



**[SUBCONTRACT/SUBAWARD] AGREEMENT BETWEEN**

**PUBLIC HEALTH FOUNDATION ENTERPRISES, INC.**

**AND**

**THE CITY AND COUNTY OF SAN FRANCISCO**

This [Subcontract/Sub-Award] Agreement (this "Agreement") is made and entered into as of December 1, 2013 by and between PUBLIC HEALTH FOUNDATION ENTERPRISES, INC., a 501(c)(3) California nonprofit corporation (hereinafter referred to as "PHFE"), and the party identified in Section 1 below (hereinafter be referred to as "Subcontractor/Subawardee").

**RECITALS**

A. PHFE has been granted an award by The National Institutes of Health (the "Funding Agency"), under contract number 2UM1A1069496-08 (the "Funding Award Agreement"), CFDA Number 93.855 under which PHFE and its subcontractors and subawardees will conduct research and participate in the San Francisco Bay Clinical Trials Unit;

B. Subcontractor/Subawardee has expertise in the areas of HIV/AIDS Vaccine Clinical Trials, Prevention and Research, which expertise can assist PHFE to perform its obligations under the Funding Award Agreement; and

C. PHFE desires to engage the services of Subcontractor/Subawardee to assist PHFE 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: CCSF/SFDPH

Type of Entity:           Sole Proprietorship                   Partnership  
                                  Corporation                               Limited Liability Company

State of Organization (if an entity): California

Address: 101 Grove Street, Room 402

City/State/Zip: San Francisco, California 94102

Business Telephone: 415-554-2778

Social Security or Employer Identification Number:

License Number and Expiration Date, if any: \_\_\_\_\_

Email Address: \_\_\_\_\_

Name of Principal Investigator/Project Coordinator: Susan Buchbinder, M.D.

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): Please complete:

Yes       No

If yes, has Subcontractor/Subawardee filed the required Single Audit?

Yes       No

(If yes, submit copy to PHFE prior to signing this Agreement)

**PHFE:**

Public Health Foundation Enterprises, Inc.  
12801 Crossroads Parkway South, Suite 200  
City of Industry, CA, 91746-3505  
Main Telephone Number (562) 699-7320

Program Name: San Francisco Bay Clinical Trials Unit

Program/CID #: 0325.014.001 CTU CRS / 0325.014.903 PrEP Demo

Contract & Grant Manager Name: Lori Thompson

Contract & Grant Manager Email Address: lthompson@phfe.org

Program Director Name: Susan Buchbinder

Telephone Number: (415) 437-7407

Program Director Email: Susan.Buchbinder@sfdph.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 Sections Exhibit C and n/a 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. PHFE 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): Please complete:

Bridge HIV 25 Van Ness Avenue  
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 PHFE 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 PHFE's and the Funding Agency's prior written approval.

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

(e) Performance Reporting. If requested by PHFE 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 PHFE. 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 PHFE. 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 PHFE 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 FUNDING AWARD 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 PHFE'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 PHFE. All Services must be completed to the satisfaction of PHFE in order to be entitled to payment hereunder.

(d) Funds Available to PHFE. PHFE shall not be obligated to make payment under this Agreement unless the corresponding funds are disbursed to PHFE under the Funding Award Agreement. In the event that PHFE has made payment to Subcontractor/Subawardee under this Agreement and PHFE 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 PHFE within ten (10) days after written notice from PHFE.

(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 PHFE 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 PHFE.

(b) Address for Invoices. Subcontractor/Subawardee shall send all timesheets and invoices to the attention of the PHFE 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 PHFE 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 PHFE may require. If any invoices are not submitted within such time periods, Subcontractor/Subawardee waives (in PHFE'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 PHFE from time to time.

## **6. TERM AND TERMINATION**

(a) Term. Unless earlier terminated as provided herein, the term of this Agreement shall be from 12/10/13 to 11/30/14 (the "Term").

(b) Termination Without Cause. Without cause, PHFE 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. PHFE 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 PHFE has received the corresponding funds from the Funding Agency under the Funding Award Agreement, PHFE 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 PHFE has terminated this Agreement for reasonable cause under Section 6(c) above, then PHFE shall have the right to offset and deduct from any payments due to Subcontractor/Subawardee hereunder any damages or losses incurred by PHFE 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 PHFE 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 PHFE and all Work Product (as defined below). PHFE shall have the right to withhold final payment to Subcontractor/Subawardee until all such items are returned to PHFE.

