardee shall procure such coverages.

(b) Additional Insureds. All such insurance shall provide that Subcontractor's/Subawardee's insurance is primary and not contributory, shall protect Subcontractor/Subawardee, HELUNA HEALTH and the Funding Agency and their affiliates from claims for personal injury (including bodily injury and death) and property damage which may arise from or in connection with the performance of the Services hereunder, or from or out of any negligent act or omission of Subcontractor/Subawardee, its officers, directors, agents or employees. All such insurance shall be written by a responsible insurance company possessing B+ VII rating or better as listed in the Best Guide, shall name HELUNA HEALTH and the Funding Agency as additional insureds for Professional Liability, Commercial General Liability and Automobile Liability only, shall contain a waiver of subrogation with respect to the additional insureds, shall be written on an occurrence basis and shall provide that the coverage thereunder may not be reduced or canceled unless 30 days' prior written notice thereof is furnished to HELUNA HEALTH and the Funding Agency. Certificates of Insurance containing such waiver of subrogation or copies of policies shall be furnished to HELUNA HEALTH upon request.

## **13. CONFIDENTIALITY**

(a) Confidential Information. Subcontractor/Subawardee agrees that during the course of this Agreement, Subcontractor/Subawardee may be exposed to and become aware of certain unique and confidential information and special knowledge (hereinafter "Confidential Information") provided to or developed by HELUNA HEALTH. Said Confidential Information includes, but is not limited to, the identity of actual and potential clients of HELUNA HEALTH, client lists, particular needs of each client, the manner in which business is conducted with each client, addresses, telephone numbers, and specific characteristics of clients; financial information about HELUNA HEALTH and/or its clients; client information reports; mailing labels;



various sales and marketing information; sales report forms; pricing information (such as price lists, quotation guides, previous or outstanding quotations, or billing information); pending projects or proposals; business plans and projections, including new product, facility or expansion plans; employee salaries; contracts and wage information; mailing plans and programs; technical know-how; designs; products ordered; business methods; processes; records; specifications; computer programs; accounting; and information disclosed to HELUNA HEALTH by any third party which HELUNA HEALTH is obligated to treat as confidential and/or proprietary. This Confidential Information derives independent actual or potential economic value from not being generally known to the public or to other persons, who can obtain economic value from its disclosure or use, is not readily available through any source other than HELUNA HEALTH and is the subject of reasonable efforts to maintain secrecy. Since Subcontractor/Subawardee may be exposed to and become aware of said Confidential Information and, because of its unique and confidential nature, the parties hereto desire to afford HELUNA HEALTH protection against its unauthorized use or its use in any manner detrimental to HELUNA HEALTH. Therefore, Subcontractor/Subawardee shall not disclose in any manner whatsoever any of the aforesaid Confidential Information, directly or indirectly, or use it in any way whatsoever, either during this Agreement or at any time thereafter, except as required in the course of Subcontractor's/Subawardee's work with HELUNA HEALTH or except as otherwise provided in this Agreement. Further, Subcontractor/Subawardee shall develop and maintain procedures and take other reasonable steps in furtherance of HELUNA HEALTH's desire to maintain the confidentiality of its Confidential Information.

(b) Funding Agency Confidentiality. Subcontractor/Subawardee shall also comply with all confidentiality obligations imposed by the Funding Agency in the Funding Award Agreement or otherwise.

(c) Return of Documents. All documents and other items which might be deemed the subject of or related to Confidential Information of HELUNA HEALTH's business, whether prepared, conceived, originated, discovered, or developed by Subcontractor/Subawardee, in whole or in part, or otherwise coming into Subcontractor's/Subawardee's possession, shall remain the exclusive property of HELUNA HEALTH and shall not be copied or removed from the premises of HELUNA HEALTH without the express written consent of HELUNA HEALTH. All such items, and any copies thereof, shall be immediately returned to HELUNA HEALTH by Subcontractor/Subawardee upon request at any time and upon termination of this Agreement.

