FDP Cost Reimbursement Research Subaward Agreement

Federal Awarding Agency: National Institutes of Health (NIH)

Pass-Through Entity (PTE):	**Subrecipient:**
The Regents of the University of California, San Francisco	City & County of San Francisco
PTE PI: Annie F. Luetkemeyer	Sub PI: Susan Buchbinder
PTE Federal Award No: R01AI143439	Subaward No: 11324sc
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	
Subaward Period of Performance (Budget Period): Start: 04/12/2019 End: 03/31/2020	Amount Funded This Action (USD): $ 101,080.00
Estimated Project Period (if incrementally funded): Start: 04/12/2019 End: 03/31/2024	Incrementally Estimated Total (USD): $ 101,080.00

Terms and Conditions

1. PTE hereby awards a cost reimbursable subaward, as described above, to Subrecipient. The Statement of Work and budget for this Subaward are as shown in Attachment 5. In its performance of Subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.
2. Subrecipient shall submit invoices not more often than monthly and not less frequently than quarterly for allowable costs incurred. Upon the receipt of proper invoices, the PTE agrees to process payments in accordance with this Subaward and 2 CFR 200.305. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), Subaward number, and certification, as required in 2 CFR 200.415 (a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments shall be directed to the party's Financial Contact, shown in Attachment 3A.
3. A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Principal Investigator Contact, as shown in Attachment 3A, not later than **60** days after the Project Period end date. The final statement of costs shall constitute Subrecipient's final financial report.
4. All payments shall be considered provisional and are subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Subrecipient.
5. Matters concerning the technical performance of this Subaward shall be directed to the appropriate party's Principal Investigator as shown in Attachments 3A and 3B. Technical reports are required as shown in Attachment 4.
6. Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this Subaward, and any changes requiring prior approval, shall be directed to each party's Authorized Official Contact, as shown in Attachments 3A and 3B. Any such change made to this Subaward requires the written approval of each party's Authorized Official, as shown in Attachments 3A and 3B.
7. The PTE may issue non-substantive changes to the Period of Performance and budget Unilaterally Unilateral modification shall be considered valid 14 days after receipt unless otherwise indicated by Subrecipient when sent to Subrecipient's Authorized Official Contact, as shown in Attachment 3B.
8. Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.
9. Either party may terminate this Subaward with 30 days written notice to the appropriate party's Principal Investigator Contact, as shown in Attachments 3A and 3B. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix IX, as applicable.
10. By signing this Subaward, including the attachments hereto which are hereby incorporated by reference, Subrecipient certifies that it will perform the Statement of Work in accordance with the terms and conditions of this Subaward and the applicable terms of the Federal Award, including the appropriate Research Terms and Conditions ("RTCs") of the Federal Awarding Agency, as referenced in Attachment 2. The parties further agree that they intend this Subaward to comply with all applicable laws, regulations and requirements.

By an Authorized Official of Pass-through Entity:	By an Authorized Official of Subrecipient:
DocuSigned by: Rachel Sievert 52A772F461AE4C6...	DocuSigned by: Tomas Aragon 0BDB2B95DBC0442...
5/22/2019	05/17/2019
Name: Rachel Sievert Date	Name: Tomas Aragon Date
Title: Assistant Director	Title: Director of Population Health Divison (PHD)

Attachment 1
Certifications and Assurances

Subaward Number: 11324sc

Certification Regarding Lobbying (2 CFR 200.450)
By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief, that no Federal appropriated funds have been paid or will be paid, by or on behalf of the Subrecipient, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement in accordance with 2 CFR 200.450.

If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or intending to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the Subrecipient shall complete and submit Standard Form -LLL, "Disclosure Form to Report Lobbying," to the PTE.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by 31 U.S.C. 1352. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Debarment, Suspension, and Other Responsibility Matters (2 CFR 200.213 and 2 CFR 180)
By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief that neither the Subrecipient nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this transaction by any federal department or agency, in accordance with 2 CFR 200.213 and 2 CFR 180.

Audit and Access to Records
Per 2 CFR 200.501- 200.521, Subrecipient certifies that it will provide notice of any adverse findings which impact this Subaward and will provide access to records as required by parts 2 CFR 200.336, 200.337, and 200.201 as applicable. If Subrecipient is not subject to the Single Audit Act, then Subrecipient will provide notice of the completion of any required audits and provide access to such audits upon request. Audit findings related to this award will be reported to PTE within 30 days.

