

File No. 120823

Committee Item No. 7

Board Item No. _____

COMMITTEE/BOARD OF SUPERVISORS

AGENDA PACKET CONTENTS LIST

Committee: Budget and Finance Committee

Date 09/19/2012

Board of Supervisors Meeting

Date _____

Cmte Board

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| <input type="checkbox"/> | <input type="checkbox"/> | Motion |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Resolution |
| <input type="checkbox"/> | <input type="checkbox"/> | Ordinance |
| <input type="checkbox"/> | <input type="checkbox"/> | Legislative Digest |
| <input type="checkbox"/> | <input type="checkbox"/> | Budget and Legislative Analyst Report |
| <input type="checkbox"/> | <input type="checkbox"/> | Legislative Analyst Report |
| <input type="checkbox"/> | <input type="checkbox"/> | Youth Commission Report |
| <input type="checkbox"/> | <input type="checkbox"/> | Introduction Form (for hearings) |
| <input type="checkbox"/> | <input type="checkbox"/> | Department/Agency Cover Letter and/or Report |
| <input type="checkbox"/> | <input type="checkbox"/> | MOU |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Grant Information Form |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Grant Budget |
| <input type="checkbox"/> | <input type="checkbox"/> | Subcontract Budget |
| <input type="checkbox"/> | <input type="checkbox"/> | Contract/Agreement |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Form 126 – Ethics Commission |
| <input type="checkbox"/> | <input type="checkbox"/> | Award Letter |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Application |
| <input type="checkbox"/> | <input type="checkbox"/> | Public Correspondence |

OTHER (Use back side if additional space is needed)

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Completed by: Victor Young Date September 14, 2012

Completed by: Victor Young Date _____

1 [Accept and Expend Grant - The Stop Study - \$747,833]
2

3 **Resolution authorizing the San Francisco Department of Public Health to retroactively**
4 **accept and expend a grant in the amount of \$747,833 from Centers for Disease Control**
5 **and Prevention to participate in a program entitled "The Stop Study" for the period of**
6 **June 15, 2012, through June 14, 2013.**
7

8 WHEREAS, The Centers for Disease Control and Prevention (CDC) has agreed to
9 fund Department of Public Health (DPH) in the amount of \$747,833 for the period of June 15,
10 2012 through June 14, 2013; and

11 WHEREAS, As a condition of receiving the grant funds, CDC requires the City to enter
12 into an agreement (Agreement), a copy of which is on file with the Clerk of the Board of
13 Supervisors in File No. 120823; which is hereby declared to be a part of this Resolution as if
14 set forth fully herein; and

15 WHEREAS, The purpose of this project is to evaluate the yield, cost-effectiveness, and
16 feasibility of enhanced partner notification/contact tracing techniques linked to acute HIV
17 infection screening; and

18 WHEREAS, DPH will subcontract with Public Health Foundation Enterprises, Inc;
19 UCSF/AIDS Health Project; SF AIDS Foundation, Magnet; and as yet to-be-determined
20 entity, and MOUs with DPH's Lab and STD units, in the total amount of \$711,557; for the
21 period of June 15, 2012 through, June 14, 2013; and

22 WHEREAS, An Annual Salary Ordinance amendment is not required as the grant
23 partially reimburses DPH for two existing positions, one Manager II (Job Class No. 0923) at
24 .10 FTE and one Health Worker III (Job Class No. 2587) at .10 FTE for the period of June 15,
25 2012 through, June 14, 2013; and

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WHEREAS, The budget includes a provision for indirect costs in the amount of \$5,163;
now, therefore, be it

RESOLVED, That DPH is hereby authorized to retroactively accept and expend a grant
in the amount of \$747,833 from CDC; and, be it

FURTHER RESOLVED, That DPH is hereby authorized to retroactively accept and
expend the grant funds pursuant to San Francisco Administrative Code section 10.170-1; and,
be it

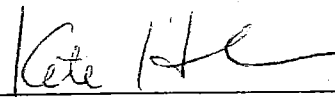
FURTHER RESOLVED, That the Director of Health is authorized to enter into the
Agreement on behalf of the City.

RECOMMENDED:



Barbara A. Garcia, MPA
Director of Health

APPROVED:



Office of the Mayor



Office of the Controller



Edwin M. Lee
Mayor

Barbara A. Garcia, MPA
Director of Health

TO: Angela Calvillo, Clerk of the Board of Supervisors

FROM: Barbara A. Garcia, MPA
Director of Health

DATE: June 28, 2012

SUBJECT: Grant Accept and Expend

GRANT TITLE: The Stop Study- \$747,833

Attached please find the original and 4 copies of each of the following:

- Proposed grant resolution, original signed by Department
- Grant information form, including disability checklist -
- Budget and Budget Justification
- Grant application: Not Applicable. No application submitted. Asked to participate in the project.
- Agreement / Award Letter
- Other (Explain):

Special Timeline Requirements:

Departmental representative to receive a copy of the adopted resolution:

Name: Richelle-Lynn Mojica

Phone: 255-3555

Interoffice Mail Address: Dept. of Public Health, Grants Administration for
Community Programs, 1380 Howard St.

Certified copy required Yes

No

File Number: _____
(Provided by Clerk of Board of Supervisors)

Grant Information Form
(Effective March 2005)

Purpose: Accompanies proposed Board of Supervisors resolutions authorizing a Department to accept and expend grant funds.

The following describes the grant referred to in the accompanying resolution:

1. Grant Title: **The STOP Study**
2. Department: **Department of Public Health
AIDS Office
HIV Prevention Section**
3. Contact Person: **Tracey Packer** Telephone: **554-9992**
4. Grant Approval Status (check one):
 Approved by funding agency Not yet approved
5. Amount of Grant Funding Approved or Applied for: **\$747,833**
- 6a. Matching Funds Required: **\$0**
b. Source(s) of matching funds (if applicable):
- 7a. Grant Source Agency: **Centers for Disease Control and Prevention (CDC)**
b. Grant Pass-Through Agency (if applicable): **N/A**
8. Proposed Grant Project Summary:
 - i) **To evaluate the yield, cost-effectiveness, and feasibility of screening for acute HIV infection (AHI) with a fourth-generation enzyme immunoassay (EIA) in high-risk/high-incidence settings compared to pooled nucleic acid amplification testing (NAAT).**
 - ii) **To evaluate the yield, cost-effectiveness, and feasibility of enhanced partner notification/contact tracing techniques linked to acute HIV infection (AHI) screening.**
9. Grant Project Schedule, as allowed in approval documents, or as proposed:
Start-Date: **06/15/2012** End-Date: **06/14/2013**
- 10a. Amount budgeted for contractual services: **\$711,557**
b. Will contractual services be put out to bid? **No.**
c. If so, will contract services help to further the goals of the department's MBE/WBE requirements? **N/A**
d. Is this likely to be a one-time or ongoing request for contracting out? **N/A**
- 11a. Does the budget include indirect costs? Yes No
b1. If yes, how much? **\$5,163**
b2. How was the amount calculated? **24.84% of total salaries**

c. If no, why are indirect costs not included?

Not allowed by granting agency

Other (please explain):

To maximize use of grant funds on direct services

c2. If no indirect costs are included, what would have been the indirect costs?

12. Any other significant grant requirements or comments:

Grant Code is: HCAO24/12

****Disability Access Checklist****

13. This Grant is intended for activities at (check all that apply):

Existing Site(s)

Existing Structure(s)

Existing Program(s) or Service(s)

Rehabilitated Site(s)

Rehabilitated Structure(s)


New Program(s) or Service(s)

New Site(s)


New Structure(s)

14. The Departmental ADA Coordinator and/or the Mayor's Office on Disability have reviewed the proposal and concluded that the project as proposed will be in compliance with the Americans with Disabilities Act and all other Federal, State and local access laws and regulations and will allow the full inclusion of persons with disabilities, or will require unreasonable hardship exceptions, as described in the comments section:

Comments:

Departmental or Mayor's Office of Disability Reviewer: 
Jason Hashimoto

Date Reviewed: 7/4/12

Department Approval:  Br
Barbara A. Garcia, MPA (Signature) Director of Public Health

**SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH
AIDS OFFICE - HIV PREVENTION SECTION**

The STOP Study
June 15, 2012 - June 14, 2013

Dept / Div: HPH/03
Fund Group: 2S/CHS/GNC
Index Code: HCHPD/HIVSVGR
Grant Code: HCAO24
Grant Detail: 1200

salary cap, 179,700

CATEGORY/LINE ITEM	Annual Salary	26% 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. Senior Physician Specialist 2332 7 G. Collax	\$ 179,700	\$ 46,722	\$ 226,422	5%	0	\$ 14,975	0	\$ -	\$ -	\$ -	
** 2. Manager II 0923 5 T Packer	\$ 116,792	\$ 30,366	\$ 147,158	10%	0.10	\$ 9,733	12	\$ 11,679	\$ 4,905	\$ 16,584	
3. Health Worker III 2587 5 Alice Heimsoth	\$ 60,164	\$ 15,643	\$ 75,807	10%	0.10	\$ 5,014	12	\$ 6,016	\$ 2,527	\$ 8,543	
4. COLA 4%	\$ -	\$ -	\$ -	0%	0	\$ -	0	\$ 3,089	\$ 1,297	\$ 4,385	
5. STEP Increases 5%	0	0	0	0%	0.00	0	0	0	0	0	
TOTAL SALARYFRINGE	356,656	92,731	449,387		0.20			20,784	8,729	29,513	

00101 SALARIES:
00103 FRNG BN:
Sub Total:

\$ 20,784
\$ 8,729
\$ 29,513

C. TRAVEL
Sub Total TRAVEL

\$ -
\$ -

D. EQUIPMENT
Sub Total EQUIPMENT

\$ -
\$ -

E. MATERIALS AND SUPPLIES
1. Office supplies (04951)
Sub Total SUPPLIES

\$ -
\$ -

F. CONTRACTUAL-SERVICES (02789)
1. PHFE
2. UCSF/AIDS Health Project
3. SF AIDS Foundation, Magnet
4. Unallocated
5. MOU - Lab
6. MOU - STD
7.

\$ 239,056
\$ 47,678
\$ 34,332
\$ 35,963
\$ 278,286
\$ 76,242
\$ 711,557

Sub Total CONTRACTUAL

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH
 AIDS OFFICE - HIV PREVENTION SECTION
 The STOP Study
 June 15, 2012 - June 14, 2013

Dept / Div: HPH/03
 Fund Group: 2S/CHS/GNC
 Index Code: HCHPD/HIVSVGR
 Grant Code: HCAO24
 Grant Detail: 1200

salary cap, 179,700

CATEGORY/LINE ITEM	Annual Salary	25% Annual Frin Ben	Total Annual Sal/Frin Ben	% OF TIME	% OF FTE	Monthly Rate	Mth	Salary Budget	Frin Ben Budget	Total Budget	Comments
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G. OTHER
 1. IRB Fees (02799)
 Sub Total OTHER
 TOTAL DIRECT COSTS

\$	1,600									\$ 1,600	
\$	1,600									\$ 1,600	
\$										\$ 742,670	

BUDGET SUMMARY

A. SALARIES	\$ 20,784	FTE = 0.20
B. MANDATORY FRINGE	\$ 8,729	
C. TRAVEL	\$ -	
D. EQUIPMENT	\$ -	
E. MATERIALS AND SUPPLIES	\$ -	
F. CONTRACT / MOU	\$ 711,557	
G. OTHER	\$ 1,600	
DIRECT COSTS	\$ 742,670	
H. INDIRECT COST (24.84% of total salaries)	\$ 5,163	
TOTAL BUDGET	\$ 747,833	
AWARD	\$ 747,833	
SURPL/(DEFICIT)	\$ 0	

San Francisco Department of Public Health (SFDPH)
 AIDS Office, HIV Prevention Section

"The STOP Study"

San Francisco Department of Public Health Budget Justification
 Year 3: June 15, 2012 – June 14, 2013

A. PERSONNEL

B. MANDATORY FRINGE

TOTAL PERSONNEL	\$20,784
Salary	\$8,729
Fringe @ 42% of salaries	\$29,513

- 0.10 FTE
 0923 Manager II, Deputy Director: T. Packer
 Annual Salary \$116,792 x 0.10 FTE for 12 months = \$11,679

The Deputy Director assists the Director in oversight of all activities of the HPS and is the Director of Community-Based Prevention. As such, oversees a team of staff members that provide capacity building, technical assistance and training for community-based providers that offer interventions such as HIV testing, comprehensive prevention with positives, and condom distribution. The team partners with providers to determine how to implement innovative, integrated, effective HIV prevention programs, assists with program and contract development, and ensures that contract deliverables are met, develops and implements trainings, policies, and procedures and provides technical assistance.