#### **14. NON-SOLICITATION OF EMPLOYEES**

During the Term of this Agreement and for two years following the termination of this Agreement, Subcontractor/Subawardee shall not induce, encourage, or advise any person who is employed by or is engaged as an agent or independent contractor by HELUNA HEALTH to leave the employment or engagement of HELUNA HEALTH or otherwise raid the employees of HELUNA HEALTH. Nothing contained in this paragraph shall constitute a waiver by HELUNA HEALTH of any rights it may have if Subcontractor/Subawardee engages in actionable conduct after the two year period referred to above.



## 15. RECORD RETENTION AND ACCESS TO RECORDS

Subcontractor/Subawardee shall grant to HELUNA HEALTH, the Funding Agency and the U.S. Comptroller General and their respective authorized representatives upon demand, access to any books, documents, papers and records of Subcontractor/Subawardee relating to this Agreement or the Services for audit, examination, excerpt and transcription. Subcontractor/Subawardee shall retain all such records for seven (7) years (or longer if required under HELUNA HEALTH's record retention policy, under the Funding Award Agreement or by law, including under Circular A-110, Subpart C, Post-Award Requirements and FAR Subpart 4.7 Contractor Records Retention - 4.703 Policy) after final payment is made under this Agreement and all pending matters are closed, unless extended by an audit, litigation, or other action involving the records, whichever is later.

## 16. GENERAL TERMS

(a) Amendments. Amendments to this Agreement shall be in writing, signed by the party to be obligated by such amendment and attached to this Agreement.

(b) Governing Law; Venue. This Agreement is entered into in Los Angeles County, California. This Agreement shall be interpreted, construed and governed by, in accordance with and consistent with the laws of the State of California without giving effect to its conflicts of laws principals. Such laws shall apply in all respects, including statutes of limitation, to any disputes or controversies arising out of or pertaining to this Agreement. The sole, exclusive and proper venue for any proceedings brought to interpret or enforce this Agreement or to obtain a declaration of the rights of the parties hereunder shall be Los Angeles County, California. Each of the parties hereto submits to the exclusive personal jurisdiction of the courts located in Los Angeles County, California and waives any defense of forum non conveniens.

(c) Equitable Relief. In light of the irreparable harm to HELUNA HEALTH that a breach by Subcontractor/Subawardee of Sections 9, 10, 13 and 14 of this Agreement would cause, in addition to other remedies set forth in this Agreement and other relief for violations of this Agreement, HELUNA HEALTH shall be entitled to enjoin Subcontractor/Subawardee from any breach or threatened breach of such Sections, to the extent permitted by law and without bond.

(d) Binding Agreement. All terms, conditions and covenants to be observed and performed by the parties hereto shall be applicable to and binding upon their respective agents, employees, heirs, executors, administrators, affiliates, subsidiaries, associates, employees, successors and assigns.

(e) Captions. All captions (section headings) set forth herein are inserted only as a matter of convenience and for reference, and shall not affect the interpretation of this Agreement.

(f) Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which, when taken together, shall constitute one and the same document.

(g) Additional Documents. The parties hereto each agree that they shall execute and, if appropriate, acknowledge any and all additional and other documents, instruments and writings which may be reasonably requested by the other party in order to fully carry out the intent and purpose of this Agreement.

(h) Attorneys' Fees; Costs. In the event that any suit in law or equity, arbitration or other formal proceeding is instituted by any party to enforce or interpret any part of this Agreement, or to recover damages for breach thereof, the prevailing party shall, in addition to any such other relief available to such party, be entitled to recover costs of suit incurred therein, and to also recover as an element of such costs (but not as damages) reasonable attorneys' fees incurred by such prevailing party.