(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 PHFE 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 PHFE'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 PHFE 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 PHFE. Without limiting the generality of the foregoing paragraph, this Agreement does not designate Subcontractor/Subawardee as the agent or legal representative of PHFE 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 PHFE or to bind it in any manner, or to make any contract or agreement on behalf of or in the name of PHFE, without the prior written consent from PHFE management. No sales, invoices nor orders for goods or services shall be valid and binding upon PHFE (whether as the provider or the recipient) unless and until accepted by PHFE, at its sole and absolute discretion, through its established channels. PHFE 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 PHFE on behalf of Subcontractor/Subawardee or the employees of Subcontractor/Subawardee. Subcontractor/Subawardee and its personnel shall not be treated as employees or PHFE 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 PHFE's retirement, health, or other fringe benefit plans.

(e) Workers' Compensation. No workers' compensation insurance shall be obtained by PHFE 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 PHFE 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, PHFE 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 PHFE's prior written approval. Any lower-tier subcontractors/subawardees who are approved by PHFE must execute all agreements and documents required by PHFE 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 PHFE 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 PHFE 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 PHFE, 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 PHFE 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 PHFE all right, title and interest in any Work Product designed and/or developed by Subcontractor/Subawardee or otherwise delivered to PHFE as part of or related to Subcontractor's/Subawardee's retention with PHFE. The Work Product shall be the sole property of PHFE, 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 PHFE 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 PHFE 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 PHFE 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 PHFE 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 PHFE 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 PHFE as part of or related to Subcontractor's/Subawardee's retention with PHFE.

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

(e) Assignment Documents. Subcontractor/Subawardee will cooperate with PHFE, with PHFE's approval and at PHFE'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 PHFE's intellectual property rights in or to the Work Product. Subcontractor/Subawardee hereby grants PHFE the exclusive right, and appoints PHFE as attorney-in-fact, to execute and prosecute in Subcontractor's/Subawardee's name as author or inventor or in PHFE'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 PHFE's approval and at PHFE's expense, Subcontractor/Subawardee will execute such other documents of registration and recordation as may be necessary to perfect in PHFE, or protect, the rights assigned to PHFE hereunder in each country in which PHFE reasonably determines to be prudent.

(f) No Infringement. Subcontractor/Subawardee represents and warrants that any Work Product delivered to PHFE 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 PHFE'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 PHFE, 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 PHFE'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 PHFE 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 PHFE'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 PHFE and the Funding Agency at least 60 days prior to the proposed publication date.

(b) Acknowledgment in Publications. On any publication approved by PHFE 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 Public Health Foundation Enterprises, Inc. or **[Name of Funding Agency]**”.

(c) Use of PHFE's or Funding Agency's Name. Subcontractor/Subawardee shall not use in any manner PHFE's name, logo or trademarks without PHFE'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 PHFE, 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 PHFE. PHFE 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 PHFE, (ii) PHFE's violation of any federal, state or local law or regulation or (iii) the breach by PHFE of any its representations, warranties or agreements under this Agreement.

## **12. INSURANCE**

(a) Required Coverages. Subcontractor/Subawardee shall, unless otherwise agreed in writing by PHFE, 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, PHFE 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 PHFE 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 PHFE and the Funding Agency. Certificates of Insurance containing such waiver of subrogation or copies of policies shall be furnished to PHFE 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 PHFE. Said Confidential Information includes, but is not limited to, the identity of actual and potential clients of PHFE, 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 PHFE 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 PHFE by any third party which PHFE 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 PHFE 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 PHFE protection against its unauthorized use or its use in any manner detrimental to PHFE. 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 PHFE or except as otherwise provided in this Agreement. Further, Subcontractor/Subawardee shall develop and maintain procedures and

take other reasonable steps in furtherance of PHFE'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 PHFE'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 PHFE and shall not be copied or removed from the premises of PHFE without the express written consent of PHFE. All such items, and any copies thereof, shall be immediately returned to PHFE 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 PHFE to leave the employment or engagement of PHFE or otherwise raid the employees of PHFE. Nothing contained in this paragraph shall constitute a waiver by PHFE 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 PHFE, 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 PHFE'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 PHFE 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, PHFE 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 PHFE, addressed to:

Public Health Foundation Enterprises, Inc.  
12801 Crossroads Parkway South, Suite 200  
City of Industry, CA 91746-3505

Attention: Lori Thompson, Sr. Contract & Grant  
Manager

Facsimile: 562-692-6950

Email: lthompson@phfe.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: 415-5-3-4710

Email: 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, PHFE may assign this Agreement to an affiliate of PHFE 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:

**PUBLIC HEALTH FOUNDATION ENTERPRISES, INC.**

DocuSigned by:  
Peter Dale  
By: Peter D. Dale  
9AAA24B90105482...  
Peter D. Dale  
Director, Contract and Grants Management

4/30/2014  
Date

**SUBCONTRACTOR/SUBAWARDEE**

Name: TOMÁS ARAGÓN  
Signature: Tomás Aragon, MD

4/28/14  
Date

Tomas Aragon, Director of Population Health Division  
Print Name, Title [If any entity]

EXHIBIT A  
TO SUBCONTRACT/SUBAWARD AGREEMENT

Scope of Work (SOW)

Scope of Work  
CTU/CRS  
0325.014.001

Susan Buchbinder, M.D.

Dr. Buchbinder serves as the Director of Bridge HIV. She has been the PI of the previous San Francisco Department of Public Health CTU, which is now affiliated with HVTN, HPTN, and MTN. She helps direct the HVTN (through the Executive Management Team) and the HPTN (by co-chairing the Integrated Strategies Working Group). Dr. Buchbinder will be PI of the SFBay CTU with Dr. Diane Havlir, as well as being the Leader of the Bridge HIV CRS. Dr. Buchbinder will be responsible for the overall scientific leadership of the CTU and Bridge HIV CRS, and will prioritize research efforts. She will have final decision-making authority for the CRS; she and Dr. Havlir will share decision-making authority for the CTU. She will oversee study implementation at the CRS, ensuring that Division Directors have the resources and skills needed to successfully carry out their protocols, and provide guidance and mentorship to them. She will lead manuscript development at the site, assisting in research design and analysis, presentation and publication of data. She will be the primary liaison to the HVTN, HPTN, and MTN. Dr. Buchbinder will provide input into local study operations including recruitment strategies, decisions about enrollment of potential study volunteers, evaluation of AEs, and quality management issues (including review of study records at the initiation of study protocols). She will review all SAEs and provide clinical cross-coverage for all HVTN study participants. She will continue to serve on the HVTN Executive Management Team, chair the HVTN Efficacy Trials Design Working Group and Investigators Group, and serve on a number of committees and working groups. She will continue to co-chair the HPTN Integrated Strategies Working Group and serve on HPTN committees. She will also chair protocols for all Networks with which she is affiliated.

Albert Liu, MD

Dr. Liu will co-chair the SFBay CTU Operations Steering Committee and be a major contributor to HPTN and MTN. He will also serve as Co-Leader of the Bridge HIV CRS, providing overarching leadership and mentorship to all of the teams. He will directly oversee all PrEP and microbicide trials conducted at Bridge HIV, including their regulatory and laboratory components, and directly supervise the clinical staff and Study Coordinator

Scope of Work  
PrEP Demo  
0325.014.903

Albert Liu, MD

Dr. Liu will be responsible for the overall scientific, operational and administrative aspects of the demonstration project. As the lead investigator of the San Francisco site, he will oversee overall study implementation at this site and will be responsible for study enrollment and retention, data collection, evaluation and reporting of AEs, clinical management of study participants, and quality management. Also, along with the protocol co-chairs, he will have responsibility for achieving the overall specific aims of the project, for maintaining the proposed project schedule, ensuring quality control over all aspects of this project, and data analyses and publication of results.