- 0.10 FTE
 2587 Health Worker III: A. Heimsoth
 Annual Salary \$59,592 x 0.10 FTE for 12 months = \$6,016

This position works with HIV testing providers to ensure quality control and inventory of HIV testing supplies, including phlebotomy supplies. In addition Ms. Heimsoth is responsible for purchasing and delivers HIV testing supplies to providers.

3. COLA	\$3,089
C. TRAVEL	\$0
D. CONSULTANTS	\$0
E. EQUIPMENT	\$0
E. MATERIALS AND SUPPLIES	\$0

F. CONTRACTUAL \$711,557

1. Name of Contractor: Public Health Foundation Enterprises, Inc. (PHFE)
Method of Selection: Request For Qualifications (RFQ) 15-2006 (Awarded 2006)

Period of Performance: 06/15/2012 - 06/14/2013

Scope of work

- i) Service category: Fiscal Intermediary
 - (1) Award amount: \$239,056
 - (2) Subcontractors: UCSD
- ii) Services provided: Fiscal intermediary services to the SFDPH HPS. PHFE pays for staff members and travel that support the goals and objectives of the STOP Study.

Method of Accountability: Annual program and fiscal and compliance monitoring

Itemized budget and justification:

- a) PHFE Personnel
- b) PHFE Mandatory Fringe

PHFE Total Personnel	\$56,209
PHFE Salary	\$45,259
PHFE Fringe @ 24.19% of salaries	\$10,950

- i. Director of Clinical Prevention: Nicholas Moss, MD
 Annual Salary \$130,000 x 0.10 FTE for 12 months = \$13,000

Dr. Moss will serve as the Project Director for this project and will be responsible for managing the project on a day to day basis. He will oversee all aspects of the project and will report directly Dr. Colfax. He will also act as the primary liaison with CDC for the project.

- ii. Data Systems Specialist: Nayla Raad
 Annual Salary \$70,000 x 0.25 FTE for 12 months = \$17,500

Ms. Raad will provide data management and data reporting for the STOP Study.

- iii. Community Interventions Coordinator: Thomas Knoble
 Annual Salary \$73,793 x .20 for 12 months = \$14,759

Mr. Knoble will provide training and technical assistance and quality assurance oversight to HIV testing sites participating in the STOP Study and will meet regularly with the sites to do so.

- c) PHFE Travel \$3,342

Funding to travel to CDC for one STOP Study meeting for 2 staff members

Airfare (\$650 x 1 trip x 1 staff)	\$650
Lodging (\$205 x 3 nights x 1 staff)	\$615
Per Diem (\$64/day x 4 days x 1staff)	\$256
Transportation (\$150 x 1 staff)	\$150
Total	\$1,671
For Two Staff	\$3,342

d) PHFE Consultants \$10,000

i. Pilcher, Chris MD (\$5,000)

Dr. Pilcher will provide consultation to project staff on NAAT testing and new testing technologies. Dr. brings expertise with NAAT testing along with extensive research and clinical work experience with persons with acute HIV.

Costs estimated at 20 hours x \$250 per hour = \$5,000

ii. Kahn, Jim, MD (\$5,000)

Dr. Kahn will provide consultation to project staff on developing and implementing an evaluation plan to measure cost effectiveness of enhanced partner notification and screening for acute HIV infection with a 4th generation EIA compared to pooled NAAT.

Costs estimated at 20 hours x \$250 per hour = \$5,000

e) PHFE Equipment \$0

f) PHFE Materials and Supplies \$1,698

Funding will cover general supplies need for study activities. Costs estimated at \$141.50 per month for 12 months.

g) PHFE Contractual \$149,471

University of California, San DiegoUCSD: Under the direction and with the input of Dr. Susan Little, MD and in close collaboration with Dr. Colfax, Dr. Pandori, the CDC, and other project team members, Sergei L. Kosakovsky Pond, PhD, (.05% FTE for 12 months) from the University of California, San Diego, will design and implement a content management system (CMS) for HIV-1 pol sequences, resistance and molecular epidemiology data. The CMS will be used to house, access and analyze polymerase sequences from project subjects. Users will be able create persistent custom queries on a number of attributes, such as patient ID, sampling dates, viral subtype, drug resistance mutations or scores and genetic distances. Query results will be available for visualization (e.g. as summary tables or phylogenetic trees) and download (e.g. Excel spreadsheets).The database module will be implemented as an extension of a powerful open source CMS

(Plone, www.plone.org) and written in Python. Sequence curation, resistance analysis and molecular epidemiology tasks will be carried out in an open source molecular evolution package HyPhy (www.hyphy.org). Dr Kosakovsky Pond will also maintain a secure server to host the CMS.

A detailed budget will be developed when contract is developed.

h) PHFE Other \$9,360

i. Courier (\$9,360)

Funds will cover costs associate with transporting samples from study sites to Microbiology Lab. Costs estimated at \$20 per pick-up (\$20 x 9 pick-ups per week x 52 weeks = \$9,360).

PHFE Total Direct costs: \$230,080

H. PHFE Indirect Costs (8.5% modified direct costs) \$8,977

PHFE Total Budget: \$239,056

2. Name of Contractor: San Francisco Dept, of Public Health, STD Prevention and Control Services

Method of Selection: Health Department Provided Service/Municipal STD Clinic

Period of performance: 06/15/2012 - 06/14/2013

Scope of work

- i) Service category: Community Based Testing and Partner Services and Linkages for Community-Based Settings
 - (1) Award amount: \$76,242
 - (2) Subcontractors: none
 - (3) Services provided: HIV Testing, Partner Services and Linkage to Care.

Method of Accountability: Annual program and fiscal and compliance monitoring

Itemized budget and justification:

a)	STD Personnel		
b)	STD Mandatory Fringe		
	STD Total Personnel		\$53,980
	STD Salary		\$39,985
	STD Fringe @ 35% of salaries		\$13,995

i. Manager I/Chief Epidemiologist

1.0 FTE Annual Salary = \$132,883 x .20 effort = No Salary Requested

This position will act as the STOP Study liaison and attend STOP Grant meetings with the AIDS Office and other project participants. They will oversee all of the epidemiologic activities performed by STD staff related to the STOP Project; generate required data and ensure that the data is electronically transmitted to the AIDS Office on a monthly basis in a mutually agreed upon format; produce reports and supervise the Epidemiologist II. The salary for this position is being provided in-kind and the funds are being redirected to fund half of the Epidemiologist II.

ii. Epidemiologist II

1.0 FTE Annual Salary \$79,970 x .50 = \$39,985

This position will oversee all of the STD Section's HIV/STD surveillance activities; perform QA of all data reported through the various surveillance streams; create, implement, and oversee policy and protocol development for HIV activities; supervise data entry and other surveillance staff; identify and problem solve around system and technologic level barriers to improving HIV surveillance; act as back-up support for the integrated data-infrastructure of the program and liaise with partners on HIV/STD surveillance and program evaluation issues.

c)	STD Travel	\$0
d)	STD Equipment	\$0
e)	STD Materials and Supplies	\$22,262
	Funds are requested to purchase materials for safer sex kits, including condoms, lube and/or written materials for use by STOP Study patients.	
f)	STD Contractual	\$0
g)	STD Other	\$0
	STD Total Direct costs:	\$76,242
H.	STD Indirect Costs (none)	\$0
	STD Total Budget:	\$76,242

3. Name of Contractor: San Francisco AIDS Foundation, Magnet

Method of Selection: Contract continuing based on approval from previous years for STOP Study

Period of performance: 06/15/2012 - 06/14/2013

Scope of work:

- i) Service category: Community-Based HIV Testing
 - (1) Award amount: \$34,332
 - (2) Subcontractors: none
 - (3) Services provided: HIV Testing

Magnet, a program of the San Francisco AIDS Foundation, provides HIV testing in the Castro neighborhood. HIV testing programs: 1) aim to increase frequency of HIV testing among males who have sex with males (MSM), injection drug users (IDU), and transfemales who have sex with males (TFSM) citywide; 2) help people living with HIV who are unaware they are HIV-positive learn their status; 3) support initial linkage to primary care, partner services, and ancillary services for people testing HIV-positive, and 4) provide people who test HIV-negative with the information, resources, and support to stay negative. The required program components are written consent for testing; confidential HIV antibody testing; face-to-face disclosure of test results; and, for people testing HIV-positive, post-test counseling, linkage to care, and linkage to partner services. As a testing program participating in the STOP Study, Magnet is responsible for drawing blood on all clients who test HIV negative on a rapid HIV test and submitting the blood samples to the SFPDH for acute/recent HIV testing.

Method of Accountability: Annual program and fiscal and compliance monitoring.

Itemized budget and justification: Contracts are currently being developed and will be submitted at a later date.

4. Name of Contractor: Tenderloin Health

Method of Selection: Contract continuing based on approval from previous years for STOP Study

Period of performance: 06/15/2012 - 06/14/2013

Scope of work:

- i) Service category: Community-Based HIV Testing
 - (1) Award amount: \$35,963
 - (2) Subcontractors: none
 - (3) Services provided: HIV Testing

Mobile Advocates for Sexual Health (MASH), a program of Tenderloin Health, provides HIV testing in the Castro neighborhood, particularly to reach males who have sex with males. This testing program: 1) aims to increase frequency of HIV testing among males who have sex with males; 2) help people living with HIV who are unaware they are HIV-positive learn their status; 3) support initial linkage to primary care, partner services, and ancillary services for people testing HIV-positive, and 4) provide people who test HIV-negative with the information, resources, and support to stay negative. The required program components are

written consent for testing; confidential HIV antibody testing; face-to-face disclosure of test results; and, for people testing HIV-positive, post-test counseling, linkage to care, and linkage to partner services. As a testing program participating in the STOP Study, MASH is responsible for drawing blood on all clients who test HIV negative on a rapid HIV test and submitting the blood samples to the SFPDPH for acute/recent HIV testing.

Method of Accountability: Annual program and fiscal and compliance monitoring

Itemized budget and justification: Contracts are currently being developed and will be submitted at a later date.

5. **Name of Contractor: University of California San Francisco, Alliance Health Project (formerly AIDS Health Project)**

Method of Selection: Contract continuing based on approval from previous years for STOP Study

Period of performance: 06/15/2012 - 06/14/2013

Scope of work

- i) Service category: Community-Based HIV Testing
 - (1) Award amount: \$47,678
 - (2) Subcontractors: none
 - (3) Services provided: HIV Testing

Alliance Health Project, a program of the University of California at San Francisco, provides HIV testing in the mid-Market Street area. HIV testing programs: 1) aim to increase frequency of HIV testing among males who have sex with males (MSM), injection drug users (IDU), and transfemales who have sex with males (TFSM) citywide; 2) help people living with HIV who are unaware they are HIV-positive learn their status; 3) support initial linkage to primary care, partner services, and ancillary services for people testing HIV-positive, and 4) provide people who test HIV-negative with the information, resources, and support to stay negative. The required program components are written consent for testing; confidential HIV antibody testing; face-to-face disclosure of test results; and, for people testing HIV-positive, post-test counseling, linkage to care, and linkage to partner services. As a testing program participating in the STOP Study, Alliance Health Project is responsible for drawing blood on all clients who test HIV negative on a rapid HIV test and submitting the blood samples to the SFPDPH for acute/recent HIV testing.

Method of Accountability: Annual program and fiscal and compliance monitoring

Itemized budget and justification: Contracts are currently being developed and will be submitted at a later date.

6. Name of Contractor: San Francisco Dept of Public Health Microbiology Lab
Method of Selection: Health Department Provided Service/Microbiology Lab

Period of performance: 06/15/2012 - 06/14/2013

Scope of work

- i) Service category: HIV Testing: Laboratory Services
 - (1) Award amount: \$278,286
 - (2) Subcontractors: none
 - (3) Services provided: Specimen processing and laboratory analysis of samples to detect acute HIV infections from STOP Study participating testing facilities.

Method of Accountability: Annual program and fiscal and compliance monitoring

Itemized budget and justification: Contracts are currently being developed and will be submitted at a later date.

