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

[SUBCONTRACT/SUBAWARD] AGREEMENT BETWEEN

HELUNA HEALTH

AND

CITY AND COUNTY OF SAN FRANCISCO

This [Subcontract/Subaward] Agreement (this "Agreement") is made and entered into as of _____ 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 Department of Health and Human Services (the "Funding Agency"); under contract number 1R34MH132405-01; Federal Award Identification Number (FAIN) R34MH132405; and 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.

D. The Parties understand and agree that any funding amount above $1,000,000, that constitutes revenue to the City requires formal approval by the San Francisco Board of Supervisors acting in its sole discretion under San Francisco Charter Section 9.118.

AGREEMENT

1. IDENTITIES OF PARTIES

SUBCONTRACTOR/SUBAWARDEE:

Legal Name of Subcontractor/Subawardee: City and County of San Francisco
DBA of Subcontractor/Subawardee: San Francisco Department of Public Health
Type of Entity: [ ] Sole Proprietorship; [ ] Partnership; [ ] Corporation;
[ ] Limited Liability Company; [X] Government

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: 94-6000417
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) 476-2300

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 $750,000 or more):
[X] Yes [ ] No

If yes, has Subcontractor/Subawardee filed the required Single Audit? [X] 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: MyPrEP Plus: Development and Pilot Testing of Novel Pre-Exposure Prophylaxis Support Tools for Transgender Women
Program/CID #: 1067.0101
Project Director Name: Susan Buchbinder
Project Director Phone #: (415) 476-2300
Project Director Email Address: Susan.buchbinder@ucsf.edu
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 Exhibit C, if attached hereto. 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):

101 Grove Street, Room 402
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 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 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, if attached hereto as Exhibit C, 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, if attached as Exhibit C (the "Flow Down Provisions"). Subcontractor/Subawardee represents and warrants that it has carefully reviewed all of the Flow Down Provisions, if attached as Exhibit C, 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, if attached as Exhibit C, 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. 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.

(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, attached hereto as Exhibit C, 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 September 7, 2023 to September 6, 2025 (the "Term").

(b) Termination Without Cause. Reserved.

(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. Reserved.

(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 venturors, 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 or 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. 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. OWNERSHIP OF WORK PRODUCT

(a) Ownership of Work Product. Subcontractor/Subawardee owns all work product developed under this Agreement.

(b) No Infringement. Subcontractor/Subawardee represents and warrants that any Work Product developed by Subcontractor/Subawardee and shall not infringe or violate any patents, copyrights, trademarks, trade secrets or other proprietary rights of any third party.

(c) 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.

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

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

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, attached as Exhibit C, Subcontractor/Subawardee shall procure such coverages. A program of self-insurance is acceptable.

13. CONFIDENTIALITY

(a) Sunshine Ordinance. HELUNA HEALTH acknowledges that this Agreement and all records related to its formation, and the performance of Services, and HELUNA HEALTH's payment are subject to the California Public Records Act, (California Government Code §6250 et. seq.), and the San Francisco Sunshine Ordinance, (San Francisco Administrative Code Chapter 67). Such records are subject to public inspection and copying unless exempt from disclosure under federal, state or local law.

(b) Confidential Information. 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; 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 or permitted by law. 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.

(c) Funding Agency Confidentiality. Subcontractor/Subawardee shall also comply with all confidentiality obligations imposed by the Funding Agency in the Funding Award Agreement, if attached as Exhibit C.

14. 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.

15. 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 shall be interpreted, construed and governed by, in accordance with and consistent with the laws of the State of California with venue in San Francisco.

(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) 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.

(i) 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.

(j) 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 arm's 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.

(k) 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.

(l) 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 91746-3505
Attention: Adam Abate
Facsimile: (562) 692-6950
Email: AAbate@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

And

San Francisco Department of Public Health
101 Grove Street, Room 410
San Francisco, CA 94102
Attention: Contract Analyst
Facsimile: (415) 554-2555
Email: DPH-ContractsRm410@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.

(m) 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.

(n) 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.

(o) 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.

(p) 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.

(q) 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: _____ Date: _____
Peter Dale
Chief Program Officer

THE CITY AND COUNTY OF SAN FRANCISCO

By: _____ Date: _____
Grant Colfax, MD
Director of Health
Department of Public Health

Approved as to Form

David Chiu
City Attorney

By: _____ Date: _____
Henry Lifton
Deputy City Attorney

Exhibits

Exhibit A: Scope of Work (SOW)
Exhibit B: Budget
Exhibit C: Flow Down Provisions
Exhibit D: Form of Invoice
Exhibit E: Certificate of Self Insurance

EXHIBIT A
TO SUBCONTRACT/SUBAWARD AGREEMENT

SCOPE OF WORK (SOW)

Susan Buchbinder, MD (Principal Investigator):
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 and publication of results.

Albert Liu, MD, MPH (Co-Investigator):
Dr. Liu will be responsible for overseeing technology development with our web developer, who will be adapting the MyPrEP website. He will also assist 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.