Program for Enhancement of Contractor Employee Protections (41 U.S.C 4712)
Subrecipient is hereby notified that they are required to: inform their employees working on any federal award that they are subject to the whistleblower rights and remedies of the pilot program; inform their employees in writing of employee whistleblower protections under 41 U.S.C §4712 in the predominant native language of the workforce; and include such requirements in any agreement made with a subcontractor or subgrantee.

The Subrecipient shall require that the language of the certifications above in this Attachment 1 be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

Use of Name
Neither party shall use the other party’s name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may use factual information regarding the existence and purpose of the relationship that is the subject of this Subaward for legitimate business purposes, to satisfy any reporting and funding obligations, or as required by applicable law or regulation without written permission from the other party. In any such statement, the relationship of the parties shall be accurately and appropriately described.

Attachment 2
Federal Award Terms and Conditions

Subaward Number: 11324sc

Required Data Elements

The data elements required by Uniform Guidance are incorporated in the attached Federal Award.

Federal Award Issue Date	FAIN	CFDA No.
04/12/19	R01AI143439	93.855

CFDA Title: Allergy and Infectious Diseases Research

Key Personnel Per NOA: Annie F. Luetkemeyer

This Subaward Is:

- [x] Research & Development
- [x] Subject to FFATA

General Terms and Conditions

By signing this Subaward, Subrecipient agrees to the following:

1. To abide by the conditions on activities and restrictions on expenditure of federal funds in appropriations acts that are applicable to this Subaward to the extent those restrictions are pertinent. This includes any recent legislation noted on the Federal Awarding Agency's website:
   http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf
2. 2 CFR 200 and 45 CFR Part 75.
3. The Federal Awarding Agency's grants policy guidance, including addenda in effect as of the beginning date of the period of performance or as amended found at:
   http://grants.nih.gov/policy/notices.htm
4. Research Terms and Conditions, including any Federal Awarding Agency's Specific Requirements found at:
   https://www.nsf.gov/awards/managing/rtc.jsp except for the following :
   a. No-cost extensions require the written approval of the PTE. Any requests for a no-cost extension shall be directed to the Principal Investigator Contact shown in Attachment 3A, not less than 30 days prior to the desired effective date of the requested change.
   b. Any payment mechanisms and financial reporting requirements described in the applicable Federal Awarding Agency Terms and Conditions and Agency-Specific Requirements are replaced with Terms and Conditions (1) through (4) of this Subaward; and
   c. Any prior approvals are to be sought from the PTE and not the Federal Awarding Agency.
   d. Title to equipment as defined in 2 CFR 200.33 that is purchased or fabricated with research funds or Subrecipient cost sharing funds, as direct costs of the project or program, shall vest in the Subrecipient subject to the conditions specified in 2 CFR 200.313.
   e. Prior approval must be sought for a change in Subrecipient PI or change in Key Personnel (defined as listed on the NOA).
5. Treatment of program income: Additive

Multiple PIs (MPI)

? This subaward is not subject to an MPI Leadership Plan.

Special Terms and Conditions:

Copyrights:

Subrecipient Grants to PTE an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted material (including any computer software and its documentation and/or databases) first developed and delivered under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Subrecipient grants to PTE the right to use any written progress reports and deliverables created under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its Federal Award.

Data Rights:

Subrecipient grants to PTE the right to use data created in the performance of this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Data Sharing and Access (Check if applicable)**:**

- [ ] Subrecipient agrees to comply with the Federal Awarding Agency's data sharing and access requirements as reflected in the NOA (or in the special terms below) and the Data Management/Sharing Plan submitted to the Federal Awarding Agency and attached.

Promoting Objectivity in Research (COI):

Subrecipient must designate herein which entity's Financial Conflicts of Interest policy (COI) will apply:

If applying its own COI policy, by execution of this Subaward, Subrecipient certifies that its policy complies with the requirements of the relevant Federal Awarding Agency as identified herein: NIH - 42 CFR Part 50 Subpart F

Subrecipient shall report any financial conflict of interest to PTE's Administrative Representative or COI contact, as designated on Attachment 3A. Any financial conflicts of interest identified shall, when applicable, subsequently be reported to Federal Awarding Agency. Such report shall be made before expenditure of funds authorized in this Subaward and within 45 days of any subsequently identified COI.