G. OTHER \$1,600

- 1. IRB Renewal (\$1,600)
Funds will cover costs associated with study IRB renewal.

TOTAL DIRECT COSTS: \$742,670

H. INDIRECT COSTS (24.84% of total salaries) \$5,163

TOTAL BUDGET: \$747,833

City and County of San Francisco
Edwin Lee
Mayor

Department of Public Health
Barbara Garcia, MPA
Director of Health



February 14, 2012

Centers for Disease Control and Prevention (CDC)
Procurement and Grants Office, Branch 1
2920 Brandywine Road, Room 3000, MS E-15
Atlanta, Georgia 30341-4146

Attn: Pamela Render, Grant Management Specialist

RE: Project Title: The STOP Study
Funding Opportunity Announcement Number: PS09-004
Grant Number: 5U01PS001564-03
Year 3 Interim Progress Report (IPR)

Enclosed is the San Francisco Department of Public Health, Population Health and Prevention, HIV Prevention Section Interim Progress Report of \$747,833 for the year 3 budget period 6/15/2012 through 6/14/2013.

If you have any questions, please contact Grant Colfax, Director of HIV Prevention at (415) 554-9173 for programmatic issues, and Sajid Shaikh, Senior Administrative Analyst at (415) 255-3512 for budgetary and fiscal issues.

Sincerely,

Handwritten signature of Grant Colfax in black ink.

Grant Colfax
Director of HIV Prevention and Research

Handwritten signature of Sajid Shaikh in black ink.

Sajid Shaikh
Senior Administrative Analyst

Cc: Eileen Yee, Program Official

San Francisco Department of Public Health

AIDS Office

The STOP Study

Funding Opportunity Announcement: PS09-004

Grant Award Number: 1U01PS001564-03

Interim Progress Report for Year 3: 6/15/2012 – 6/14/2013

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FY 2012 Interim Progress Report

1. Description of Progress During Budget Period (06/15/11-06/14/12)

1.A. Research Aims:

1.A.a. Research Aims/Project: Detection of acute HIV infection (AHI) – defined as the time between HIV acquisition and seroconversion¹ – is of great public health importance. AHI is a highly infectious period during which persons unaware of their HIV infection may be particularly likely to transmit HIV to partners. While estimates vary, studies indicate that transmissions during acute infection account for a disproportionate number of new HIV infections. Supporting the prevention importance of AHI detection, persons newly diagnosed with HIV dramatically reduce their risk behavior, and testing partners of AHI index cases results in a high percentage of newly diagnosed HIV cases. However, the detection of AHI remains a challenge: while third-generation assays have narrowed the window period of HIV diagnosis, commonly used immunoassays, designed to detect antibody alone, will not identify individuals who have not yet begun to produce HIV-specific antibodies. Attempts to detect AHI have mostly involved RNA-detection algorithms using pooled HIV antibody-negative specimens, commonly known as pooled nucleic acid amplification testing (NAAT). Such efforts have detected new HIV infections in a variety of communities, but pooling can be expensive, laborious, operationally daunting and, in some settings, the time to results takes 7-14 days. An alternative for AHI detection is to use antigen-antibody combination tests, so called “fourth-generation” immunoassays. These tests, recently approved by the FDA, are easy to perform, relatively inexpensive, and easily automated; in general they significantly narrow the window period compared with third-generation assays. However, there is a paucity of data available on the performance of fourth-generation assays relative to HIV RNA detection algorithms in the public health setting. Whether the potential increased efficiency of fourth-generation testing and possible lower cost of such tests compensate for missing infections otherwise detectable by NAAT pooling remains to be determined. While at least one evaluation demonstrated the relatively high yield of detecting new HIV infections among partners of index cases diagnosed with AHI in certain settings, the overall public health effect and cost-effectiveness of sexual partner and social network partner notification and testing in the setting of routine AHI screening requires further study. Therefore, as required in the RFA-PS-09-004, “Screening Targeted

Populations to Interrupt On-going Chains of Transmission with Enhanced Partner Notification – The STOP Study,” the specific aims of this project are:

- To evaluate the yield, cost-effectiveness, and feasibility of screening for AHI with a fourth-generation immunoassay compared to pooled NAAT in high-risk/high-incidence settings.
- To evaluate the yield, cost-effectiveness, and feasibility of enhanced partner notification/contact tracing techniques linked to AHI screening.

The study protocol was finalized in collaboration with CDC and the other two study sites in New York City and North Carolina and the San Francisco Department of Public Health (SFDPH). On October 20, 2011, the University of California San Francisco’s (UCSF) Committee on Human Research provided IRB approval for the STOP Study efforts in San Francisco. Obtaining IRB approval took longer than anticipated. Thus, the rollout of STOP Study activities and protocols at the testing facilities began later than planned. Since the rollout, testing facilities have conducted over 2000 HIV tests using the STOP Study protocol with no significant issues and have identified eight acute infections.

I.A.b. Leadership/Partnership: The San Francisco STOP Study has worked closely with Phil Peters, MD, the CDC Project Officer, and the staff at the other two study sites in New York City and University of North Carolina. An initial study orientation for the testing sites was held on August 10th. Dr. Peters was in San Francisco for a site visit on August 25th & 26th to meet with the San Francisco STOP Study team and the testing venues’ staff members. The San Francisco STOP Study team, along with partners from North Carolina and New York City, attended a Principal Investigators meeting at CDC on November 16, 2011. Internally the San Francisco STOP Study staff has developed a working group with the Director of SFDPH’s Microbiology Lab and the Director and Epidemiologist of SFDPH’s STD Prevention and Control Section. The four major testing sites in San Francisco that are part of this study include San Francisco City Clinic (the municipal STD clinic), San Francisco AIDS Foundation’s Magnet program, UCSF’s Alliance Health Project (formerly AIDS Health Project), and Tenderloin Health. The rollout of STOP Study protocols and activities at participating testing facilities began in a staggered fashion, starting with Magnet on November 15, 2011, followed by Alliance Health Project on November 29, 2011, Tenderloin Health on December 10, 2011, and City Clinic on January 5, 2012.

2. Translation of Research & Public Health Relevance and Impact: While the study is in progress and there are no findings to report at this time, it is anticipated that there will be a public health impact of this research. Attempts to detect acutely infected individuals have mostly involved RNA-detection algorithms using pooled HIV antibody-negative specimens, as described above. Such efforts have yielded significant returns in detection of recent HIV infection in certain communities. However, the use of RNA-based detection methods may be expensive, laborious and are operationally daunting. Moreover, in most cases the time to results ranges from 7-14 days. This amount of time is less than ideal from an HIV prevention perspective, because the ability to find the infected index case may be decreased with time, resulting in the potential for continued risk behavior and onward transmission of HIV when infectiousness is extremely high. Furthermore, due to temporal delays, it is possible that the ability to maximize partner notification and testing is decreased. A potential alternative to the detection of AHI using RNA-based methods is to use antigen-antibody combination tests, also known as "fourth-generation" assays. Fourth-generation assays simultaneously function as both third-generation assays (for the detection of IgG and IgM antibody) and capture EIA for the direct detection of p24 antigen (the most abundant protein of HIV virions). Because fourth-generation assays are standard immunoassays, they are easy to perform, relatively inexpensive, and easily automated. However, given the paucity of data available on performance of fourth-generation assays relative NAAT pooling, it is of considerable interest from a public health perspective to assess the ability of these assays to detect AHI cases.

3. Current Budget Period Financial Progress: We currently do not estimate an unobligated balance for budget year 6/15/2011-6/14/2012.

4. New Budget Period Proposal:

A. Detailed operational plan and Measures of Effectiveness.

B. Project Timeline

Primary Objectives

1. To evaluate the number of persons with acute HIV infection (AHI) detected with a 4th generation enzyme immunoassay (EIA) compared with the number detected with pooled nucleic acid amplification testing (NAAT).
2. To evaluate the number new HIV infections detected with enhanced partner services among partners of persons diagnosed with acute HIV infection compared with partners of persons newly diagnosed with established HIV infection.

Secondary Objectives

1. To evaluate if molecular phylogenetic techniques confirm transmission networks identified with partner services or identify unanticipated case linkages and novel transmission patterns.
2. To evaluate the cost-effectiveness of screening for AHI with a 4th generation EIA compared with pooled NAAT.

To make progress toward achieving the objectives above, in year three (June 15, 2012-June 14, 2013), we will:

- Test at least 11,000 specimens to detect acute HIV.
- Diagnose at least 143 cases of HIV.
- Identify at least 14 acute HIV infections.
- Conduct phylogenetic testing on all samples identified with HIV.
- Conduct at least 72 partner services investigations for HIV index patients.
- Complete at least 11 partner services investigations for index patients with AHI.
- Have complete data for 90% of people tested.

Planned milestones for year three include:

- By July 1, 2012, review the performance of each testing facility and provide them with feedback regarding the testing results and any project-related problems we have identified.

5 (PS-09-004 2012 IPR San Francisco Department of Public Health)

- By June 14, 2013, conduct at least 2 meetings with the San Francisco STOP Study working group discuss progress to date, successes and challenges.
- By October 1, 2012, renew STOP Study IRB with University of California at San Francisco.
- By June 14, 2013, attend one meeting at CDC with all STOP Study sites.

5. New Budget Period Budget: See attached budget and justification.

6. Publications/Presentations: One presentation was made during this budget period, on November 16, 2011 as part of DHAP's Translating Research Into Practice Presentation in Atlanta. This presentation, conducted in conjunction with North Carolina and New York City, provided an overview of the study sites and the initial roll out of the STOP Study activities and protocol at the testing facilities participating in the STOP Study.

7. IRB Approval Certification: See attached letter from the University of California at San Francisco (*Human Research Protection Program Committee on Human Research, Notification of Expedited Review Approval*).

San Francisco Department of Public Health
AIDS Office
HIV Prevention Section
PS09-004 The STOP Study
Budget and Budget Justification
6/15/12 – 6/14/13

A.	Personnel	\$20,784
B.	Mandatory Fringe	\$8,729
C.	Travel	\$0
D.	Equipment	\$0
E.	Materials and Supplies	\$0
F.	Contractual	\$711,557
G.	Other Expenses	\$1,600
	TOTAL DIRECT COSTS	\$742,670
H.	Indirect Costs (24.84% of Total Salaries)	\$5,163
	TOTAL BUDGET	\$747,833

Detailed Budget Justification: 6/15/2012 – 6/14/2013

A. PERSONNEL

B. MANDATORY FRINGE

TOTAL PERSONNEL	\$20,784
Salary	\$8,729
Fringe @ 42% of salaries	\$29,513

- 0.05 FTE
2232 Director of HIV Prevention and Research, Sr. Phys Spec: G. Colfax
Annual Salary \$179,700 x 0.05 FTE for 12 months = \$8,985

As PI, Dr. Colfax will be responsible for the overall scientific, operational and administrative aspects of the project. In close collaboration with Drs. Philips (SFDPH STD Prevention and Control) and Pandori (SFDPH Microbiology Lab), San Francisco AIDS Foundation/Magnet, AIDS Health Project, Tenderloin Health, City Clinic and DPH staff and consultants, Dr. Colfax will direct the design, implementation and analysis of all other scientific aspects of this project. As Director of the HIV Prevention Section, which oversees HIV testing and partner services at the project sites, Dr. Colfax has overall responsibility for ensuring that all staff adhere to good clinical practice guidelines in keeping with DPH regulations. Dr. Colfax will oversee project design, development of data, collection instruments, data analysis, evaluation, and presentation and publication of results. He is primarily responsible to insure project goals are being met in a timely manner, and that high-quality data are collected. He is the principal contact for all parties involved.

- 0.05 FTE
0923 Manager I, Deputy Director: T. Packer
Annual Salary \$116,792 x 0.05 FTE for 12 months = \$5,840

The Deputy Director assists the Director in oversight of all activities of the HPS and is the Director of Community-Based Prevention. As such, oversees a team of staff members that provide capacity building, technical assistance and training for community-based providers that offer interventions such as HIV testing, comprehensive prevention with positives, and condom distribution. The team partners with providers to determine how to implement innovative, integrated, effective HIV prevention programs, assists with program and contract development, and ensures that contract deliverables are met, develops and implements trainings, policies, and procedures and provides technical assistance.