(i) Entire Agreement. This Agreement, and all documents referred to in it, or incorporated in it, is an integrated document containing and expressing all terms, covenants, conditions, warranties and agreements of the parties relating to the subject matter hereof. No other or prior agreements or understandings, written or oral, pertaining to the same shall be valid or of any force or effect.

(j) Facsimile or Email Transmissions. A facsimile transmission or transmission by Email of the executed signature page of this Agreement shall be accepted as, relied upon as, and deemed to be, an original.

(k) Fair Interpretation. The language appearing in all parts of this Agreement shall be construed, in all cases, according to its fair meaning in the English language, and not strictly construed for or against any party hereto. This Agreement has been prepared jointly by the parties hereto after arms length negotiations and any uncertainty or ambiguity contained in this Agreement, if any, shall not be interpreted or construed against any party, but according to its fair meaning applying the applicable rules of interpretation and construction of contracts.

(l) No Waiver. No failure or delay by any party in exercising a right, power or remedy under the Agreement shall operate as a waiver of any such right or other right, power or remedy. No waiver of, or acquiescence in, any breach or default of any one or more of the terms, provisions or conditions contained in this Agreement shall be deemed to imply or constitute a waiver of any other or succeeding or repeated breach or default hereunder. The consent or approval by any party hereto to or of any act of the other party hereto requiring further consent or approval shall not be deemed to waive or render unnecessary any consent or approval to or of any subsequent similar acts.

(m) Notices. Any notice, demand, consent or other communication required or permitted to be given hereunder shall be made in the English language and shall be so given by



personal delivery, by (i) registered or certified (return receipt) or First Class United States Postal Service mail, postage pre-paid, or (ii) recognized overnight national courier service, or (iii) facsimile transmission confirmed by letter sent by First Class United States Postal Service mail, postage pre-paid, or (iv) by email confirmed by letter sent by First Class United States Postal Service mail, postage pre-paid, addressed to the recipient of such notice at the following address or facsimile number, as the case may be, or any other address or facsimile number or email address provided by a party in the manner described hereinabove:

In the case of HELUNA HEALTH, addressed to:

Heluna Health  
13300 Crossroads Parkway North, Suite 450  
City of Industry, CA 91746  
Attention: Adam Abate  
Facsimile: (562) 692-6950  
Email: [Contracts@helunahealth.org](mailto:Contracts@helunahealth.org)

In the case of Subcontractor, addressed to:

San Francisco Department of Public Health  
1380 Howard Street  
San Francisco, CA 94103  
Attention: Sajid Shaikh  
Facsimile: (415) 503-4710  
Email: [Sajid.shaikh@sfdph.org](mailto:Sajid.shaikh@sfdph.org)

Any such notice shall be deemed to have been received by the addressee, and service thereof shall be deemed effective, five (5) days following deposit thereof with the United States Postal Service, or upon actual receipt, whichever first occurs, unless the address for delivery is not within one of the United States or its territories or possessions, in which case service shall be effective seven (7) days following deposit, or upon actual receipt, whichever first occurs.

(n) Remedies Non-Exclusive. Except where otherwise expressly set forth herein, all remedies provided by this Agreement shall be deemed to be cumulative and additional and not in lieu of or exclusive of each other or of any other remedy available to the respective parties at law or in equity.

(o) Severability. If any term, provision, condition or other portion of this Agreement is determined to be invalid, void or unenforceable by a forum of competent jurisdiction, the same shall not affect any other term, provision, condition or other portion hereof, and the remainder of this Agreement shall remain in full force and effect, as if such invalid, void or unenforceable term, provision, condition or other portion of this Agreement did not appear herein.

