FDP Amendment									
Number 02									
Pass-Through Entity (PTE)				Subr	ecipie	nt			
The Regents of the University of California, San Fra	ncisco E	Intity Name	ity & Cou	nty of San Francis	00				
cgsuboutteam@ucsf.edu	En	nail Address	ajid.shaik	h@sfdph.org					
Annie Luetkemeyer		ے ipal Investigate		n Buchbinder					
Project Title: Evaluation of doxycycline post-exposure prophylaxis to reduce sexually transmitted infections in PrEP users and HIV-infected men who have sex with men									
PTE Federal Award No:			Awarding						
5R01Al143439-02		INationa	ii institutes	s of Health (NIH)					
	Amount	: Funded This	\ ation:	Subaward No					
Revised Subaward Period of Performance: Start Date: April 12, 2019 End Date: Mar 31, 2021	\$ 44,59		Action:	11324sc	•				
Total Amount of Federal Funds Obligated to Date:	<u> </u>	Cost Sh	are:	Subject to FFAT	A: Auto	omatic Carryover:			
\$ 144,230.00		Oyes (	● No	Yes ON	lo 💽	•			
Amendme This Amendment revises		riginal Terms -referenced Su			/s:				
Additional Money and Time: The approved budget period for this Amendment is April 01, 2020 through March 31, 2021. Funding is awarded for this budget period in the amount of \$44,594 and is to be used as indicated in Attachment A, incorporated herein.									
For clarity: all amounts state  All other terms and conditions o					e and	effect.			
By an Authorized Official of PTE:		Docus	Signed by:	Official of Subrecip					
Docusigned by: Phillip De Biase	7/9/2020		2B95DBC0442.			Jul 7, 2020			
Dhillin Do Riaso	L——— Date	Name:	Tomas Ar		$\overline{}$	Date			
Title: Associate Manager, Subcontracts		Title:		of Population Health	Divsion				

# SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

AIDS Office - Bridge HIV

Dept / Div: HPH-% sure prophylaxis to reduce sexually transmitted infections in PrEP users and HIV-infected men who have sex with men

Fund Group: 2S/CHS/GNC 04/01/20-03/31/21

Index Code: HCHIVRSRCHGR Monthly Expenditure and Projection Report

Grant Code: UCSF Grant

Grant Detail:

CATEGORY/LINE ITEM	Annual Salary	35% Annual Frin Ben	Total Annual Sal/Frin Ben	% OF TIME	% OF FTE	Monthly Rate	Mth	Salary Budget	Frin Ben Budget	Total Budget	Comments
A. PERSONNEL											
1. Director 0943 5 S. Buchbinder	197,300	68,069	265,369	5%	0.050	16,442	12.0	9,865	3,403	13,268	
2 Sr Phyisican 2233 5 C Cohen	197,300	68,069	265,369	10%	0.100	16,442	12.0	19,730	6,818	26,548	
TOTAL SALARY/FRINGE	394,600	136,137	530,737	15.0%	0.150	32,883	24.00	29,595	10,221	39,816	
00101 SALARIES 00103 FRNG BN SUB TOTAL										29,595 10,221 <b>39,816</b>	
<ul> <li>TRAVEL</li> <li>1. Local Travel (02301)</li> <li>2. Out-of-Jurisdiction Travel (021</li> <li>Sub Total TRAVEL</li> </ul>	01)									0 0 <b>0</b>	
D. EQUIPMENT 1. Computer <b>(06061)</b> Sub Total EQ	QUIPMENT									0	
<ul> <li>MATERIALS AND SUPPLIES</li> <li>1. Office supplies (04951)</li> <li>2. Non-inventoried equipmt (0492)</li> <li>3. Clinical supplies (04431)</li> <li>4. Laboratory supplies (04431)</li> <li>Sub Total SU</li> </ul>										0 0 0 <b>0</b>	
CONTRACTUAL SERVICES (0278 1. PHFE Sub Total CC										0	
5. OTHER 1. Rent 2. Photocopier maint (02931) 3. Repro srvc (In House)(03551) 4. Print/Slide srvc (Outside)(0355) 5. Promotion and advertising(0356) 6. Client Stipends (02783) Sub TOTAL 0	52) 599)									0 0 0 0 0 0	

# SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

AIDS Office - Bridge HIV

Dept / Div: HPH-06sure prophylaxis to reduce sexually transmitted infections in PrEP users and HIV-infected men who have sex with men

Fund Group: 2S/CHS/GNC 04/01/20-03/31/21

SURPL/(DEFICIT)

Index Code: HCHIVRSRCHGR Monthly Expenditure and Projection Report

Grant Code: UCSF Grant

Grant Detail:

CATEGORY/LINE ITEM	Annual Salary	35% Annual Frin Ben	Total Annual Sal/Frin Ben		% OF FTE	Monthly Rate	Mth	Salary Budget	Frin Ben Budget	Total Budget	Comments
TOTAL DIRE	ECT COST									39,816	
			BUDGET SUM	MARY							
A. SALARIES										29,595	
B. MANDATORY FRI	NGE									10,221	
C. TRAVEL										0	
D. EQUIPMENT										0	
E. MATERIALS AND	SUPPLIES									0	
F. CONTRACT / MOU	J									0	
G. OTHER										0	
DIRECT CO	STS									39,816	
H. INDIRECT COST (	12% of Direc	ct Cost)								4,778	
TOTAL BUD	GET									44,594	
AWARD										0	

(44,594)