- 0.25 FTE
2587 Health Worker III: A. Heimsoth
Annual Salary \$59,592 x 0.10 FTE for 12 months = \$5,959

This position works with HIV testing providers to ensure quality control and inventory of HIV testing supplies, including phlebotomy supplies. In addition Ms. Heimsoth is responsible for purchasing and delivers HIV testing supplies to providers.

C.	TRAVEL	\$0
D.	CONSULTANTS	\$0
E.	EQUIPMENT	\$0
E.	MATERIALS AND SUPPLIES	\$0
F.	CONTRACTUAL	\$711,557

1. **Name of Contractor: Public Health Foundation Enterprises, Inc. (PHFE)**
Method of Selection: Request For Qualifications (RFQ) 15-2006 (Awarded 2006)

Period of Performance: 06/15/2012 - 06/14/2013

Scope of work

- i) Service category: Fiscal Intermediary
 - (1) Award amount: \$239,056
 - (2) Subcontractors: UCSD
- ii) Services provided: Fiscal intermediary services to the SFDPH HPS. PHFE pays for staff members and travel that support the goals and objectives of the STOP Study.

Method of Accountability: Annual program and fiscal and compliance monitoring

Itemized budget and justification:

- a) PHFE Personnel
- b) PHFE Mandatory Fringe

PHFE Total Personnel	\$56,209
PHFE Salary	\$45,259
PHFE Fringe @ 24.19% of salaries	\$10,950
- i. Director of Clinical Prevention: Nicholas Moss, MD
 Annual Salary \$130,000 x 0.10 FTE for 12 months = \$13,000

Dr. Moss will serve as the Project Director for this project and will be responsible for managing the project on a day to day basis. He will oversee all aspects of the project and will report directly Dr. Colfax. He will also act as the primary liaison with CDC for the project.

- ii. Data Systems Specialist: Nayla Raad

Annual Salary \$70,000 x 0.25 FTE for 12 months = \$17,500

Ms. Raad will provide data management and data reporting for the STOP Study.

iii. Community Interventions Coordinator: Thomas Knoble
Annual Salary \$73,793 x .20 for 12 months = \$14,759

Mr. Knoble will provide training and technical assistance and quality assurance oversight to HIV testing sites participating in the STOP Study and will meet regularly with the sites to do so.

c)	PHFE Travel	\$3,342
	Funding to travel to CDC for one STOP Study meeting for 2 staff members	
	Airfare (\$650 x 1 trip x 1 staff)	\$650
	Lodging (\$205 x 3 nights x 1 staff)	\$615
	Per Diem (\$64/day x 4 days x 1staff)	\$256
	Transportation (\$150 x 1 staff)	\$150
	Total	\$1,671
	For Two Staff	\$3,342

d)	PHFE Consultants	\$10,000
	i. Pilcher, Chris MD (\$5,000)	
	Dr. Pilcher will provide consultation to project staff on NAAT testing and new testing technologies. Dr. brings expertise with NAAT testing along with extensive research and clinical work experience with persons with acute HIV.	

Costs estimated at 20 hours x \$250 per hour = \$5,000

ii. Kahn, Jim, MD (\$5,000)

Dr. Kahn will provide consultation to project staff on developing and implementing an evaluation plan to measure cost effectiveness of enhanced partner notification and screening for acute HIV infection with a 4th generation EIA compared to pooled NAAT.

Costs estimated at 20 hours x \$250 per hour = \$5,000

e)	PHFE Equipment	\$0.
f)	PHFE Materials and Supplies	\$1,698
	Funding will cover general supplies need for study activities. Costs estimated at \$141.50 per month for 12 months.	
g)	PHFE Contractual	\$149,471

University of California, San DiegoUCSD: Under the direction and with the input of Dr. Susan Little, MD and in close collaboration with Dr. Colfax, Dr. Pandori, the CDC, and other project team members, Sergei L. Kosakovsky Pond, PhD, (.05% FTE for 12 months) from the University of California, San Diego, will design and implement a content management system (CMS) for HIV-1 pol sequences, resistance and molecular epidemiology data. The CMS will be used to house, access and analyze polymerase sequences from project subjects. Users will be able create persistent custom queries on a number of attributes, such as patient ID, sampling dates, viral subtype, drug resistance mutations or scores and genetic distances. Query results will be available for visualization (e.g. as summary tables or phylogenetic trees) and download (e.g. Excel spreadsheets).The database module will be implemented as an extension of a powerful open source CMS (Plone, www.plone.org) and written in Python. Sequence curation, resistance analysis and molecular epidemiology tasks will be carried out in an open source molecular evolution package HyPhy (www.hyphy.org). Dr Kosakovsky Pond will also maintain a secure server to host the CMS.

A detailed budget will be developed when contract is developed.

- h) PHFE Other \$9,360
 - i. Courier (\$9,360)

Funds will cover costs associate with transporting samples from study sites to Microbiology Lab. Costs estimated at \$20 per pick-up (\$20 x 9 pick-ups per week x 52 weeks = \$9,360).

PHFE Total Direct costs:	\$230,080
H. PHFE Indirect Costs (8.5% modified direct costs)	\$8,977
PHFE Total Budget:	\$239,056

2. Name of Contractor: San Francisco Dept, of Public Health, STD Prevention and Control Services

Method of Selection: Health Department Provided Service/Municipal STD Clinic

Period of performance: 06/15/2012 - 06/14/2013

Scope of work

- i) Service category: Community Based Testing and Partner Services and Linkages for Community-Based Settings
(1) Award amount: \$76,242

- (2) Subcontractors: none
- (3) Services provided: HIV Testing, Partner Services and Linkage to Care.

Method of Accountability: Annual program and fiscal and compliance monitoring

Itemized budget and justification:

a)	STD Personnel		
b)	STD Mandatory Fringe		
		STD Total Personnel	\$53,980
		STD Salary	\$39,985
		STD Fringe @ 35% of salaries	\$13,995

- i. Manager I/Chief Epidemiologist
1.0 FTE Annual Salary = \$132,883 x .20 effort = No Salary Requested

This position will act as the STOP Study liaison and attend STOP Grant meetings with the AIDS Office and other project participants. They will oversee all of the epidemiologic activities performed by STD staff related to the STOP Project; generate required data and ensure that the data is electronically transmitted to the AIDS Office on a monthly basis in a mutually agreed upon format; produce reports and supervise the Epidemiologist II. The salary for this position is being provided in-kind and the funds are being redirected to fund half of the Epidemiologist II.

- ii. Epidemiologist II
1.0 FTE Annual Salary \$79,970 x .50 = \$39,985

This position will oversee all of the STD Section's HIV/STD surveillance activities; perform QA of all data reported through the various surveillance streams; create, implement, and oversee policy and protocol development for HIV activities; supervise data entry and other surveillance staff; identify and problem solve around system and technologic level barriers to improving HIV surveillance; act as back-up support for the integrated data-infrastructure of the program and liaise with partners on HIV/STD surveillance and program evaluation issues.

c)	STD Travel	\$0
d)	STD Equipment	\$0
e)	STD Materials and Supplies	\$22,262
	Funds are requested to purchase materials for safer sex kits, including condoms, lube and/or written materials for use by STOP Study patients.	

f)	STD Contractual	\$0
g)	STD Other	\$0
	STD Total Direct costs:	\$76,242
H.	STD Indirect Costs (none)	\$0
	STD Total Budget:	\$76,242

3. **Name of Contractor: San Francisco AIDS Foundation, Magnet**
Method of Selection: Contract continuing based on approval from previous years for STOP Study

Period of performance: 06/15/2012 - 06/14/2013

Scope of work:

- i) **Service category: Community-Based HIV Testing**
 - (1) Award amount: \$34,332
 - (2) Subcontractors: none
 - (3) Services provided: HIV Testing

Magnet, a program of the San Francisco AIDS Foundation, provides HIV testing in the Castro neighborhood. HIV testing programs: 1) aim to increase frequency of HIV testing among males who have sex with males (MSM), injection drug users (IDU), and transfemales who have sex with males (TFSM) citywide; 2) help people living with HIV who are unaware they are HIV-positive learn their status; 3) support initial linkage to primary care, partner services, and ancillary services for people testing HIV-positive, and 4) provide people who test HIV-negative with the information, resources, and support to stay negative. The required program components are written consent for testing; confidential HIV antibody testing; face-to-face disclosure of test results; and, for people testing HIV-positive, post-test counseling, linkage to care, and linkage to partner services. As a testing program participating in the STOP Study, Magnet is responsible for drawing blood on all clients who test HIV negative on a rapid HIV test and submitting the blood samples to the SFPDPH for acute/recent HIV testing.

Method of Accountability: Annual program and fiscal and compliance monitoring.

Itemized budget and justification: Contracts are currently being developed and will be submitted at a later date.

4. **Name of Contractor: Tenderloin Health**

Method of Selection: Contract continuing based on approval from previous years for STOP Study

Period of performance: 06/15/2012 - 06/14/2013

Scope of work:

- i) Service category: Community-Based HIV Testing
 - (1) Award amount: \$35,963
 - (2) Subcontractors: none
 - (3) Services provided: HIV Testing

Mobile Advocates for Sexual Health (MASH), a program of Tenderloin Health, provides HIV testing in the Castro neighborhood, particularly to reach males who have sex with males. This testing program: 1) aims to increase frequency of HIV testing among males who have sex with males; 2) help people living with HIV who are unaware they are HIV-positive learn their status; 3) support initial linkage to primary care, partner services, and ancillary services for people testing HIV-positive, and 4) provide people who test HIV-negative with the information, resources, and support to stay negative. The required program components are written consent for testing; confidential HIV antibody testing; face-to-face disclosure of test results; and, for people testing HIV-positive, post-test counseling, linkage to care, and linkage to partner services. As a testing program participating in the STOP Study, MASH is responsible for drawing blood on all clients who test HIV negative on a rapid HIV test and submitting the blood samples to the SFPDPH for acute/recent HIV testing.

Method of Accountability: Annual program and fiscal and compliance monitoring

Itemized budget and justification: Contracts are currently being developed and will be submitted at a later date.

5. Name of Contractor: University of California San Francisco, Alliance Health Project (formerly AIDS Health Project)

Method of Selection: Contract continuing based on approval from previous years for STOP Study

Period of performance: 06/15/2012 - 06/14/2013

Scope of work

- i) Service category: Community-Based HIV Testing
 - (1) Award amount: \$47,678
 - (2) Subcontractors: none
 - (3) Services provided: HIV Testing

Alliance Health Project, a program of the University of California at San Francisco, provides HIV testing in the mid-Market Street area. HIV testing programs: 1) aim to increase frequency of HIV testing among males who have sex with males (MSM), injection drug users (IDU), and transfemales who have sex

with males (TFMS) citywide; 2) help people living with HIV who are unaware they are HIV-positive learn their status; 3) support initial linkage to primary care, partner services, and ancillary services for people testing HIV-positive, and 4) provide people who test HIV-negative with the information, resources, and support to stay negative. The required program components are written consent for testing; confidential HIV antibody testing; face-to-face disclosure of test results; and, for people testing HIV-positive, post-test counseling, linkage to care, and linkage to partner services. As a testing program participating in the STOP Study, Alliance Health Project is responsible for drawing blood on all clients who test HIV negative on a rapid HIV test and submitting the blood samples to the SFDPH for acute/recent HIV testing.

Method of Accountability: Annual program and fiscal and compliance monitoring

Itemized budget and justification: Contracts are currently being developed and will be submitted at a later date.

6. **Name of Contractor:** San Francisco Dept of Public Health Microbiology Lab
Method of Selection: Health Department Provided Service/Microbiology Lab

Period of performance: 06/15/2012 - 06/14/2013

Scope of work

- i) Service category: HIV Testing: Laboratory Services
 - (1) Award amount: \$278,286
 - (2) Subcontractors: none
 - (3) Services provided: Specimen processing and laboratory analysis of samples to detect acute HIV infections from STOP Study participating testing facilities.

Method of Accountability: Annual program and fiscal and compliance monitoring

Itemized budget and justification: Contracts are currently being developed and will be submitted at a later date.

G. OTHER \$1,600

- 1. IRB Renewal (\$1,600)
 Funds will cover costs associated with study IRB renewal.