(p) Limitation of Liability. EXCEPT FOR A BREACH OF SECTIONS 9 AND 13 ABOVE AND EXCEPT TO THE EXTENT INCLUDED IN A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 11 ABOVE, IN NO EVENT SHALL ANY PARTY BE LIABLE TO THE OTHER FOR ANY INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES, WHETHER BASED ON BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHERWISE, AND WHETHER OR NOT THAT PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

(q) Non-Assignability. None of the parties shall assign, transfer, sell, encumber, hypothecate, alienate or otherwise dispose of this Agreement, or any right, title or interest to or in this Agreement, nor shall a party delegate any duty or obligation to be performed hereunder, without the express written consent of the other party having been first obtained, except that any party may assign this Agreement without the consent of the other party in the case of a reorganization, merger, consolidation, or sale of all or substantially all of its assets so long as the assignee expressly assumes all of the obligations of the assignor under this Agreement. Notwithstanding the foregoing, HELUNA HEALTH may assign this Agreement to an affiliate of HELUNA HEALTH without the consent of the other party. Any attempt to assign this Agreement other than as permitted above shall be null and void.

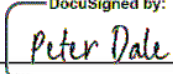
(r) Signing Person. The individuals signing this Agreement on behalf of an entity represents and warrants that he/she has authority to bind such entity to this Agreement.

[Signatures follow on next page]



The undersigned have caused this Subcontract/Subaward Agreement to be executed as of the date first set forth above:

**HELUNA HEALTH**

By:  \_\_\_\_\_  
Peter Dale 0CB6AFEE59C3427...  
Chief Program Officer

**THE CITY AND COUNTY OF SAN FRANCISCO**

Name: Tomas Aragon  
Signature:  \_\_\_\_\_  
0BDB2B95DBC0442...  
Director of PHD  
Print Name, Title [If any entity]

EXHIBIT A  
TO SUBCONTRACT/SUBAWARD AGREEMENT

SCOPE OF WORK (SOW)

**Susan Buchbinder, MD (Principal Investigator):** Dr. Buchbinder is Director of Bridge HIV at the San Francisco Department of Public Health. She provides scientific leadership in the NIH sponsored HIV Vaccine Trials Network and HIV Prevention Trials Network and leads several multi-site HIV prevention efficacy trials, with a focus on advancing integrated prevention strategies in diverse populations of MSM in the US and globally. Most recently, she has focused on the use of mHealth technology to increase access to prevention and treatment services for populations at risk for or living with HIV infection, and implementation of prevention strategies. As Principal Investigator (PI) of this proposal, she will be responsible for the overall scientific vision and implementation of the specific aims of this study. Dr. Buchbinder will have responsibility for maintaining the proposed study schedule, ensuring quality control over all aspects of the study, protecting participant safety, and data analysis, presentation, publication, and dissemination of results. She will lead weekly team meetings and bi-weekly safety meetings for the technical pilot and RCT; she will also serve as the primary liaison with the DSMB for the RCT. Dr. Buchbinder will serve as primary liaison with the NIH and will oversee all budgetary issues for these studies.

**Albert Liu, MD, MPH (Co-Investigator):** **Albert Liu, MD, MPH (Co-Investigator):** Dr. Liu is the Clinical Research Director at Bridge HIV at the San Francisco Department of Public Health and Assistant Clinical Professor of Medicine at UCSF. Dr. Liu has served as the Chief Medical Officer of iPrEx and iPrEx OLE, Protocol Chair of the PrEP Demonstration Project in MSM and the NIMH-sponsored EPIC study to develop PrEP adherence interventions for young MSM of color. Dr. Liu will be responsible for overseeing technology development with Alto Pharmacy, data management for all of the studies, and assisting with scientific design of research protocols. He will maintain frequent contact with Dr. Buchbinder and the other Co-Investigators through in-person meetings, conference calls, e-mail, and drafting and presenting emerging findings of the research. He will also work closely with the research team in data analysis, manuscript preparation, and dissemination of results.