EXHIBIT B  
TO SUBCONTRACT/SUBAWARD AGREEMENT

Budget

<b>DETAILED BUDGET FOR NEXT BUDGET PERIOD - DIRECT COSTS ONLY</b>	<b>FROM</b> 12/10/2013	<b>THROUGH</b> 11/30/14	<b>GRANT NUMBER</b> U01 AI069496
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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	Summ. Mnths	SALARY	FRINGE	TOTAL
					REQUESTED	BENEFITS	
Susan Buchbinder	Principal Investigator	2.34			35,439	13,467	48,906
Albert Liu	Co-Investigator	1.60			24,200	9,196	33,396
<b>Note on Susan Buchbinder: Salary Rate Used \$181382 Combines Previous Cap Rate and New Rate as Follows: 24 Work Days at \$179700 and \$181500 For Remainder. New Salary Cap Rate is Effective 1.12.2014</b>							
<b>Note on Al Liu: Employment Date 4.1.2014 @ 20% Effort. This portion of Budget is for CTU/CRS Activities</b>							
STEP							
					59,639	22,663	82,302

CONSULTANT COSTS

EQUIPMENT

0

SUPPLIES

0

TRAVEL

0

PATIENT CARE COSTS	INPATIENT	
	OUTPATIENT	

ALTERATIONS AND RENOVATIONS

0

OTHER EXPENSES

0

<b>SUBTOTAL DIRECT COST FOR NEXT BUDGET PERIOD</b>		<b>82,302</b>
CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	0
CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS	15,029
<b>TOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD</b>		<b>97,331</b>

<b>DETAILED BUDGET FOR NEXT BUDGET PERIOD - DIRECT COSTS ONLY</b>	<b>FROM</b> 12/10/2013	<b>THROUGH</b> 11/30/14	<b>GRANT NUMBER</b> U01 AI069496
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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	Summ. Mnths	SALARY	FRINGE	TOTAL
					REQUESTED	BENEFITS	
Albert Liu	Co-Investigator	2.80			42,350	16,093	58,443
<b>Note on Al Liu: Employment Date 4.1.2014 @ 35% Effort. This portion of Budget is for PrEP Demo Activities</b>							
STEP							
					42,350	16,093	58,443

CONSULTANT COSTS

EQUIPMENT

0

SUPPLIES

0

TRAVEL

0

PATIENT CARE COSTS	INPATIENT	
	OUTPATIENT	

ALTERATIONS AND RENOVATIONS

0

OTHER EXPENSES

0

<b>SUBTOTAL DIRECT COST FOR NEXT BUDGET PERIOD</b>		<b>58,443</b>
CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	0
CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS	10,672
<b>TOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD</b>		<b>69,115</b>



EXHIBIT C  
TO SUBCONTRACT/SUBAWARD AGREEMENT  
FLOW DOWN PROVISIONS



**Grant Number:** 2UM1AI069496-08 REVISED  
**FAIN:** UM1AI069496

**Principal Investigator(s):**  
SUSAN P BUCHBINDER (contact), MD  
Diane V Havlir, MD

**Project Title:** San Francisco Bay Clinical Trials Unit

PETER DALE  
PUBLIC HEALTH FOUNDATION ENTERPRISES, INC  
12801 CROSSROADS PARKWAY SOUTH  
SUITE 200  
CITY OF INDUSTRY, CA 917466050

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

**Budget Period:** 12/10/2013 – 11/30/2014  
**Project Period:** 03/02/2007 – 11/30/2020

Dear Business Official:

The National Institutes of Health hereby revises this award to reflect an increase in the amount of \$387,016 (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 31 USC 6305 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number UM1AI069496. 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 42 CFR Part 50 Subpart F. Subsequent to the compliance date of the 2011 revised FCOI regulation (i.e., on or before August 24, 2012), Awardees must be in compliance with all aspects of the 2011 revised regulation; until then, Awardees must comply with the 1995 regulation. 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,

Donna R. Sullivan  
Grants Management Officer  
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

**SECTION I – AWARD DATA – 2UM1AI069496-08 REVISED**

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

Salaries and Wages	\$1,060,474
Fringe Benefits	\$318,142
Personnel Costs (Subtotal)	\$1,378,616
Supplies	\$14,900
Travel Costs	\$44,388
Other Costs	\$940,544
Consortium/Contractual Cost	\$1,837,300

Federal Direct Costs	\$4,215,748
Federal F&A Costs	\$240,438
Approved Budget	\$4,456,186
Federal Share	\$4,456,186
Less Unobligated Balance	\$37,256
<b>TOTAL FEDERAL AWARD AMOUNT</b>	<b>\$4,418,930</b>