TOTAL DIRECT COSTS: \$742,670

H. INDIRECT COSTS (24.84% of total salaries) \$5,163

TOTAL BUDGET: \$747,833



Human Research Protection Program
Committee on Human Research

Notification of Expedited Review Approval

Principal Investigator
Grant N Colfax

Co-Principal Investigator
Mark W Pandori, Susan S Philip, MD MPH

Type of Submission: Initial Review Submission Packet
Study Title: The STOP Study - Screening Targeted Populations to Interrupt On-going Chains of HIV Transmission with Enhanced Partner Notification
IRB #: 11-07686
Reference #: 032491
Committee of Record: San Francisco General Hospital Panel
Study Risk Assignment: Minimal

Approval Date: 10/20/2011 **Expiration Date:** 10/19/2012

Regulatory Determinations Pertaining to this Approval (if applicable):

This research satisfies the following condition(s) for the involvement of children:

Because the adolescents being enrolled in this study are legally entitled to consent to the treatments and procedures involved in the study, Subpart D of 45 CFR 46 does not apply. Parental consent is not required.

The research meets all of the conditions of 45 CFR 46.204 for the involvement of pregnant women or fetuses.

The requirement for individual HIPAA authorization is waived for all subjects. The use or disclosure of the requested information does not adversely affect the rights and welfare of the individuals and involves no more than a minimal risk to their privacy based on, at least, the presence of the following elements: (1) an adequate plan to protect the identifiers from improper use and disclosure; (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or if such retention is otherwise required by law; (3) adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule; (4) the research could not practicably be conducted without the waiver; and (5) the research could not practicably be conducted without access to and use of the requested information.

IRB Comments (if applicable):

Consent is waived for the same reasons that authorization is waived. Given the size of the subject population, the press of business in the clinics, and the fact that the testing will routinely will be performed on all patients who fit the criteria, it is not practicable to perform the study without a waiver of consent.

All changes to a study must receive CHR approval before they are implemented. Follow the modification request instructions. The only exception to the requirement for prior CHR review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103.b.4, 21 CFR 56.108.a). In such cases, report the actions taken by following these instructions.

Expiration Notice: The iMedRIS system will generate an email notification eight weeks prior to the expiration of

this study's approval. However, it is your responsibility to ensure that an application for continuing review approval has been submitted by the required time. In addition, you are required to submit a study closeout report at the completion of the project.

Approved Documents: To obtain a list of documents that were approved with this submission, follow these steps: Go to My Studies and open the study – Click on Submissions History – Go to Completed Submissions – Locate this submission and click on the Details button to view a list of submitted documents and their outcomes.

For a list of all currently approved documents, follow these steps: Go to My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

San Francisco Veterans Affairs Medical Center (SFVAMC): If the SFVAMC is engaged in this research, you must secure approval of the VA Research & Development Committee in addition to CHR approval and follow all applicable VA and other federal requirements. The CHR website has more information.

Department of Health and Human Services Public Health Services <h2 style="margin: 0;">Grant Progress Report</h2>	Review Group	Type	Activity	Grant Number 5U01PS001564-03
	Total Project Period			
	From: 06/15/2010		Through: 06/14/2013	
	Requested Budget Period			
From: 06/15/2012				Through: 06/14/2013

1. TITLE OF PROJECT
The STOP Study

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR
(Name and address, street, city, state, zip code)
Grant Colfax, MD.
San Francisco Department of Public Health
25 Van Ness Ave, Suite 500
San Francisco, CA 94102

2b. E-MAIL ADDRESS
grant.colfax@sfdph.org

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
San Francisco Department of Public Health

2d. MAJOR SUBDIVISION
AIDS Office

2e. Tel: 415-554-9173 Fax: 415-431-7154

3a. APPLICANT ORGANIZATION
(Name and address, street, city, state, zip code)
San Francisco Department of Public Health
AIDS Office
25 Van Ness Ave, Suite 500
San Francisco, CA 94102

3b. Tel: 415-554-9173 Fax: 415-431-7154

3c. DUNS: 103717336

4. ENTITY IDENTIFICATION NUMBER
94-6000417

6. HUMAN SUBJECTS No Yes

6a. Research Exempt No Yes

If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
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5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Sajid Shaikh
Sr Adminstrative Analyst
1380 Howard St, Suite 423A, SF, CA 94103

6b. Federal Wide Assurance No. FWA00000162

6c. NIH-Defined Phase III Clinical Trial No Yes

Tel: 415-255-3512 Fax: 415-503-4710

E-MAIL: saj_shaikh@yahoo.com

7. VERTEBRATE ANIMALS No Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: San Francisco Dept of Public Health
DUNS: 103717336

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT \$742,670 8b. TOTAL \$747,833

Street 1: 25 Van Ness Ave
Street 2:

9. INVENTIONS AND PATENTS No Yes


If "Yes," Previously Reported Not Previously Reported

City: San Francisco	County:
State: CA	Province:
Country:	Zip/Postal Code: 94102
Congressional Districts: 8th	

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 13)
Marcellina A. Ogbu, DrPH

TEL: 415-255-3524 FAX: 415-327-6640 E-MAIL: marcellina.ogbu@sfdph.org

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 11. (In ink)	DATE
		2/15/12

Contact Program Director/Principal Investigator: Coflax, Grant MD

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code) Grant Coflax, MD 25 Van Ness, Suite 500 San Francisco, CA 94102	2b. E-MAIL ADDRESS grant.coflax@sfdph.org
	2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT San Francisco Department of Public Health
	2d. MAJOR SUBDIVISION AIDS Office

2e. TELEPHONE AND FAX (Area code, number and extension)

TEL: 415-554-9173	FAX: 415-431-7154
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2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)	2b. E-MAIL ADDRESS
	2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
	2d. MAJOR SUBDIVISION

2e. TELEPHONE AND FAX (Area code, number and extension)

TEL:	FAX:
------	------

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)	2b. E-MAIL ADDRESS
	2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
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2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)	2b. E-MAIL ADDRESS
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	2d. MAJOR SUBDIVISION

2e. TELEPHONE AND FAX (Area code, number and extension)

TEL:	FAX:
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Program Director/Principal Investigator (Last, First, Middle): Colfax, Grant MD

DETAILED BUDGET FOR NEXT BUDGET PERIOD - DIRECT COSTS ONLY	FROM 06/15/2012	THROUGH 06/14/2013	GRANT NUMBER 5U01PS001564-03
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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	Summer Mnths	SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Grant Colfax, MC	PD/PI	.60			8,935	3,774	12,759
Tracey Packer	Deputy Director	.60			5,840	2,453	8,292
Alice Heimsoth	Health Worker	1.2			5,959	2,503	8,462
SUBTOTALS					20,784	8,729	29,513
CONSULTANT COSTS							0
EQUIPMENT (<i>Itemize</i>)							0
SUPPLIES (<i>Itemize by category</i>)							0
TRAVEL							0
INPATIENT CARE COSTS							0
OUTPATIENT CARE COSTS							0
ALTERATIONS AND RENOVATIONS (<i>Itemize by category</i>)							0
OTHER EXPENSES (<i>Itemize by category</i>)							
IRB Renewal							1,600
SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD							\$ 31,113
CONSORTIUM/CONTRACTUAL COSTS					DIRECT COSTS		711,557
CONSORTIUM/CONTRACTUAL COSTS					FACILITIES AND ADMINISTRATIVE COSTS		5,163
TOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD (<i>Item 8a, Face Page</i>)							\$ 747,833

Program Director/Principal Investigator (Last, First, Middle): Colfax, Grant MD

BUDGET JUSTIFICATION

GRANT NUMBER

5U01PS001564-03

Provide a detailed budget justification for those line items and amounts that represent a significant change from that previously recommended. Use continuation pages if necessary.

see attached detailed budget justification

CURRENT BUDGET PERIOD

FROM

06/15/2011

THROUGH

06/14/2012

Explain any estimated unobligated balance (including prior year carryover) that is greater than 25% of the current year's total budget.

N/A

Program Director/Principal Investigator (Last, First, Middle): Colfax, Grant MD

PROGRESS REPORT SUMMARY	GRANT NUMBER 5U01PS001564-03	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Grant Colfax MD	FROM 06/15/2012	THROUGH 06/14/2013
APPLICANT ORGANIZATION San Francisco Department of Public Health		
TITLE OF PROJECT (Repeat title shown in Item 1 on first page) The STOP Study		

A. Human Subjects (Complete Item 6 on the Face Page)

Involvement of Human Subjects No Change Since Previous Submission Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)

Use of Vertebrate Animals No Change Since Previous Submission Change

C. Select Agent Research

No Change Since Previous Submission Change

D. Multiple PD/PI Leadership Plan

No Change Since Previous Submission Change

E. Human Embryonic Stem Cell Line(s) Used

No Change Since Previous Submission Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

See attached interim progress report. No inclusion enrollment report has been included because data is currently not available. This has been discussed with the project officer. In March, we will submit our first HIV testing data and will submit it every other month following that. In September (and semi-annually thereafter) we will submit PS data.

Program Director/Principal Investigator (Last, first, middle): Colfax, Grant MD

GRANT NUMBER
5U01PS001564-03

CHECKLIST

1. PROGRAM INCOME (See instructions.)

All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)
N/A		

2. ASSURANCES/CERTIFICATIONS (See instructions.)

In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instructions when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398, and listed in Part I, 4.1 under Item 14. If unable to certify compliance, where applicable, provide an explanation and place it after the Progress Report (Form Page 5).

3. FACILITIES AND ADMINISTRATIVE (F&A) COSTS

Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

F&A costs will *not* be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

DHHS Agreement dated: _____ No Facilities and Administrative Costs Requested.
 No DHHS Agreement, but rate established with SFDPH Internal Date 10/25/2010

CALCULATION*

Entire proposed budget period: Amount of base \$ 0 x Rate applied 0.24 % = F&A costs \$ 0
Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):

Salary and wages base Modified total direct cost base Other base (Explain)
 Off-site, other special rate, or more than one rate involved (Explain)

Explanation (Attach separate sheet, if necessary.):

Indirect cost based on 24.81% of total salaries

Program Director/Principal Investigator (Last, First, Middle): Colfax, Grant MD

ALL PERSONNEL REPORT

GRANT NUMBER
5U01PS001564-03

Place this form at the end of the signed original copy of the application. Do not duplicate.

Always list the PD/PI(s). In addition, list all other personnel who participated in the project during the current budget period for at least one person month or more, regardless of the source of compensation (a person month equals approximately 160 hours or 8.3% of annualized effort). Use the following abbreviated categories for describing Role on Project:

- PD/PI
- Co-Investigator
- Faculty Collaborator
- Staff Scientist (doctoral level)
- Postdoc (Postdoctoral Scholar, Fellow, or Other Postdoctoral Position)
- Grad Rsch Asst (Graduate Research Assistant)
- Undergrad Rsch Asst (Undergraduate Research Assistant)
- Rsch Asst (Research Assistant/Coordinator)
- Technician
- Consultant
- Biostatistician
- Other (Specify)

If personnel are supported by a Reentry or Diversity Supplement or American Recovery and Reinvestment Act (ARRA) funding, please indicate such after the Role on Project, using the following abbreviations: RS - Reentry Supplement; DS - Diversity Supplement; AF - General ARRA Supplement; ASE - ARRA Summer Experience funding.

Use Cal (calendar), Acad, or Summer to enter months devoted to project.

Commons ID	Name	Degree(s)	SSN (last 4 digits)	Role on Project	DoB (MM /YY)	Cal	Acad	Summer

Program Director/Principal Investigator (Last, first, middle): Colfax, Grant MD

NEXT BUDGET PERIOD <i>(Follow instructions carefully)</i>	FROM 06/15/2012	THROUGH 06/14/2013	GRANT NUMBER 5U01PS001564-03
ITEMIZE DIRECT COSTS REQUESTED FOR NEXT BUDGET PERIOD			DOLLAR AMOUNT REQUESTED (omit cents)
PREDOCTORAL STIPENDS <i>(List trainee names)</i>			
N/A			
POSTDOCTORAL STIPENDS <i>(Itemize) (List trainee names and levels)</i>			No. Requested: \$
N/A			
OTHER STIPENDS <i>(Specify)</i>			No. Requested: \$
N/A			
TOTAL STIPENDS			\$
TUITION and FEES <i>(including Health Insurance when applicable – see new instructions) (Itemize)</i>			\$
<i>(List each category separately)</i>			
N/A			
TRAINEE TRAVEL <i>(Describe)</i>			\$
N/A			
TRAINING-RELATED EXPENSES <i>(including Health Insurance when applicable – see new instructions)</i>			\$
N/A			
TOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD <i>(Also enter on Page 1, Item 8a)</i>			\$

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: The STOP Study

Total Planned Enrollment: 22,000

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Females	Males	Total
Hispanic or Latino	748	3,652	4,400
Not Hispanic or Latino	2,993	14,607	17,600
Ethnic Category: Total of All Subjects *	3,741	18,259	22,000
Racial Categories			
American Indian/Alaska Native	75	365	440
Asian	449	2,191	2,640
Native Hawaiian or Other Pacific Islander	75	365	440
Black or African American	449	2,191	2,640
White	2,693	13,147	15,840
Racial Categories: Total of All Subjects *	3,741	18,259	22,000

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The STOP Study
 Total Enrollment: Data currently unavailable Protocol Number: _____
 Grant Number: 5U01PS001564-03

**PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative)
 by Ethnicity and Race**

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				*
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*				*



PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**				**

* These totals must agree.
 ** These totals must agree.