Hyman Scott, MD, MPH (Co-Investigator):
He will provide overall operational oversight of the clinical research team at Bridge HIV. 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

DETAILED BUDGET FOR INITIAL BUDGET PERIOD						FROM	THROUGH	
DIRECT COSTS ONLY						09/07/23	09/06/25	
List PERSONNEL *(Applicant organization only)*								
Use Cal, Acad, or Summer to Enter Months Devoted to Project								
Enter Dollar Amounts Requested *(omit cents)* for Salary Requested and Fringe Benefits								
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST. BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Susan Buchbinder	PD/PI	3.60			212,100	63,630	23,543	87,173
Albert Liu	Co-PI	1.20			212,100	21,210	7,848	29,058
Hyman Scott	Co-PI	1.20			212,100	21,210	7,795	29,005
						0	0	0
	SUBTOTALS					106,050	39,186	145,236
CONSULTANT COSTS								
								0
EQUIPMENT *(Itemize)*								
								0
SUPPLIES *(Itemize by category)*								
								0
TRAVEL 0								
								0
INPATIENT CARE COSTS								0
OUTPATIENT CARE COSTS								0
ALTERATIONS AND RENOVATIONS *(Itemize by category)*								
								0
OTHER EXPENSES *(Itemize by category)*								
								0
CONSORTIUM/CONTRACTUAL COSTS								0
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)*							DIRECT COSTS	**145,236**
CONSORTIUM/CONTRACTUAL COSTS				22.46%			FACILITIES AND ADMINISTRATIVE COSTS	32,623
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD								**177,860**

Total budget not to exceed $177,860.

EXHIBIT C
TO SUBCONTRACT/SUBAWARD AGREEMENT

FLOW DOWN PROVISIONS

Refer to the following pages.

Recipient Information

1. Recipient Name
PUBLIC HEALTH FOUNDATION ENTERPRISES, INC.
13300 CROSSROADS PKWY N
STE 450
CITY OF INDUSTRY, CA 91746

2. Congressional District of Recipient
32

3. Payment System Identifier (ID)
1952557063A1

4. Employer Identification Number (EIN)
952557063

5. Data Universal Numbering System (DUNS)
082199324

6. Recipient's Unique Entity Identifier
L4EEW9SQX2F6

7. Project Director or Principal Investigator
Susan Buchbinder, MD
Director
Susan.Buchbinder@sfdph.org
628-217-7479

8. Authorized Official
Adam Abate
aabate@helunahealth.org
562-222-7804

Federal Agency Information

9. Awarding Agency Contact Information
Julie M. Bergerud
Grants Management Officer
NATIONAL INSTITUTE OF MENTAL HEALTH
julie.bergerud@nih.gov
301-827-6184

10. Program Official Contact Information
Michael J Stirratt
Chief, Adherence To Treatment & Prevention Program And Hiv Small Business Program (sbir/sttr)
NATIONAL INSTITUTE OF MENTAL HEALTH
stirrattm@mail.nih.gov
240-627-3875

Federal Award Information

11. Award Number
1R34MH132405-01

12. Unique Federal Award Identification Number (FAIN)
R34MH132405

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
MyPrEP Plus: Development and Pilot Testing of Novel Pre-Exposure Prophylaxis Support Tools for Transgender Women

15. Assistance Listing Number
93.242

16. Assistance Listing Program Title
Mental Health Research Grants

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 09/07/2023 **– End Date** 09/06/2025	
20. Total Amount of Federal Funds Obligated by this Action	$521,875
20 a. Direct Cost Amount	$482,440
20 b. Indirect Cost Amount	$39,435
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$521,875
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$521,875
26. Project Period Start Date 09/07/2023 **– End Date** 09/06/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$521,875

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Christine Clarkson

30. Remarks

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

CLINICAL TRIAL PLANNING GRANT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF MENTAL HEALTH

SECTION I – AWARD DATA – 1R34MH132405-01

Principal Investigator(s):
Susan Buchbinder, MD

Award e-mailed to: pdale@helunahealth.org

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $521,875 (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 recipient when funds are drawn down or otherwise requested 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 R34MH132405. 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 direct questions to the Federal Agency contacts.

Sincerely yours,

Christine Clarkson
Grants Management Officer
NATIONAL INSTITUTE OF MENTAL HEALTH

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$136,657
Fringe Benefits	$45,595
Personnel Costs (Subtotal)	$182,252
Consultant Services	$5,200
Equipment	$3,400
Other	$77,310
Subawards/Consortium/Contractual Costs	$177,778
Participant Stipends	$36,500
Federal Direct Costs	$482,440
Federal F&A Costs	$39,435
Approved Budget	$521,875
Total Amount of Federal Funds Authorized (Federal Share)	$521,875
TOTAL FEDERAL AWARD AMOUNT	$521,875
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$521,875

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$521,875	$521,875

Fiscal Information:

Payment System Identifier:	1952557063A1
Document Number:	RMH132405A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2023

IC	CAN	2023
MH	8472592	$521,875

NIH Administrative Data:
PCC: 9A-ASGA / **OC**: 41021 / **Released**: Clarkson, Christine 08/30/2023
Award Processed: 09/07/2023 12:06:30 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R34MH132405-01

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 – STANDARD TERMS AND CONDITIONS – 1R34MH132405-01

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

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.