**AMOUNT OF THIS ACTION (FEDERAL SHARE) \$387,016**

SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
8	\$4,418,930	\$4,418,930
9	\$1,190,123	\$1,190,123
10	\$1,190,123	\$1,190,123
11	\$1,190,123	\$1,190,123
12	\$1,190,123	\$1,190,123
13	\$1,190,123	\$1,190,123
14	\$1,190,123	\$1,190,123

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

**Fiscal Information:**

CFDA Number: 93.855  
 EIN: 1952557063A1  
 Document Number: UAI069496B  
 PMS Account Type: P (Subaccount)  
 Fiscal Year: 2014

I C	CAN	2014	2015	2016	2017	2018	2019	2020
A I	847229 7	\$1,815,3 66	\$1,190,1 23	\$1,190,1 23	\$1,190,1 23	\$1,190,1 23	\$1,190,1 23	\$1,190,1 23
A I	849058 7	\$2,603,5 64						

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

**NIH Administrative Data:**

PCC: A28Z / OC: 414M / Released: SULLIVANDO 02/14/2014  
 Award Processed: 12/26/2013 10:57:56 AM

**SECTION II – PAYMENT/HOTLINE INFORMATION – 2UM1AI069496-08 REVISED**

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

**SECTION III – TERMS AND CONDITIONS – 2UM1AI069496-08 REVISED**

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

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
- d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. 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.)

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

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the Central Contractor Registration. 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) UM1AI069496. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

This award is not subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170.

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/)

This award provides support for one or more NIH defined Phase III Clinical Trials. The NIH Policy for research supported as an NIH Phase III Clinical Trial has been amended in Section II.B. of the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended October 2001 (see [http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm)).

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

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

National Institute Of Allergy And Infectious Diseases (NIAID)
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**SECTION IV – AI Special Terms and Conditions – 2UM1AI069496-08 REVISED**

THIS AWARD CONTAINS GRANT SPECIFIC RESTRICTIONS. THESE RESTRICTIONS MAY ONLY BE LIFTED BY A REVISED NOTICE OF AWARD.

REVISED AWARD: This award provides supplemental funds in the amount of \$202,247 Total Costs (\$184,196 Direct Costs and \$18,051 F&A Costs) for the enrollment of additional patient participants in Protocol HPTN 069. These funds provide support for the period 02/15/2014-11/30/2014 and are restricted for enrollment on the stated protocol, in request dated 02/06/2014, from Peter Dale at Public Health Foundation Enterprises. These funds may not be rebudgeted or used for any other purpose, without NIAID awarding unit approval.

REVISED AWARD: This award was revised to restore funding at NIAID Funding Plan Levels, and consistent with NIH FY2014 Fiscal Policy per NOT-OD-14-055, <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-055.html>.

Supersedes Notice of Award (NOA) issued 02/06/2014.

\*\*\*\*\*

This award provides supplemental funds of \$1,343,975 Total Costs (\$1,224,021 Direct Costs and \$119,954 F&A Costs) for the San Francisco PrEP Demonstration Project. These funds provide support for the period 02/01/2014-11/30/2014. These funds are restricted for stated purpose, in request dated 12/02/2013, from Peter Dale at Public Health Foundation Enterprises and may not be rebudgeted or used for any other purpose, without NIAID awarding unit approval.

This award provides supplemental funds of \$1,057,342 Total Costs (\$1,054,892 Direct Costs and \$2,450 F&A Costs) for the Miami PrEP Demonstration Project. These funds provide support for the period 02/01/2014-11/30/2014. These funds are restricted for stated purpose, in request dated 01/21/2014, from Peter Dale at Public Health Foundation Enterprises and may not be rebudgeted or used for any other purpose, without NIAID awarding unit approval.

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This award is revised to provide protocol funds (PF) and transition funding.

This award provides PF in the amount of \$158,817 for the following site:  
BRIDGE HIV/ HVTN 505 (\$144,642 Direct Cost; \$14,175 Indirect Cost)

Additional funding for protocol activity if necessary, is expected to be provided by the respective Network LOC(s) through sub-contracts later in the budget period.