Program Director/Principal Investigator (Last, First, Middle): Colfax, Grant MD

Trainee Diversity Report

This report format should NOT be used for data collection from trainees.

Training Grant Title: The STOP Study

Total Number of Appointed: Not Applicable

Grant Number: 5U01PS001564-03

PART A. TOTAL TRAINEE APPOINTMENTS REPORT: Number of Trainees Appointed by Ethnicity and Race				
Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Trainees*				*
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Trainees*				*
PART B. HISPANIC TRAINEE APPOINTMENTS REPORT: Number of Hispanics or Latinos Appointed				
Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**				**
PART C. TRAINEES WITH DISABILITIES OR FROM DISADVANTAGED BACKGROUNDS				
Number of Trainees with Disabilities:				
Number of Trainees from Disadvantaged Backgrounds:				

(*) (**) These totals must agree.



Grant Number: 5U01PS001564-03

Principal Investigator(s):
Grant Nash Colfax, MD

Project Title: The STOP Study

Colfax, Grant Nash, MD
Director of HIV Prevention, AIDS Office
25 Van Ness Ave. Suite 500
San Francisco, CA 94102

Award e-mailed to: barbara.garcia@sfdph.org

Budget Period: 06/15/2012 – 06/14/2013

Project Period: 06/15/2010 – 06/14/2014

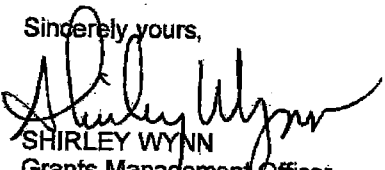
Dear Business Official:

The Centers for Disease Control and Prevention hereby awards a grant in the amount of \$747,833 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to SAN FRANCISCO CITY BOARD OF SUPERVISORS 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.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,


SHIRLEY WYNN
Grants Management Officer
Centers for Disease Control and Prevention

Additional information follows

SECTION I – AWARD A – 5U01PS001564-03**Award Calculation (U.S. Dollars)**

Salaries and Wages	\$20,784
Fringe Benefits	\$8,729
Personnel Costs (Subtotal)	\$29,513
Other Costs	\$1,600
Consortium/Contractual Cost	\$711,557

Federal Direct Costs	\$742,670
Federal F&A Costs	\$5,163
Approved Budget	\$747,833
Federal Share	\$747,833
TOTAL FEDERAL AWARD AMOUNT	\$747,833

AMOUNT OF THIS ACTION (FEDERAL SHARE) **\$747,833**

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

04 \$153,090

Fiscal Information:

CFDA Number: 93.943
EIN: 1946000417A1
Document Number: UPS001564A

IC	CAN	2012	2013
PS	939ZRJX	\$747,833	\$153,090

SUMMARY TOTALS FOR ALL YEARS			
YR	THIS AWARD	CUMULATIVE TOTALS	
3	\$747,833	\$747,833	
4	\$153,090	\$153,090	

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

CDC Administrative Data:

PCC: / OC: 4151 / Processed: ERAAPPS 05/21/2012

SECTION II – PAYMENT/HOTLINE INFORMATION – 5U01PS001564-03

For payment information see Payment Information section in Additional Terms and Conditions.

INSPECTOR GENERAL: The HHS Office Inspector General (OIG) maintains a toll-free number (1-800-HHS-TIPS [1-800-447-8477]) for receiving information concerning fraud, waste or abuse under grants and cooperative agreements. Information also may be submitted by e-mail to hhstips@oig.hhs.gov or by mail to Office of the Inspector General, Department of Health and Human Services, Attn: HOTLINE, 330 Independence Ave., SW, Washington DC 20201. Such reports are treated as sensitive material and submitters may decline to give their names if they choose to remain anonymous. This note replaces the Inspector General contact information cited in previous notice of award.

SECTION III – TERMS AND CONDITIONS – 5U01PS001564-03

This award is based on the application submitted to, and as approved by, CDC 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. The restrictions on the expenditure of federal funds in appropriations acts to the extent those restrictions are pertinent to the award.
- c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
- d. The HS 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.

Treatment of Program Income:
Additional Costs

SECTION IV – PS Special Terms and Conditions – 5U01PS001564-03

Funding Opportunity Announcement Number (FOA): PS09-004
Award Number: 5 U01 PS001564-03

ADDITIONAL TERMS AND CONDITIONS OF THIS AWARD

NOTE 1. INCORPORATION: Funding Opportunity/Program Announcement Number PS09-004 titled, Screening Targeted Populations to Interrupt On-Going Chains of Transmission with Enhanced Partner Notification the STOP Study, additional requirements, and the application dated February 25, 2012 are made a part of this award by reference.

NOTE 2A. TECHNICAL REVIEW RESPONSE STATEMENT REQUIREMENT: The technical review comments on the strengths and weaknesses of the proposal are provided as part of this award. A response to the weaknesses in these statements must be submitted to and approved, in writing, by the Grants Management Specialist as noted in the CDC Contact section of this Notice of Award, not later than July 1, 2012. Should these terms not be satisfactorily adhered to, it may result in denial of your authority to expend additional funds.

NOTE 2B. BUDGET SPECIAL CONDITION: Please provide a copy of the PHFE contract with UCSD to perform pol sequencing once finalized to the Grants Management Specialist listed in this Notice of Award.

NOTE 3. INDIRECT COSTS:

Indirect costs are approved based on the Indirect Cost Rate Agreement dated October 25, 2010, which calculates indirect costs as follows: a Fixed is approved at a rate of 24.8% of the base, which includes: Salaries.

NOTE 4. RENT OR SPACE COSTS: Recipients are responsible for ensuring that all costs included in this proposal to establish billing or final indirect cost rates are allowable in accordance with the requirements of the Federal award(s) to which they apply and 2 CFR Part 225, Cost Principles for State, Local, and Indian Tribal Governments (OMB Circular A-87). The recipient also has a responsibility to ensure sub-recipients expend funds in compliance with federal laws and regulations. Furthermore, it is the responsibility of the recipient to ensure rent is a legitimate direct cost line item which the recipient has supported in current and/or prior projects and these same costs have been treated as indirect costs that have not been claimed as direct costs. If rent is claimed as direct cost, the recipient must provide a narrative justification which describes their prescribed policy to include the effective date to the assigned Grants Management Specialist noted in Section IV. Staff Contacts.

NOTE 5. HUMAN SUBJECTS NOTICE: Under governing regulations, federal funds administered by the Department of Health and Human Services shall not be expended for research involving human subjects, and individuals shall not be enrolled in such research, without prior approval by the Office for Human Research Protections (OHRP) of an assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. Whenever an institution receives funding from a DHHS agency award to support such research, the awardee institution bears the ultimate responsibility for protecting human subjects under the award. This restriction applies to all performance sites engaged in human subject research, whether domestic, foreign, or international without OHRP-approved assurances. Compliance for all performance sites must be ensured by the awardee.

- a. IRB approval must be provided to the grants management specialist for the following research sites:

1. San Francisco Department of Public Health
2. Public Health Foundation Enterprises
3. UCSF - Alliance Health Project
4. San Francisco AIDS Foundation, Magnet
5. Tenderloin Health

b. **NOTICE OF CDC INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL.** It has been determined that this project will involve participation by CDC investigators in the research activities, therefore, the CDC IRB is required to approve the protocol prior to beginning any tasks or using Federal funds that involve human subjects. Once the CDC IRB approval of the protocol is rendered, the Grants Management Officer will provide written notification removing the award restriction.

NOTE 6. REPORTING REQUIREMENTS

CENTRAL CONTRACTOR REGISTRATION AND UNIVERSAL IDENTIFIER REQUIREMENTS:

All applicant organizations must obtain a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS.

Additionally, all applicant organizations must register in the Central Contractor Registry (CCR) and maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. CCR is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the CCR internet site at www.ccr.gov. If an award is granted, the grantee organization must notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the grantee organization.

FEDERAL INFORMATION SECURITY MANAGEMENT ACT (FISMA):

All information systems, electronic or hard copy which contain federal data need to be protected from unauthorized access. This also applies to information associated with CDC grants. Congress and the OMB have instituted laws, policies and directives that govern the creation and implementation of federal information security practices that pertain specifically to grants and contracts. The current regulations are pursuant to the Federal Information Security Management Act (FISMA), Title III of the E-Government Act of 2002 Pub. L. No. 107-347.

FISMA applies to CDC grantees only when grantees collect, store, process, transmit or use information on behalf of HHS or any of its component organizations. In all other cases, FISMA is not applicable to recipients of grants, including cooperative agreements. Under FISMA, the grantee retains the original data and intellectual property, and is responsible for the security of this data, subject to all applicable laws protecting security, privacy, and research. If and when information collected by a grantee is provided to HHS, responsibility for the protection of the HHS copy of the information is transferred to HHS and it becomes the agency's responsibility to protect that information and any derivative copies as required by FISMA. For the full text of the requirements under Federal Information Security Management Act (FISMA), Title III of the E-Government Act of 2002 Pub. L. No. 107-347, please review the following website:
http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_public_laws&docid=f:publ347.107.pdf

- () FFATA DOES APPLY. THE GRANTEE MUST FOLLOW THIS SECTION
 (X) FFATA DOES NOT APPLY ? THE GRANTEE MAY SKIP THIS SECTION

Pursuant to A-133 (see ____205(h) and ____205(i)), a grant sub-award includes the provision of any commodities (food and non-food) to the sub-recipient where the sub-recipient is required to abide by terms and conditions regarding the use or future administration of those goods. If the sub-awardee merely consumes or utilizes the goods, the commodities are not in and of themselves considered sub-awards.

In accordance with 2 CFR Chapter 1, Part 170 REPORTING SUB-AWARD AND EXECUTIVE COMPENSATION INFORMATION, Prime Awardees awarded a federal grant are required to file a FFATA sub-award report by the end of the month following the month in which the prime awardee awards any sub-grant equal to or greater than \$25,000.

A. Reporting of first-tier subawards.

1. **Applicability.** Unless you are exempt as provided in paragraph D. of this award term, you must report each action that obligates \$25,000 or more in Federal funds that does not include Recovery funds (as defined in section 1512(a)(2) of the American Recovery and Reinvestment Act of 2009, Pub. L. 111-5) for a subaward to an entity (see definitions in paragraph E. of this award term).

2. **Where and when to report.**

i. You must report each obligating action described in paragraph A.1. of this award term to <http://www.fsrs.gov>.

ii. For subaward information, report no later than the end of the month following the month in which the obligation was made. (For example, if the obligation was made on November 7, 2010, the obligation must be reported by no later than December 31, 2010).

3. **What to report.** You must report the information about each obligating action that the submission instructions posted at <http://www.fsrs.gov> specify.

B. Reporting Total Compensation of Recipient Executives.

1. **Applicability and what to report.** You must report total compensation for each of your five most highly compensated executives for the preceding completed fiscal year, if-

i. The total Federal funding authorized to date under this award is \$25,000 or more;

ii. In the preceding fiscal year, you received-

(a) 80 percent or more of your annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

(b) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

iii. The public does not have access to information about the compensation of the executives 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. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at <http://www.sec.gov/answers/execomp.htm>).

2. **Where and when to report.** You must report executive total compensation described in paragraph A.1. of this award term:

i. As part of your registration profile at <http://www.ccr.gov>.

ii. By the end of the month following the month in which this award is made, and annually thereafter.