Work Involving Human or Vertebrate Animals (Select Applicable Options)

■ Human Subjects ☐ Vertebrate Animals ☐ No Human or Vertebrate Animals

Subrecipient agrees that any non-exempt human and/or vertebrate animal research protocol conducted under this Subaward shall be reviewed and approved by its Institutional Review Board (IRB) and/or its Institutional Animal Care and Use Committee (IACUC), as applicable and that it will maintain current and duly approved research protocols for all periods of the Subaward involving human and/or vertebrate animal research. Subrecipient certifies that its IRB and/or IACUC are in full compliance with applicable state and federal laws and regulations. The Subrecipient certifies that any submitted IRB / IACUC approval represents a valid, approved protocol that is entirely consistent with the Project associated with this Subaward. In no event shall Subrecipient invoice or be reimbursed for any human or vertebrate animals related expenses incurred in a period where any applicable IRB / IACUC approval is not properly in place.

The PTE requires verification of IRB and/or IACUC approval be sent to the Administrative Contact as follows:

IRB

Upon Request

Human Subjects Data (Select One) Not Applicable

This section left intentionally blank

Additional Terms

Attachment 3A
Pass-Through Entity (PTE) Contacts

Subaward Number: 11324sc

PTE Information

Entity Name:	The Regents of the University of California, San Francisco
Legal Address:	c/o Office of Sponsored Research, Box 0962 3333 California Street, Suite 315 San Francisco, CA 94143 (Use 94118-6215 for Federal Express)
Website:	www.ucsf.edu

PTE Contacts

Central Email:	cgsuboutteam@ucsf.edu		
Principal Investigator Name:	Annie F. Luetkemeyer		
Email:	Annie.Luetkemeyer@ucsf.edu	Telephone Number:	
Administrative Contact Name:	Julia Mathis		
Email:	Julia.Mathis@ucsf.edu	Telephone Number:	
COI Contact email (if different to above):			
Financial Contact Name:	Brandi Moretz		
Email:	scmap@ucsf.edu	Telephone Number:	
Email invoices? (●) Yes ( ) No	Invoice email (if different):		
Authorized Official Name:	Rachel Sievert		
Email:	Rachel.Sievert@ucsf.edu	Telephone Number:	415-502-5697

PI Address:

same as legal address above

Administrative Address:

same as legal address above

Invoice Address:

subcontract@ucsf.edu
same as legal address above

Attachment 3B

Subrecipient Contacts

Subaward Number: 11324sc

Subrecipient Information for FFATA reporting

Entity's DUNS Name: City and County of San Francisco

EIN No.: 94-6000417

Institution Type: Other

DUNS: 103717336

Currently registered in SAM.gov: (•) Yes ( ) No

Exempt from reporting executive compensation: (•) Yes ( ) No *(if no, complete 3Bpg2)*

Parent DUNS: 103717336

This section for U.S. Entities:

Congressional District: 12

Zip Code Look-up

Zip Code+4: 94102-2614

Place of Performance Address

25 Van Ness Ave, SF, CA 94102

Subrecipient Contacts

Central Email:

Website: www.sfdph.org

Principal Investigator Name: Susan Buchbinder

Email: susan.buchbinder@sfdph.org Telephone Number: 415-437-7479

Administrative Contact Name: Delia Molloy

Email: Delia.Molly@sfdph.org Telephone Number: 415-437-7478

Financial Contact Name: Sajid Shaikh

Email: sajid.shaikh@sfdph.org Telephone Number: 415-255-3512

Invoice/Payment Email: David.Anabu@sfdph.rog

Authorized Official Name: Tomas Aragon

Email: tomas.aragon@sfdph.org Telephone Number: 415-787-2583

Legal Address:

101 Grove St, SF, CA 94102

Administrative Address:

25 Van Ness Ave, SF, CA 94102

Payment Address:

1380 Howard St, 4th Fl, SF, CA 94103

Attachment 3B-2

Highest Compensated Officers

Subaward Number: 11324sc

Subrecipient:

Institution Name: City & County of San Francisco

PI Name: Susan Buchbinder

Highest Compensated Officers

The names and total compensation of the five most highly compensated officers of the entity(ies) must be listed if the entity in the preceding fiscal year received 80 percent or more of its annual gross revenues in Federal awards; and $25,000,000 or more in annual gross revenues from Federal awards; and the public does not have access to this information about the compensation of the senior executives of the entity through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. See FFATA § 2(b)(1) Internal Revenue Code of 1986.