**EXHIBIT B**  
**TO SUBCONTRACT/SUBAWARD AGREEMENT**

**BUDGET**

Program Director/Principal Investigator (Last, First, Middle):						Buchbinder, Susan		<b>SUBCONTRACT</b>	
<b>DETAILED BUDGET FOR INITIAL BUDGET PERIOD</b>						FROM		THROUGH	
<b>DIRECT COSTS ONLY</b>						04/01/20		03/31/21	
List PERSONNEL ( <i>Applicant organization only</i> ) Use Cal, Acad, or Summer to Enter Months Devoted to Project Enter Dollar Amounts Requested ( <i>omit cents</i> ) for Salary Requested and Fringe Benefits									
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST. BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL	
Liu, Albert	PD/PI	1.20			189,600	18,960	6,636	25,596	
Buchbinder, Susan	PD/PI	2.40			189,600	37,920	13,272	51,192	
		0.00				0	0	0	
		0.00				0	0	0	
		0.00				0	0	0	
		0.00				0	0	0	
		0.00				0	0	0	
<b>SUBTOTALS</b> →						56,880	19,908	76,788	
CONSULTANT COSTS		0					0	0	
EQUIPMENT ( <i>Itemize</i> )		0					0	0	
		0					0	0	
SUPPLIES ( <i>Itemize by category</i> )		0					0	0	
		0					0	0	
TRAVEL		0					0	0	
INPATIENT CARE COSTS		0					0	0	
OUTPATIENT CARE COSTS		0					0	0	
ALTERATIONS AND RENOVATIONS ( <i>Itemize by category</i> )		0					0	0	
OTHER EXPENSES ( <i>Itemize by category</i> )		0					0	0	
		0					0	0	
		0					0	0	
		0					0	0	
CONSORTIUM/CONTRACTUAL COSTS					DIRECT COSTS				
					0				
<b>SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD</b> ( <i>Item 7a, Face Page</i> )								<b>\$ 76,788</b>	
					FACILITIES AND ADMINISTRATIVE COSTS				
					19,197				
<b>TOTAL COSTS FOR INITIAL BUDGET PERIOD</b>								<b>\$ 95,985</b>	

EXHIBIT C  
TO SUBCONTRACT/SUBAWARD AGREEMENT  
FLOW DOWN PROVISIONS

Refer to following pages.





RESEARCH  
Department of Health and Human Services  
National Institutes of Health

Notice of Award

Federal Award Date: 03/31/2020



NATIONAL INSTITUTE OF MENTAL HEALTH

**Grant Number:** 5R01MH119956-02  
**FAIN:** R01MH119956

**Principal Investigator(s):**  
Susan Buchbinder, MD

**Project Title:** PrEP-3D: An Integrated Pharmacy Digital Diary and Delivery Strategy to Increase PrEP Use Among MSM

Tehrani, Vida  
PUBLIC HEALTH FOUNDATION ENTERPRISES  
13300 Crossroads Parkway North, Ste. 450  
City of Industry, CA 917463417

**Award e-mailed to:** pdale@phfe.org

**Period Of Performance:**

**Budget Period:** 04/01/2020 – 03/31/2021

**Project Period:** 04/08/2019 – 03/31/2024

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$485,572 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to PUBLIC HEALTH FOUNDATION ENTERPRISES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 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 Mental Health of the National Institutes of Health under Award Number R01MH119956. 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,

Heather Weiss  
Grants Management Officer  
NATIONAL INSTITUTE OF MENTAL HEALTH

Additional information follows



**Award Calculation (U.S. Dollars)**

Salaries and Wages	\$130,728
Fringe Benefits	\$48,198
Personnel Costs (Subtotal)	\$178,926
Consultant Services	\$6,388
Materials & Supplies	\$900
Travel	\$900
Other	\$83,354
Subawards/Consortium/Contractual Costs	\$169,265
Participant Stipends	\$9,450

Federal Direct Costs	\$449,183
Federal F&A Costs	\$36,389
Approved Budget	\$485,572
Total Amount of Federal Funds Obligated (Federal Share)	\$485,572
<b>TOTAL FEDERAL AWARD AMOUNT</b>	<b>\$485,572</b>