C. Reporting of Total Compensation of Subrecipient Executives.

1. Applicability and what to report. Unless you are exempt as provided in paragraph D. of this award term, for each first-tier subrecipient under this award, you shall report the names and total compensation of each of the subrecipient's five most highly compensated executives for the subrecipient's preceding completed fiscal year, if-

i. In the subrecipient's preceding fiscal year, the subrecipient received-

(a) 80 percent or more of its annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

(b) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts), and Federal financial assistance subject to the Transparency Act (and subawards); and

ii. The public does not have access to information about the compensation of the executives 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. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at <http://www.sec.gov/answers/execomp.htm>).

2. Where and when to report. You must report subrecipient executive total compensation described in paragraph c.1. of this award term:

i. To the recipient.

ii. By the end of the month following the month during which you make the subaward. For example, if a subaward is obligated on any date during the month of October of a given year (i.e., between October 1 and 31), you must report any required compensation information of the subrecipient by November 30 of that year.

D. Exemptions

If, in the previous tax year, you had gross income, from all sources, under \$300,000, you are exempt from the requirements to report:

i. Subawards, and

ii. The total compensation of the five most highly compensated executives of any subrecipient.

E. Definitions. For purposes of this award term:

1. Entity means all of the following, as defined in 2 CFR part 25:

i. A Governmental organization, which is a State, local government, or Indian tribe;

ii. A foreign public entity;

iii. A domestic or foreign nonprofit organization;

iv. A domestic or foreign for-profit organization;

v. A Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity.

2. Executive means officers, managing partners, or any other employees in management positions.

3. Subaward:

i. This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.

ii. The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see Sec. ____210 of the attachment to OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations").

iii. A subaward may be provided through any legal agreement, including an agreement that you or a subrecipient considers a contract.

4. Subrecipient means an entity that:

i. Receives a subaward from you (the recipient) under this award; and

ii. Is accountable to you for the use of the Federal funds provided by the subaward.

5. Total compensation means the cash and noncash dollar value earned by the executive during the recipient's or subrecipient's preceding fiscal year and includes the following (for more information see 17 CFR 229.402(c)(2)):

i. Salary and bonus.

ii. Awards of stock, stock options, and stock appreciation rights. Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Statement of Financial Accounting Standards No. 123 (Revised 2004) (FAS 123R), Shared Based Payments.

iii. Earnings for services under non-equity incentive plans. This does not include group life, health, hospitalization or medical reimbursement plans that do not discriminate in favor of executives, and are available generally to all salaried employees.

iv. Change in pension value. This is the change in present value of defined benefit and actuarial pension plans.

v. Above-market earnings on deferred compensation which is not tax-qualified.

vi. Other compensation, if the aggregate value of all such other compensation (e.g. severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property) for the executive exceeds \$10,000.

NON-DELINQUENCY on FEDERAL DEBT

The Federal Debt Collection Procedures Act of 1990 (Act), 28 U.S.C. 3201(e), provides that an organization or individual that is indebted to the United States, and has a judgment lien filed against it, is ineligible to receive a Federal grant. CDC cannot award a grant unless the AOR of the applicant organization (or individual in the case of a Kirschstein-NRSA individual fellowship) certifies, by means of his/her signature on the application, that the organization (or individual) is not delinquent in repaying any Federal debt. If the applicant discloses delinquency on a debt owed to the Federal government, CDC may not award the grant until the debt is satisfied or satisfactory arrangements are made with the agency to which the debt is owed. In addition, once the debt is repaid or satisfactory arrangements made, CDC will take that delinquency into account when determining whether the applicant would be a responsible CDC grant recipient.

Anyone who has been judged to be in default on a Federal debt and who has had a judgment lien filed against him or her should not be listed as a participant in an application for a CDC grant until the judgment is paid in full or is otherwise satisfied. No funds may be used for or rebudgeted following an award to pay such an individual. CDC will disallow costs charged to awards that provide funds to individuals in violation of this Act.

These requirements apply to all types of organizations and awards, including foreign grants

NOTE 7. AUDIT REQUIREMENT: An organization that expends \$500,000 or more in a year in Federal awards shall have a single or program-specific audit conducted for that year in accordance with the provisions of OMB Circular A-133, Audit of States, Local Governments, and Non-Profit Organizations. The audit must be completed along with a data collection form, and the reporting package shall be submitted within the earlier of 30 days after receipt of the auditor's report(s), or nine months after the end of the audit period.

The audit report must be sent to:

Federal Audit Clearing House
Bureau of the Census
1201 East 10th Street
Jeffersonville, IN 47132

Should you have questions regarding the submission or processing of your Single Audit Package, contact the Federal Audit Clearinghouse at: (301) 763-1551, (800) 253-0696 or email: govs.fac@census.gov.

It is very helpful to CDC managers if the recipient sends a courtesy copy of completed audits and any management letters on a voluntary basis to the following address.

Centers for Disease Control and Prevention (CDC)
ATTN: Audit Resolution, Mail Stop E-14
2920 Brandywine Road
Atlanta, GA 30341-4146

The grantee is to ensure that the sub-recipients receiving CDC funds also meet these requirements (if total Federal grant or cooperative agreement funds received exceed \$500,000). The grantee must also ensure that appropriate corrective action is taken within six months after receipt of the sub-recipient audit report in instances of non-compliance with Federal law and regulations. The grantee is to consider whether sub-recipient audits necessitate adjustment of the grantee's own accounting records. If a sub-recipient is not required to have a program-specific audit, the Grantee is still required to perform adequate monitoring of sub-recipient activities. The grantee is to require each sub-recipient to permit independent auditors to have access to the sub-recipient's records and financial statements. The grantee should include this requirement in all sub-recipient contracts.

NOTE 8. ANNUAL FINANCIAL STATUS REPORT (FSR, SF 269 or SF 269A)/FEDERAL FINANCIAL REPORT (FFR):

a.) The Annual Financial Status Report (FSR) is required and must be submitted 90 days after the end of each budget period. The FSR for this budget period is due to the Grants Management Specialist by 09/14/2013. Reporting timeframe is June 15, 2012 through June 14, 2013. The FSR should only include those funds authorized and disbursed during the timeframe covered by the report. If the FSR is not finalized by the due date, an interim FSR must be submitted, marked "NOT FINAL" and an amount of un-liquidated obligations should be annotated to reflect unpaid expenses. Electronic versions of the form can be downloaded into Adobe Acrobat and completed on-line by reviewing, <http://www.whitehouse.gov/omb/grants/sf269a.pdf> (short form) or <http://www.whitehouse.gov/omb/grants/sf269.pdf> (long form).

Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information.

b.) PROGRESS REPORTING:

SEMI-ANNUAL PROGRESS REPORTING: Semi-annual progress reports are a requirement of this program, due 90 days following the end of each budget period.

i. The Interim Progress Report (IPR) will serve as the non-competing continuation application. IPR reporting timeframe is June 15, 2012 thru June 14, 2013. A due date and specific IPR guidance will be provided at a later date.

ii. The Annual Progress Report (APR) will be due 30 days following the end of the budget period, September 14, 2013. APR programmatic guidance will be provided at a later date.

- A comparison of actual accomplishments to the goal established for the period;
- The reasons for failure, if established goals were not met; and
- Other pertinent information including, when appropriate, analysis and explanation of performance costs significantly higher than expected.

iii. The Final Progress Report is required no later than 90 days after the end of the project period. All manuscripts published as a result of the work supported in part or whole by the cooperative agreement will be submitted with the progress reports.

NOTE: An original plus two copies of the reports must be mailed to the Grants Management Specialist for approval by the Grants Management Officer by the due date noted. Ensure the Award and Program Announcement numbers shown above are on the reports.

NOTE 9. TRAVEL COST: In accordance with Health and Human Services (HHS) Grants Policy Statement, travel is only allowable for personnel directly charged and approved on the grant/cooperative agreement. There must be a direct benefit imparted on behalf of the traveler as it applies to the approved activities of the Notice of Award. To prevent disallowance of cost, Recipient is responsible for ensuring that only allowable travel reimbursements are applied in accordance with their organization's established travel policies and procedures.

NOTE 10. FOOD AND MEALS: Costs associated with food or meals are NOT permitted unless included with per diem as a part of official travel.

NOTE 11. HIV PROGRAM REVIEW PANEL REQUIREMENT: All written materials, audiovisual materials, pictorials, questionnaires, survey instruments, websites, educational curricula and other relevant program materials must be reviewed and approved by an established program review panel. A list of reviewed materials and approval dates must be submitted to the CDC Grants Management Specialist.

Note 12. PRIOR APPROVAL: All requests, which require prior approval, must bear the signature of an authorized official of the business office of the grantee organization as well as the principal investigator or program or project director named on this notice of award. The request must be postmarked no later than 120 days prior to the end date of the current budget period and submitted with an original plus two copies. Any requests received that reflect only one signature will be returned to the grantee unprocessed. Additionally, any requests involving funding issues must include an itemized budget and a narrative justification of the request.

Prior approval is required but is not limited to the following types of requests: 1) Use of unobligated funds from prior budget period (Carryover); 2) Lift funding restriction, withholding, or disallowance, 3) Redirection of funds, 4) Change in Contractor/Consultant; 5) Supplemental funds; 6) Response to Technical Review or Summary Statement, 7) Change in Key Personnel, or 8) Liquidation Extensions.

NOTE 13. CORRESPONDENCE: ALL correspondence (including emails and faxes) regarding this award must be dated, identified with the AWARD NUMBER, and include a point of contact (name, phone, fax, and email). All correspondence should be addressed to the Grants Management Specialist listed below and submitted with an original plus two copies.

Pamela Render, Grants Management Specialist
Centers for Disease Control, PGO, Branch I
2920 Brandywine Road, Mail Stop E-15
Atlanta, GA 30341-4146
Telephone: 770-488-2712
Fax: (770-488-8360
Email: plr3@cdc.gov

NOTE 14. INVENTIONS: Acceptance of grant funds obligates recipients to comply with the standard patent rights clause in 37 CFR 401.14.

NOTE 15. PUBLICATIONS: Publications, journal articles, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from The Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention.

NOTE 16. CANCEL YEAR. 31 U.S.C. 1552(a) Procedure for Appropriation Accounts Available for Definite Periods states the following, On September 30th of the 5th fiscal year after the period of availability for obligation of a fixed year appropriation account ends, the account shall be closed and any remaining balances (whether obligated or unobligated) in the account shall be

canceled and thereafter all not be available for obligation or expenditure for any purpose. An example is provided below.

FY 2005 funds will expire September 30, 2010. All FY 2005 funds should be drawn down and reported to Payment Management System (PMS) prior to September 30, 2010. After this date, corrections or cash requests will not be permitted.

NOTE 17. CONFERENCE DISCLAIMER AND USE OF LOGOS:

Disclaimer. If a conference is funded by a grant, cooperative agreement, sub-grant and/or a contract the recipient must include the following statement on conference materials, including promotional materials, agenda, and internet sites:

Funding for this conference was made possible (in part) by the Centers for Disease Control and Prevention. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily do not reflect the official policies of the Department of Health and Human Services, nor does the mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.

Logos. Neither the HHS nor the CDC logo may be displayed if such display would cause confusion as to the conference source or give false appearance of Government endorsement. Use of the HHS name or logo is governed by U.S.C. 1320b-10, which prohibits misuse of the HHS name and emblem in written communication. A non-federal entity is unauthorized to use the HHS name or logo governed by U.S.C. 1320b-10. The appropriate use of the HHS logo is subject to review and approval of the Office of the Assistant Secretary for Public Affairs (OASPA).

Moreover, the Office of the Inspector General has authority to impose civil monetary penalties for violations (42 C.F.R. Part 1003). Neither the HHS nor the CDC logo can be used on conference materials, under a grant, cooperative agreement, and contract or co-sponsorship agreement without the expressed, written consent of either the Project Officer or the Grants Management Officer. It is the responsibility of the grantee (or recipient of funds under a cooperative agreement) to request consent for use of the logo in sufficient detail to ensure a complete depiction and disclosure of all uses of the Government logos. In all cases for utilization of Government logos, the grantee must ensure written consent is received from the Project Officer and/or the Grants Management Officer.

NOTE 18. EQUIPMENT AND PRODUCTS: To the greatest extent practicable, all equipment and products purchased with CDC funds should be American-made. CDC defines equipment as tangible non-expendable personal property (including exempt property) charged directly to an award having a useful life of more than one year AND an acquisition cost of \$5,000 or more per unit. However, consistent with recipient policy, a lower threshold may be established. Please provide the information to the Grants Management Officer to establish a lower equipment threshold to reflect your organization's policy.