Officer 1 Name: n/a

Officer 1 Compensation:

Officer 2 Name:

Officer 2 Compensation:

Officer 3 Name:

Officer 3 Compensation:

Officer 4 Name:

Officer 4 Compensation:

Officer 5 Name:

Officer 5 Compensation:

Attachment 4
Reporting and Prior Approval Terms

Subaward Number: 11324sc

Subrecipient agrees to submit the following reports (PTE contacts are identified in Attachment 3A):

Technical Reports:

☐ Monthly technical/progress reports will be submitted to the PTE's Administrative Contact within 15 days of of the end of the month.

☐ Quarterly technical/progress reports will be submitted within 30 days after the end of each project quarter to the PTE's Administrative Contact

☒ Annual technical / progress reports will be submitted within 60 days prior to the end of each budget period to the PTE's Administrative Contact . Such report shall also include a detailed budget for the next Budget Period, updated other support for key personnel, certification of appropriate education in the conduct of human subject research of any new key personnel, and annual IRB or IACUC approval, if applicable.

☒ A Final technical/progress report will be submitted to the PTE's Administrative Contact within 60 days of the end of the Project Period or after termination of this award, whichever comes first.

☐ Technical/progress reports on the project as may be required by PTE's Administrative Contact in order for the PTE to satisfy its reporting obligations to the Federal Awarding Agency.

Prior Approvals:

Carryover:
Carryover is automatic

Other Reports:

☐ In accordance with 37 CFR 401.14, Subrecipient agrees to notify PTE's Administrative Contact within 60 days after Subrecipient's inventor discloses invention(s) in writing to Subrecipient's personnel responsible for patent matters. The Subrecipient will submit a final invention report using Federal Awarding Agency specific forms to the PTE's Administrative Contact within 60 days of the end of the Project Period to be included as part of the PTE's final invention report to the Federal Awarding Agency.

A negative report is required:

☐ Property Inventory Report (only when required by Federal Awarding Agency), specific requirements below.

Other Special Reporting Requirements:

Attachment 5
Statement of Work, Cost Sharing, Indirects & Budget

Subaward Number: 11324sc

Statement of Work

(●) Below ( ) Attached, [ ] pages

If award is FFATA eligible and SOW exceeds 4000 characters, include a *Subrecipient Federal Award Project Description*

San Francisco Department of Public Health (SFDPH): Two study investigators, Drs Buchbinder and Cohen, are DPH employees and receive their salary support through DPH. Dr. Buchbinder is the senior PREP lead on the study and Dr. Cohen is the site principal investigator for the City Clinic site. Dr Cohen will oversee planning and implementation of the DoxyPEP study at SF City CIinic and supervise recruitment and retention. The SFCC site is expected to enroll approximately 190 participants over 2-2.5 years. Drs Buchbinder and Cohen will contribute to the scientific conduct of the study, including input into the analysis plan, DSMB plan, manuscript preparation and dissemination of results.

Budget Information

Indirect Information Indirect Cost Rate (IDC) Applied: 12 %

Rate Type: Modified Total Direct Costs

Cost Sharing: No

If Yes, include Amount: $

Budget Details

(●) Below ( ) Attached, [ ] pages

Budget Totals

Direct Costs	$ 90,250.00
Indirect Costs	$ 10,830.00
Total Costs	$ 101,080.00

All amounts are in United States Dollars

RESEARCH & RELATED BUDGET - Budget Period 1

OMB Number: 4040-0001
Expiration Date: 10/31/2019

ORGANIZATIONAL DUNS: 0000000000000 **Enter name of Organization:** San Francisco Department of Public Health

Budget Type: ☐ Project ☒ Subaward/Consortium **Budget Period: 1** **Start Date:** 04/12/2019 **End Date:** 03/31/2020

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary ($)	Months Cal.	Months Acad.	Months Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)
Dr.	Susan		Buchbinder		189,600.00	2.30			36,024.00	14,410.00	50,434.00
Project Role:	Co-Investigator										
Dr.	Stephanie		Cohen		189,600.00	1.80			28,440.00	11,376.00	39,816.00
Project Role:	Co-Investigator										