**AMOUNT OF THIS ACTION (FEDERAL SHARE)** \$485,572

SUMMARY TOTALS FOR ALL YEARS			
YR	THIS AWARD		CUMULATIVE TOTALS
2		\$485,572	\$485,572
3		\$496,981	\$496,981
4		\$495,258	\$495,258
5		\$471,332	\$471,332

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

**Fiscal Information:**

**CFDA Name:** Mental Health Research Grants  
**CFDA Number:** 93.242  
**EIN:** 1952557063A1  
**Document Number:** RMH119956A  
**PMS Account Type:** P (Subaccount)  
**Fiscal Year:** 2020

IC	CAN	2020	2021	2022	2023
MH	8472592	\$485,572	\$496,981	\$495,258	\$471,332

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

**NIH Administrative Data:**

**PCC:** 9A-ASGA / **OC:** 41025 / **Released:** WEISSHE 03/24/2020

**Award Processed:** 03/31/2020 12:06:15 AM

**SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01MH119956-02**

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 – 5R01MH119956-02**

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

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

- 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).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

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) R01MH119956. 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/](http://grants.nih.gov/ClinicalTrials_fdaaa/)

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



Continued discussion 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 – MH Special Terms and Conditions – 5R01MH119956-02**

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.

**RESTRICTION - HUMAN SUBJECTS FOR AIMS 2 and 3:**

In the absence of certification of IRB approval for Aim 2 and 3, this award is issued with the following restriction: only activities associated with Aims 1 may be conducted pending acceptance by the National Institute of Mental Health (NIMH) of certification of IRB approval for Aims 2 and 3 that is consistent with 45 CFR Part 46. Failure to comply with this term may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

**AWARD NOTICE:**

This award has been made in response to the application submitted under the Funding Opportunity Announcement PA18-281 which can be referenced at:

<https://grants.nih.gov/grants/guide/pa-files/PA-18-281.html>

**CONSORTIUM / CONTRACTUAL COSTS:**

This award includes funds for consortium activity with the organizations listed below. Each consortium is to be established and administered in accordance with the NIH Grants Policy Statement (<http://grants.nih.gov/grants/policy/nihgps/index.htm>). No foreign performance site may be added to this project without the written prior approval of the National Institute of Mental Health.

1. City and County of San Francisco
2. University of California, San Francisco
3. New York University School of Medicine

**PARTICIPANT RECRUITMENT - MILESTONES:**

Future NIMH support for this study is contingent upon adequate participant recruitment based on projected milestones as approved in the Recruitment Milestone Reporting system (RMR) on 03/19/2019. It is expected that 30 of the 180 total projected participants will be recruited by 12/01/2020. This tri-yearly recruitment report should be submitted electronically to NIMH after each milestone period of April 1, August 1 and December 1

at: <http://wwwapps.nimh.nih.gov/rmr/displayHome.action>. In the event that actual recruitment falls significantly below projected milestones, NIMH may consider withholding future support and/or negotiating an orderly phase-out of this study. Information regarding the NIMH Policy for the Recruitment of Participants in Clinical Research is available at: <http://grants.nih.gov/grants/guide/notice-files/NOT-MH-05-013.html>.

**GCP TRAINING:**

NIH expects that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) as stated in NOT-OD-16-148.

**CLINICAL TRIAL DISSEMINATION PLAN:**

The clinical trial(s) supported by this award is subject to the plan dated 09/07/2018 on page 235 of the application submitted to NIH and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The plan states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the

Completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

#### **CLINICAL TRIAL REQUIREMENTS:**

This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:

In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

#### **DATA AND SAFETY MONITORING:**

The level and frequency of human subject data and safety monitoring should always be commensurate with the risk and nature of the research. Human subject data and safety monitoring for this grant is the responsibility of the Principal Investigator(s) and the IRB of record for this grant. The recipient is reminded of required reporting pursuant to NIHGPS 4.1.15.3 and the [NIMH Reportable Events Policy](#) cited in NOT-MH-15-025, as appropriate.