This award provides transition activities in the amount of \$498,781 for the following sites:  
BRIDGE HIV/ HVTN (\$114,632 Direct Cost; \$11,234 Indirect Cost)  
BRIDGE HIV/ MTN (\$126,412 Direct Cost; \$12,388 Indirect Cost)  
UCSF/ACTG (\$174,713 Direct Cost; \$59,402 Indirect Cost)

This award is revised to reflect the NIH awarding component's acceptance of the certification of Human Subject Education and revised Other Support for Dr. Buchbinder, and releases all restrictions on the Notice of Award issued on 12/10/2013. Accordingly, the special condition prohibiting research involving human subjects for named personnel is removed, effective as of 12/05/2013 from Peter Dale at Public Health Foundation Enterprises, INC.

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The budget period anniversary start date for future years will be December 1.

\*\*\*\*\*

This grant has been offset by \$37,256. This amount represents funds provided to 5 UM1 AI 069496-07, originally intended to support core functions at BRIDGE HIV CRS CRS during the month of December 2013.

\*\*\*\*\*

This award includes funds awarded for consortium activity with SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH, BRIDGE HIV in the amount of \$55,778 (\$46,722 direct costs + \$9,056 facilities and administrative costs).

This award includes funds awarded for consortium activity with UNIVERSITY OF CALIFORNIA SAN FRANCISCO in the amount of \$492,515 (\$367,549 direct costs + \$124,966 facilities and administrative costs).

Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at [http://grants.nih.gov/grants/policy/nihgps\\_2012/nihgps\\_ch15.htm#\\_Toc271265264](http://grants.nih.gov/grants/policy/nihgps_2012/nihgps_ch15.htm#_Toc271265264).

\*\*\*\*\*

This award provides core funding for the following Clinical Research Sites (CRS) in support of the following Networks:

MTN, HVTN, and HPTN	BRIDGE HIV CRS
ACTG	University of California San Francisco HIV/AIDS CRS

Continued support will be based on a satisfactory evaluation at the end of a time period designated as appropriate by each Network.

Satisfactory evaluation will be based on meeting the following performance objectives:

1. Sites must meet Network and NIAID performance standards by the end of each performance period.
2. The Network will assist sites and negotiate deadlines to address performance or accrual deficiencies.

IF ANY CRS IS UNABLE TO MEET THE REQUIREMENTS OF THE NETWORK LEADERSHIP AND OPERATIONS CENTER (LOC) AND NIAID BY ITS NEGOTIATED DEADLINE, FUNDING MAY BE WITHDRAWN AND A PLAN TO PHASE-OUT THE CRS WILL BE ESTABLISHED.

If it is determined by NIAID in collaboration with the Network LOC that the CTU and/or affiliated CRS has performance or other issues, the grantee will first be notified in writing by the Network LOC. A plan of action will be developed by the Network LOC in conjunction with NIAID including expectations for corrective actions and timelines for implementing such corrective actions.

\*\*\*\*\*

In addition, if the scope of work changes in a given year, NIAID/NIH reserves the right to negotiate effort and funds upward or downward as appropriate for that year.

\*\*\*\*\*

ONCE PROTOCOL SUPPORT (PF) IS PROVIDED, THE CTU IS REQUIRED TO:

Enter into a consortium agreement developed by the LOC that documents the work the CTU is required to perform for that network, indicate how PF will be awarded to sites and specify that the LOC will give the CTUs detailed information on funds provided to CRSs, including the amount and purpose of the money.

If the LOC provides PF directly to the CRS, the CRS must also provide the CTU with the amount they received by the LOC, and the purpose. The CTUs will be responsible for cross checking the information and keeping track by site of all Network PF provided and the purpose of the funds. This information must be provided to NIAID as part of the yearly progress report. A template will be provided in the yearly funding request.

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The following personnel are considered key and as such need prior NIAID approval before they may be replaced on the grant. Approval will be granted via revised Notice of Award.

- Dr. Susan Buchbinder
- Dr. Diane Havlir

In addition, changes to the individuals who occupy the following positions: CTU Coordinator, each CRS Coordinator, and each Pharmacist(s) of Record must also be approved by NIAID staff. These changes will not require a revised Notice of Award, but NIAID approval of the change will be granted via e-mail.

The grantee is required to follow any applicable Network policies and procedures for obtaining prior approval for changes in these positions.

All components of the CTU are required to comply with NIH, NIAID, and DAIDS policies & procedures, including NIAID Clinical Terms of Award; and affiliated Network policies &

procedures. See DAIDS Clinical Research Policies and Standard Procedures located at:  
<http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/Default.aspx>.