Additional Senior Key Persons: Add Attachment | Delete Attachment | View Attachment

Total Funds requested for all Senior Key Persons in the attached file

Total Senior/Key Person 90,250.00

B. Other Personnel

Number of Personnel	Project Role	Months Cal.	Months Acad.	Months Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						

Total Number Other Personnel

Total Other Personnel

Total Salary, Wages and Fringe Benefits (A+B) 90,250.00

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment item	Funds Requested ($)

Additional Equipment: Add Attachment | Delete Attachment | View Attachment

Total funds requested for all equipment listed in the attached file	
Total Equipment	

D. Travel

	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs

	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other	
Number of Participants/Trainees — **Total Participant/Trainee Support Costs**	

F. Other Direct Costs

		Funds Requested ($)
1.	Materials and Supplies	
2.	Publication Costs	
3.	Consultant Services	
4.	ADP/Computer Services	
5.	Subawards/Consortium/Contractual Costs	
6.	Equipment or Facility Rental/User Fees	
7.	Alterations and Renovations	
8.		
9.		
10.		
	Total Other Direct Costs	

G. Direct Costs

	Funds Requested ($)
Total Direct Costs (A thru F)	90,250.00

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)
MTDC	12.00	90,250.00	10,830.00

Total Indirect Costs 10,830.00

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs

	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	101,080.00

J. Fee

Funds Requested ($)

K. Total Costs and Fee

	Funds Requested ($)
Total Costs and Fee (I + J)	101,080.00

L. Budget Justification

(Only attach one file.) Add Attachment | Delete Attachment | View Attachment

BUDGET JUSTIFICATION
San Francisco Department of Public Health (SF DPH)

PERSONNEL

Key Personnel

Susan Buchbinder, MD, MPH, Co-investigator and Senior Lead, PrEP Cohort (2.3 calendar months Year 1, 0.6 calendar months Years 2,3,4, 1.7 calendar months Year 5). Dr. Buchbinder is a Professor of Medicine and Epidemiology at UCSF and the Director of Bridge HIV, a grant-funded HIV prevention research unit based in the San Francisco Department of Public Health (SF DPH). She has over 30 year of experience leading multi-site efforts to understand risk factors for HIV infection and conduct HIV prevention intervention trials, including providing scientific direction and oversight of the implementation of multi-site PrEP trials. She had led her team in the development of smartphone applications to help MSM assess their sexual risk, and to measure and improve adherence to PrEP. Dr. Buchbinder will serve as Senior Lead of the PrEP cohorts, providing scientific direction and oversight for the PrEP cohorts in San Francisco and Seattle for recruitment, retention, protocol implementation, and strategies to engage with MSM stakeholders and community members. As an expert in PrEP and clinical trials in MSM populations highly impacted by STI, she will play in integral role in study development, implementation, data analysis, interpretation and dissemination of study results. Additionally, Dr. Buchbinder will provider mentorship and oversight to Dr. Cohen in her role as site Principal Investigator for SF City Clinic (municipal STI clinic and enrolling study site)and to Dr. Scott, who will lead the development and modification of the smartphone application Blackbook for use in this project.

Stephanie Cohen, MD, Co-Investigator, Site Principal Investigator of the PrEP Clinic, San Francisco City Clinic (SFCC), SF DPH (1.8 calendar months Year 1, 1.2 calendar months Year 2, 1.0 calendar months Year 3, 1.0 calendar months Year 4). Dr. Cohen is an Assistant Professor of Medicine at UCSF and the Medical Director of SFCC). She will be responsible for the overall scientific, operational and administrative aspects of the study at SFCC, which will enroll MSM on PrEP. Dr. Cohen will be responsible for study implementation, enrollment and retention, data collection, evaluation and reporting of AEs, clinical management of study participants, and quality management. Along with the study Principal Investigators, she 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 will participate in data analyses and publication of results.

Professional Staff

Trang Nguyen, PhD, MPH, Epidemiologist (0.8 calendar months, Year 5). Dr. Nguyen is an epidemiologist in the Applied Epidemiology, Community Health Epidemiology, and Surveillance (ARCHES) division of the Sn Francisco Department of Public Health, which coordinates data collection, processing management, analysis, and interpretation of San Francisco public health data. As the lead for STI data analysis for SF DPH, Dr. Nguyen will review and extract all available citywide STI diagnosis for San Francisco study participants at the SFCC and ZSFG HIV Clinic sites during the time of their study enrollment, to identify incident STIs that occurred outside of the study setting.