#### Notice of Award

Federal Award Date: 03/17/2020





## NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

**Grant Number:** 5R01Al143439-02 **FAIN:** R01Al143439

Principal Investigator(s):
CONNIE L CELUM, MD
Anne Frey Luetkemeyer (contact), MD

**Project Title:** Evaluation of doxycycline post-exposure prophylaxis to reduce sexually transmitted infections in PrEP users and HIV-infected men who have sex with men

Mathis, Julia K Research Services Coordinator 1001 Potrero Avenue Building 20, Rm 2407 4th floor San Francisco, CA 941431240

Award e-mailed to: cgrasteam@ucsf.edu

**Period Of Performance:** 

**Budget Period:** 04/01/2020 – 03/31/2021 **Project Period:** 04/12/2019 – 03/31/2024

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$1,410,621 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to The Regents of the UCSF in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI143439. 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 <a href="http://grants.nih.gov/grants/policy/coi/">http://grants.nih.gov/grants/policy/coi/</a> 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.

Gregory P. Smith Grants Management Officer NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

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

Federal Direct Costs	\$1,291,221
Federal F&A Costs	\$119,400
Approved Budget	\$1,410,621
Total Amount of Federal Funds Obligated (Federal Share)	\$1,410,621
TOTAL FEDERAL AWARD AMOUNT	\$1,410,621
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$1,410,621

SUMMARY TOTALS FOR ALL YEARS								
YR	THIS AWARD	CUMULATIVE TOTALS						
2	\$1,410,621	\$1,410,621						
3	\$1,410,670	\$1,410,670						
4	\$1,412,232	\$1,412,232						
5	\$1,412,385	\$1,412,385						

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

Fiscal Information:

CFDA Name: Allergy and Infectious Diseases Research

**CFDA Number:** 93.855

EIN: 1946036493A6

Document Number: RAI143439A

PMS Account Type: P (Subaccount)

Fiscal Year: 2020

IC	CAN	2020	2021	2022	2023
ΑI	8023029	\$1,410,621	\$1,410,670	\$1,412,232	\$1,412,385

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

**NIH Administrative Data:** 

PCC: M37B BR / OC: 41025 / Released: SMITHG 03/16/2020

Award Processed: 03/17/2020 12:01:01 AM

## SECTION II - PAYMENT/HOTLINE INFORMATION - 5R01AI143439-02

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

### SECTION III - TERMS AND CONDITIONS - 5R01AI143439-02

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

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain

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).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VI Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

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

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

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See <a href="http://grants.nih.gov/grants/policy/awardconditions.htm">http://grants.nih.gov/grants/policy/awardconditions.htm</a> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01Al143439. 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 <a href="http://grants.nih.gov/grants/policy/awardconditions.htm">http://grants.nih.gov/grants/policy/awardconditions.htm</a> 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 <a href="Public Law 110-85">Public Law 110-85</a>), the "responsible party" must register "applicable clinical trials" on the <a href="ClinicalTrials.gov Protocol Registration System Information Website">ClinicalTrials.gov Protocol Registration System Information Website</a>. NIH encourages registration of all trials whether required under the law or not. For more information, see <a href="http://grants.nih.gov/ClinicalTrials">http://grants.nih.gov/ClinicalTrials</a> fdaaa/

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make 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:** 

## SECTION IV - AI Special Terms and Conditions - 5R01AI143439-02

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

This award includes human subject research studies and must conform to the DHHS policies for the <u>Protection of Human Subjects</u> 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 <u>45 CFR 46</u>. Failure to comply with the terms and conditions of award may result in the disallowance of costs and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

\*\*\*\*

This award is subject to the Clinical Terms of Award referenced in the NIH Guide for Grants and Contracts, July 8, 2002, NOT Al-02-032. These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address: <a href="https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award">https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award</a> 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 Award.

This award may include collaborations with and/or between foreign organizations. Please be advised that short term travel visa expenses are an allowable expense on this grant, if justified as critical and necessary for the conduct of the project.

\*\*\*\*

The Research Performance Progress Report (RPPR), Section G.9 (Foreign component), includes reporting requirements for all research performed outside of the United States. Research conducted at the following site(s) must be reported in your RPPR:

#### • Assistance publique Hopitaux de Paris - FRANCE

\*\*\*\*

This Notice of Award (NoA) includes funds for activity with The University of Washington.

This Notice of Award (NoA) includes funds for activity with **Heluna Health**.

This Notice of Award (NoA) includes funds for activity with **San Francisco Department of Public Health.** 

\*\*\*\*

#### Select Agents:

Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

#### Highly Pathogenic Agent:

NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)

(http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm). Research funded under this grant

DocuSign Envelope ID: D6D2D901-5507-438C-A135-49BEB61E1310 are BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest

recommended containment level must be used.

When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- o A list of the new and/or additional Agent(s) that will be studied;
- o A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- o The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

#### 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: Yoon-sun Brennan

Email: brennany@mail.nih.gov Phone: 240-206-6435 Fax: 301-493-0597

Program Official: Delmyra B. Turpin

Email: turpindb@niaid.nih.gov Phone: 240-669-5597

SPREADSHEET SUMMARY

**GRANT NUMBER:** 5R01Al143439-02

**INSTITUTION:** The Regents of the UCSF

Facilities and Administrative Costs	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	37%	37%	37%	37%
F&A Cost Base 1	\$322,704	\$323,576	\$328,143	\$499,260
F&A Costs 1	\$119,400	\$119,723	\$121,413	\$184,726