#### **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:** John E. Fonda

**Email:** john.fonda@nih.gov **Phone:** 301-402-8158 **Fax:** 301-480-1956

**Program Official:** Michael J Stirratt

**Email:** stirrattm@mail.nih.gov **Phone:** 240-627-3875 **Fax:** 240-627-3107

#### **SPREADSHEET SUMMARY**

**GRANT NUMBER:** 5R01MH119956-02

**INSTITUTION:** PUBLIC HEALTH FOUNDATION ENTERPRISES

Budget	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	\$130,728	\$90,609	\$115,455	\$92,714
Fringe Benefits	\$48,198	\$33,407	\$42,568	\$34,183
Personnel Costs (Subtotal)	\$178,926	\$124,016	\$158,023	\$126,897
Consultant Services	\$6,388	\$6,388	\$6,601	\$26,040
Materials & Supplies	\$900		\$930	
Travel	\$900			
Other	\$83,354	\$187,009	\$169,650	
Subawards/Consortium/Contractual Costs	\$169,265	\$94,065	\$95,985	\$290,168
Participant Stipends	\$9,450	\$39,150	\$18,135	
TOTAL FEDERAL DC	\$449,183	\$450,628	\$449,324	\$443,105
TOTAL FEDERAL F&A	\$36,389	\$46,353	\$45,934	\$28,227
TOTAL COST	\$485,572	\$496,981	\$495,258	\$471,332

Facilities and Administrative Costs	Year 2	Year 3	Year 4	Year 5
-------------------------------------	--------	--------	--------	--------



F&A Cost Base 1	13%	13%	13%	13%
F&A Costs 1	\$279,918	\$356,563	\$353,339	\$217,127
F&A Costs 1	\$36,389	\$46,353	\$45,934	\$28,227

EXHIBIT D  
TO SUBCONTRACT/SUBAWARD AGREEMENT  
FORM OF INVOICE

The final invoice must be marked FINAL.



EXHIBIT E  
TO SUBCONTRACT/SUBAWARD AGREEMENT  
CERTIFICATE OF SELF-INSURANCE COVERAGE DOCUMENT

Refer to following pages.



**CITY AND COUNTY OF SAN FRANCISCO  
OFFICE OF THE  
CITY ADMINISTRATOR  
RISK MANAGEMENT DIVISION**



London N. Breed, Mayor  
Naomi Kelly, City Administrator

August 24, 2020

Blayne Cutler, Ph.D., M.D.  
President, CEO  
Heluna Health  
12801 Crossroads Parkway South, Suite 200  
City of Industry, CA 91746

RE: Program PrEP-3D – CID#0597.0102

This letter certifies that the City and County of San Francisco is self-insured and self-funded for the following insurance coverages, which cover the City and County of San Francisco, its officers and employees.

General Liability insurance in the amount of \$1,000,000 per occurrence and \$2,000,000 general aggregate for bodily injury, property damage, and personal injury to third parties for liability arising out of the City's negligence in performance of this agreement.

Professional Liability insurance with limits of \$1,000,000 per claim and \$2,000,000 in the aggregate.

Automobile Liability insurance with limits not less than \$1,000,000 combined single limit per accident for bodily injury and property damage including owned, and non-owned and hired auto coverage as applicable.

Workers' Compensation in statutory amounts with Employer's Liability of \$1,000,000 per accident, injury or illness.

The City and County of San Francisco's self-insurance program is not commercial insurance and has no legal capacity to name another entity as additional insured.

Do not hesitate to contact this office should you have any questions.

Sincerely,

A handwritten signature in blue ink that reads "Matt Hansen".

Matt Hansen  
Director

cc: Sajid Shaik  
Budget & Finance  
SF Department of Public Health