Indirects are calculated at a rate of 12%

Attachment 6

Notice of Award (NOA) and any additional documents

◉ The following pages include the NOA and if applicable any additional documentation referenced throughout this Subaward.

○ Not incorporating the NOA or any additional documentation to this Subaward.

Notice of Award

RESEARCH

Federal Award Date: 04/12/2019

Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 1R01AI143439-01A1
FAIN: R01AI143439

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: 04/12/2019 – 03/31/2020
Project Period: 04/12/2019 – 03/31/2024

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $1,418,675 (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 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,

Philip E. Smith
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

SECTION I – AWARD DATA – 1R01AI143439-01A1

Award Calculation (U.S. Dollars)

Salaries and Wages	$169,569
Fringe Benefits	$64,228
Personnel Costs (Subtotal)	$233,797
Consultant Services	$5,000
Materials & Supplies	$7,000
Travel	$6,500
Other	$63,417
Subawards/Consortium/Contractual Costs	$955,421
ADP/Computer Services	$2,172
Federal Direct Costs	$1,273,307
Federal F&A Costs	$145,368
Approved Budget	$1,418,675
Total Amount of Federal Funds Obligated (Federal Share)	$1,418,675
TOTAL FEDERAL AWARD AMOUNT	$1,418,675
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$1,418,675

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$1,418,675	$1,418,675
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:	2019

IC	CAN	2019	2020	2021	2022	2023
AI	8023029	$1,418,675	$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**: 414A / **Released**: SMITHPE 04/08/2019
Award Processed: 04/12/2019 05:52:58 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01AI143439-01A1

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 – 1R01AI143439-01A1

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 references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

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 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) R01AI143439. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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

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

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

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

Treatment of Program Income:
Additional Costs

SECTION IV – AI Special Terms and Conditions – 1R01AI143439-01A1

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.

The budget period anniversary start date for future year(s) will be **April** 1.
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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.
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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
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This Notice of Award (NoA) includes funds for activity with **San Francisco Department of Public Health** in the amount of **$101,080** (**$90,250** direct costs + **$10,830** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Heluna Health** in the amount of **$175,458** (**$155,273** direct costs + **$20,185** F&A costs).

This Notice of Award (NoA) includes funds for activity with **University of Washington** in the amount of **$678,883** (**$436,581** direct costs + **$242,302** F&A costs).
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This award includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.
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This award is subject to the Clinical Terms of Award referenced in the 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: https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award 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.
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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 must adhere to the BMBL, including using the 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:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- 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: Trevor T Alford
Email: trevor.alford@nih.gov **Phone**: 240-669-2916 **Fax**: 301-493-0597

Program Official: Delmyra B. Turpin
Email: turpindb@niaid.nih.gov **Phone**: 240-669-5597

SPREADSHEET SUMMARY
GRANT NUMBER: 1R01AI143439-01A1

INSTITUTION: The Regents of the UCSF

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$169,569	$147,771	$140,683	$159,059	$194,217
Fringe Benefits	$64,228	$58,638	$56,091	$62,963	$72,696
Personnel Costs (Subtotal)	$233,797	$206,409	$196,774	$222,022	$266,913
Consultant Services	$5,000	$5,000	$5,000	$5,000	$5,000
Materials & Supplies	$7,000		$1,000		$1,000
Travel	$6,500				$10,000
Other	$63,417	$109,114	$118,707	$98,752	$210,453
Subawards/Consortium/Contractual Costs	$955,421	$968,517	$967,371	$962,676	$728,399
Publication Costs					$3,500
ADP/Computer Services	$2,172	$2,181	$2,095	$2,369	$2,394
TOTAL FEDERAL DC	$1,273,307	$1,291,221	$1,290,947	$1,290,819	$1,227,659
TOTAL FEDERAL F&A	$145,368	$119,400	$119,723	$121,413	$184,726
TOTAL COST	$1,418,675	$1,410,621	$1,410,670	$1,412,232	$1,412,385

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	37%	37%	37%	37%	37%
F&A Cost Base 1	$392,886	$322,704	$323,576	$328,143	$499,260
F&A Costs 1	$145,368	$119,400	$119,723	$121,413	$184,726