\*\*\*\*\*

This award is issued as a Cooperative Agreement, and as such, substantial NIH scientific and programmatic involvement is anticipated in the performance of the activity. This award is subject to the Terms and Conditions of Award as set forth in Section VI: Award Administration Information of RFA AI-12-018, AIDS Clinical Trials Units release date 01/27/2012, which are hereby incorporated by reference as special terms and conditions of this award. This RFA may be accessed at : <http://grants.nih.gov/grants/guide/rfa-files/RFA-AI-12-018.html>

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This award is subject to the Clinical Terms of Award included in Monitoring of Clinical Trials and Studies - NIAID (see NIH Guide for Grants and Contracts, July 8, 2002, NOT AI-02-032). These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address: <http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf>. All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Grant Award.

In addition to the NIAID Clinical Terms of Award and all NIH clinical research policies, awardees must comply with the applicable DAIDS Clinical Research Policies and Standard Procedures Documents for all new studies submitted for NIAID DAIDS scientific committee (Clinical Science or Prevention Science Review Committee) review  
<http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/Default.aspx>.

Grantees may contact the appropriate NIAID DAIDS staff with questions regarding these policies and standard procedures. For general questions, the assigned Program Officer should be contacted. Questions about a specific policy or standard procedure should be directed to the DAIDS Policy Group ([NIAIDOPCROPolicyGroup@niaid.nih.gov](mailto:NIAIDOPCROPolicyGroup@niaid.nih.gov)).

**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:** Julia L. Shriner  
**Email:** [julia.shriner@nih.gov](mailto:julia.shriner@nih.gov) **Phone:** 301-451-2690 **Fax:** 301-480-3780

**Program Official:** Patricia L. Jones  
**Email:** [jonespl@mail.nih.gov](mailto:jonespl@mail.nih.gov)

**SPREADSHEET SUMMARY**

**GRANT NUMBER:** 2UM1AI069496-08 REVISED

**INSTITUTION:** PUBLIC HEALTH FOUNDATION ENTERPRISES

Budget	Year 8	Year 9	Year 10	Year 11	Year 12	Year 13	Year 14
Salaries and Wages	\$1,060,474	\$439,699	\$439,699	\$439,699	\$439,699	\$439,699	\$439,699
Fringe Benefits	\$318,142	\$131,910	\$131,910	\$131,910	\$131,910	\$131,910	\$131,910
Personnel Costs (Subtotal)	\$1,378,616	\$571,609	\$571,609	\$571,609	\$571,609	\$571,609	\$571,609
Supplies	\$14,900	\$2,400	\$2,400	\$2,400	\$2,400	\$2,400	\$2,400
Travel Costs	\$44,388	\$5,310	\$5,310	\$5,310	\$5,310	\$5,310	\$5,310
Other Costs	\$940,544	\$5,226	\$5,226	\$5,226	\$5,226	\$5,226	\$5,226
Consortium/Contractual Cost	\$1,837,300	\$548,293	\$548,293	\$548,293	\$548,293	\$548,293	\$548,293
<b>TOTAL FEDERAL</b>	<b>\$4,215,</b>	<b>\$1,132,</b>	<b>\$1,132,</b>	<b>\$1,132,</b>	<b>\$1,132,</b>	<b>\$1,132,</b>	<b>\$1,132,8</b>



DC	748	838	838	838	838	838	38
TOTAL FEDERAL F&A	\$240,438	\$57,285	\$57,285	\$57,285	\$57,285	\$57,285	\$57,285
TOTAL COST	\$4,418,930	\$1,190,123	\$1,190,123	\$1,190,123	\$1,190,123	\$1,190,123	\$1,190,123

Facilities and Administrative Costs	Year 8	Year 9	Year 10	Year 11	Year 12	Year 13	Year 14
F&A Cost Rate 1	9.8%	9.8%	9.8%	9.8%	9.8%	9.8%	9.8%
F&A Cost Base 1	\$2,453,448	\$584,545	\$584,545	\$584,545	\$584,545	\$584,545	\$584,545
F&A Costs 1	\$240,438	\$57,285	\$57,285	\$57,285	\$57,285	\$57,285	\$57,285

EXHIBIT D  
TO SUBCONTRACT/SUBAWARD AGREEMENT

FORM OF INVOICE