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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).

MULTI-YEAR FUNDED AWARD: This is a multi-year funded award. A progress report is due annually on or before the anniversary of the budget/project period start date of the award, in accord with the instructions posted at: http://grants.nih.gov/grants/policy/myf.htm.

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI 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) R34MH132405. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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

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

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/
This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated

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funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by

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persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

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

Treatment of Program Income:

Additional Costs

SECTION IV – MH SPECIFIC AWARD CONDITIONS – 1R34MH132405-01

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:

In the absence of certification of IRB approval for Aim 3 for this project, this award is issued with the following restriction: only activities that are clearly severable and independent from Aim 3 activities that involve human subjects may be conducted under this award until the project has received IRB approval consistent with 45 CFR Part 46, and certification of IRB approval has been submitted to and accepted by the National Institute of Mental Health (NIMH). 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.

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Funds included in this award for research involving human subjects in Aim 3 in this project are restricted pending acceptance of certification of IRB approval for Aim 3 by the NIMH. Funds will not be available for carryover under the expanded authorities or Federal Demonstration Partnership without the written prior approval of the NIMH. In addition, no funds may be drawn down from the Payment Management System or expended for any research involving human subjects until the NIMH has accepted the certification of IRB approval.

AWARD NOTICE:
This award has been made in response to the application submitted under the Funding Opportunity Announcement PA-20-141 which can be referenced at: PA-20-141: Formative and Pilot Intervention Research for Prevention and Treatment of HIV/AIDS (R34 Clinical Trial Optional) (nih.gov)

CHANGE TO A MULTIYEAR FUNDED AWARD:
Although the application was submitted as a 2-year grant request, in order to meet Institute program priorities and objectives within Fiscal Year 2023, this grant has been converted to a multi-year funded award, with all years of funding provided in the current fiscal year. Special monitoring requirements specific to multiyear funded awards, including the progress report due on or before the anniversary of the budget/project period start date of the award, are detailed in Section III in this Notice of Award.

MULTI-YEAR FUNDED REQUIREMENT:
This grant may be deemed materially non-compliant if annual RPPRs are not submitted on September 1st each year. Further enforcement actions may be necessary in accordance with the NIH Grants Policy Statement Section 8.5 (http://grants.nih.gov/grants/policy/nihgps/index.htm).

CONSORTIUM / CONTRACTUAL COSTS:
This award includes funds for consortium activity with **Department of Public Health, City and County of San Francisco (DPH/CCSF).**

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.

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 6/20/23. It is expected that 60 of the 60 total projected participants will be recruited by 8/1/25. 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: https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html.

DATA AND SAFETY MONITORING: Study ID 419992
This grant is subject to the clinical research policies outlined in NOT-MH-19-027. The recipient will adhere to the NIH (NIH GPS 4.1.15) and NIMH policies (NOT-MH-19-027) including appropriately providing adequate data and safety monitoring and timely reporting of key events

as defined in the NIMH Reportable Events Policy. The level and frequency of human subject data and safety monitoring should always be commensurate with the risk and nature of the research.

Each RPPR submitted is expected to include, in Section **G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS**, a summary of key safety indices (e.g., cumulative rates of AEs/SAEs) during the reporting period and cumulatively over the course of the project; and a summary of any safety recommendations from the IRB reviews and any actions taken based on the recommendations.

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 Harmonization (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 within the competing application dated 5/4/22 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.

HUMAN SUBJECTS RESEARCH:

This award includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and collected data and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

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SPREADSHEET SUMMARY
AWARD NUMBER: 1R34MH132405-01

INSTITUTION: PUBLIC HEALTH FOUNDATION ENTERPRISES

Budget	Year 1
Salaries and Wages	$136,657
Fringe Benefits	$45,595
Personnel Costs (Subtotal)	$182,252
Consultant Services	$5,200
Equipment	$3,400
Other	$77,310
Subawards/Consortium/Contractual Costs	$177,778
Participant Stipends	$36,500
TOTAL FEDERAL DC	$482,440
TOTAL FEDERAL F&A	$39,435
TOTAL COST	$521,875

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	11%
F&A Cost Base 1	$148,920
F&A Costs 1	$16,381
F&A Cost Rate 2	13%
F&A Cost Base 2	$147,557
F&A Costs 2	$19,182
F&A Cost Rate 3	13%
F&A Cost Base 3	$29,784
F&A Costs 3	$3,872

EXHIBIT D
TO SUBCONTRACT/SUBAWARD AGREEMENT

FORM OF INVOICE

Please send monthly invoices to Tyler Norgord at TNorgord@helunahealth.org.

The final invoice must be marked FINAL.

The final invoice is due by October 5, 2025.

EXHIBIT E
TO SUBCONTRACT/SUBAWARD AGREEMENT

CERTIFICATE OF INSURANCE

Refer to the following page.