The grantee may use its own property management standards and procedures provided it observes provisions of the following sections in the Office of Management and Budget (OMB) Circular A-110 and 45 CFR Part 92:

i. Office of Management and Budget (OMB) Circular A-110, Sections 31 through 37 provides the uniform administrative requirements for grants and agreements with institutions of higher education, hospitals, and other non-profit organizations. For additional information, please review the following website: <http://www.whitehouse.gov/omb/circulars/a110/a110.html>

ii. 45 CFR Parts 92.31 and 92.32 provides the uniform administrative requirements for grants and cooperative agreements to state, local and tribal governments. For additional information, please review the following website listed: http://www.access.gpo.gov/nara/cfr/waisidx_03/45cfr92_03.html

NOTE 19. PROGRAM INCOME: Any program income generated under this cooperative agreement will be used in accordance with the additional cost alternative. The disposition of program income must have written prior approval from the Grants Management Officer.

Additional Costs Alternative—Used for costs that are in addition to the allowable costs of the project for any purposes that further the objectives of the legislation under which the cooperative agreement was made. General program income subject to this alternative shall be reported on lines 10r and 10s, as appropriate, of the FSR (Long Form).

NOTE 20. KEY PERSONNEL: In accordance with 45 CFR 74.25(c)(1), & (3) CDC recipients shall obtain prior approvals from CDC for (1) change in the project director or principal investigator or other key persons specified in the application or award document, and (2) the absence for more than three months, or a 25 percent reduction in time devoted to the project, by the approved project director or principal investigator.

Note 21. TRAFFICKING IN PERSONS. This award is subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. 7104). For the full text of the award terms and conditions, please review the following website:
http://www.cdc.gov/od/pgo/funding/grants/Award_Term_and_Condition_for_Trafficking_in_Persons.shtml

NOTE 22. ACKNOWLEDGMENT OF FEDERAL SUPPORT: When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all awardees receiving Federal funds, including and not limited to State and local governments and recipients of Federal research grants, shall clearly state (1) the percentage of the total costs of the program or project which will be financed with Federal money, (2) the dollar amount of Federal funds for the project or program, and (3) percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

NOTE 23. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA):

Pursuant to the Standards for Privacy of Individually Identifiable Health Information promulgated under the Health Insurance Portability and Accountability Act (HIPAA)(45 CFR Parts 160 and 164) covered entities may disclose protected health information to public health authorities authorized by law to collect or received such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions. The definition of a public health authority includes a person or entity acting under a grant of authority from or contract with such public agency. Through this agreement, the [Insert recipient Name] is acting under a grant of authority from CDC to carry out [Insert: Name of project/activity] which is authorized by [Insert: Statutory authority from Public Health Service Act, Comprehensive Environmental Response, Compensation, and Liability Act, or other legislation (this information should be provided by the awarding program)]. The CDC grants this authority to [Insert: partner name] for purposes of this project. Further, CDC considers this to be [Insert: type of public health activity, i.e. disease/injury reporting, vital events, surveillance, investigations, intervention, registry] for which disclosure of protected health information by covered entities is authorized by section 164.512(b)).

NOTE 24. PAYMENT INFORMATION:

Automatic Drawdown (Direct/Advance Payments):

PAYMENT INFORMATION: Payment under this award will be made available through the Department of Health and Human Services (HHS) Payment Management System (PMS). PMS will forward instructions for obtaining payments.

a.) PMS correspondence, mailed through the U.S. Postal Service, should be addressed as follows:

Director, Division of Payment Management, OS/ASAM/PSC/FMS/DPM
P.O. Box 6021
Rockville, MD 20852
Phone Number: (877) 614-5533
University and Non-Profit Payment Branch (301) 443-2672
Governmental and Tribal Payment Branch (301) 443-2569
Cross Servicing Payment Branch: (301) 443-0377
Email: PMSSupport@psc.gov
Website: http://www.dpm.psc.gov/grant_recipient/shortcuts/shortcuts.aspx?explorer.event=true

Please Note: To obtain the contact information of DPM staff within respective Payment Branches refer to the links listed below:

University and Non-Profit Payment Branch:

http://www.dpm.psc.gov/contacts/dpm_contact_list/univ_nonprofit.aspx?explorer.event=true

Governmental and Tribal Payment Branch:

http://www.dpm.psc.gov/contacts/dpm_contact_list/gov_tribal.aspx?explorer.event=true

Cross Servicing Payment Branch:

http://www.dpm.psc.gov/contacts/dpm_contact_list/cross_servicing.aspx

International Payment Branch:

Bhavin Patel (301) 443-9188

Note: Mr. Patel is the only staff person designated to handle all of CDC's international cooperative agreements.

b.) If a carrier other than the U.S. Postal Service is used, such as United Parcel Service, Federal Express, or other commercial service, the correspondence should be addressed as follows:

US Department of Health and Human Services
PSC/DFO/Division of Payment Management
7700 Wisconsin Avenue -10th Floor
Bethesda, MD 20814

To expedite your first payment from this award, attach a copy of the Notice of Grant/Cooperative Agreement to your payment request form.

NOTE 25. ACCEPTANCE OF THE TERMS OF AN AWARD:

By drawing or otherwise obtaining funds from the grant payment system, the recipient acknowledges acceptance of the terms and conditions of the award and is obligated to perform in accordance with the requirements of the award. If the recipient cannot accept the terms, the recipient should notify the Grants Management Officer.

NOTE 26. CERTIFICATION STATEMENT: By drawing down funds, Awardee certifies that proper financial management controls and accounting systems to include personnel policies and procedures have been established to adequately administer Federal awards and funds drawn down are being used in accordance with applicable Federal cost principles, regulations and Budget and Congressional intent of the President.

NOTE 27. ADDITIONAL REQUIREMENTS:

The Additional Requirements that apply to this grant or cooperative agreement are indicated below. The full text of the Additional Requirements may be found on the CDC web site at: http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm.

AR 32 - FY 2012 Enacted General Provisions

NOTE 28. FY 2012 APPROPRIATIONS PROVISION:

HHS recipients must comply with all terms and conditions outlined in their grant award, including grant policy terms and conditions contained in applicable Department of Health and Human Services (HHS) Grant Policy Statements, and requirements imposed by program statutes and regulations and HHS grant administration regulations, as applicable; as well as any regulations or limitations in any applicable appropriations acts.

NOTE 29. CDC CONTACTS

Programmatic and Technical Contact:

Phillip Peters, M.D., Project Officer
Centers for Disease Control and Prevention
HIV Clinical Epidemiology Team
Corporate Square, Building 8, Mailstop E-45
Telephone: (404) 639-6158
Email: pjpeters@cdc.gov

STAFF CONTACTS

Grants Management Specialist: Pamela L Render
Centers for Disease Control and Prevention
Procurement and Grants Office
Koger Center, Colgate Building
2920 Brandywine Road, Mail Stop K 70
Atlanta, GA 30341
Email: prender@cdc.gov **Phone:** 770-488-2712 **Fax:** 770-488-2670

Program Official: Eileen Yee
Center for Disease Control and Prevention
NCHHSTP
Executive Park Drive, MS E-60
Atlanta, GA 30329
Email: eyee@cdc.gov **Phone:** 404-498-0097 **Fax:** 404-498-2626

Grants Management Officer: Shirley Wynn
Centers for Disease Control and Prevention
Procurement and Grants Office
Koger Center, Colgate Building
2920 Brandywine Road, Mailstop K75
Atlanta, GA 30341
Email: zbx6@cdc.gov **Phone:** 770-488-1515 **Fax:** 770.488.2688

SPREADSHEET SUMMARY

GRANT NUMBER: 5U01PS001564-03

INSTITUTION: SAN FRANCISCO DEPT OF PUBLIC HEALTH

<i>Budget</i>	<i>Year 3</i>	<i>Year 4</i>
Salaries and Wages	\$20,784	
Fringe Benefits	\$8,729	
Personnel Costs (Subtotal)	\$29,513	
Other Costs	\$1,600	
Consortium/Contractual Cost	\$711,557	
TOTAL FEDERAL DC	\$742,670	\$153,090
TOTAL FEDERAL F&A	\$5,163	
TOTAL COST	\$747,833	\$153,090

FORM SFEC-126:
NOTIFICATION OF CONTRACT APPROVAL
 (S.F. Campaign and Governmental Conduct Code § 1.126)

City Elective Officer Information <i>(Please print clearly.)</i>	
Name of City elective officer(s): Members, SF Board of Supervisors	City elective office(s) held: Members, SF Board of Supervisors

Contractor Information <i>(Please print clearly.)</i>	
Name of contractor: San Francisco AIDS Foundation	
Please list the names of (1) members of the contractor's board of directors; (2) the contractor's chief executive officer, chief financial officer and chief operating officer; (3) any person who has an ownership of 20 percent or more in the contractor; (4) any subcontractor listed in the bid or contract; and (5) any political committee sponsored or controlled by the contractor. Use additional pages as necessary.	
<ol style="list-style-type: none"> 1. See Attached 2. Neil Guiliano, Chief Executive Officer 3. N/A 4. N/A 5. N/A 	
Contractor address: 1035 Market Street, Suite 400, San Francisco, CA 94103	
Date that contract was approved:	Amount of contract: \$34,332
Describe the nature of the contract that was approved: HIV Prevention	
Comments: San Francisco AIDS Foundation, Magnet is a 501 (c) 3 Nonprofit with a Board of Directors	

This contract was approved by (check applicable):

the City elective officer(s) identified on this form

a board on which the City elective officer(s) serves San Francisco Board of Supervisors
Print Name of Board

the board of a state agency (Health Authority, Housing Authority Commission, Industrial Development Authority Board, Parking Authority, Redevelopment Agency Commission, Relocation Appeals Board, Treasure Island Development Authority) on which an appointee of the City elective officer(s) identified on this form sits

Print Name of Board

Filer Information <i>(Please print clearly.)</i>	
Name of filer: Clerk of the SF Board of Supervisors	Contact telephone number: (415) 554-5184
Address: City Hall, Room 244 1 Dr. Carlton B. Goodlett Place	E-mail: Bos.Legislation@sfgov.org

 Signature of City Elective Officer (if submitted by City elective officer)

 Date Signed

 Signature of Board Secretary or Clerk (if submitted by Board Secretary or Clerk)

 Date Signed

San Francisco AIDS Foundation

Board of Directors:

Steven Abbott
Philip Besirof
Wesley Burwell
Hamish Chandra
Bruno Delagneau
Dale Freeman
David A. Hendricks
Don Howard
Tim Jones
Michael Kidd
Tom Perrault (Chair)
Mike Richey
Lisa Serman
Alan Taylor

Neil Giuliano, Chief Executive Officer

FORM SFEC-126:
NOTIFICATION OF CONTRACT APPROVAL
(S.F. Campaign and Governmental Conduct Code § 1.126)

City Elective Officer Information <i>(Please print clearly.)</i>	
Name of City elective officer(s): Members, SF Board of Supervisors	City elective office(s) held: Members, SF Board of Supervisors
Contractor Information <i>(Please print clearly.)</i>	
Name of contractor: University of California, San Francisco	
<i>Please list the names of (1) members of the contractor's board of directors; (2) the contractor's chief executive officer, chief financial officer and chief operating officer; (3) any person who has an ownership of 20 percent or more in the contractor; (4) any subcontractor listed in the bid or contract; and (5) any political committee sponsored or controlled by the contractor. Use additional pages as necessary.</i>	
<ol style="list-style-type: none"> 1. See Attachment 1 2. Susan Desmond-Hellman, MD, MPH, President 3. N/A 4. N/A 5. N/A 	
Contractor address: 1930 Market Street, San Francisco, CA 94102	
Date that contract was approved:	Amount of contract: \$46,678
Describe the nature of the contract that was approved: HIV Prevention	
Comments: UCSF is a state agency with a Board of Directors	

This contract was approved by (check applicable):

the City elective officer(s) identified on this form

a board on which the City elective officer(s) serves San Francisco Board of Supervisors

Print Name of Board

the board of a state agency (Health Authority, Housing Authority Commission, Industrial Development Authority Board, Parking Authority, Redevelopment Agency Commission, Relocation Appeals Board, Treasure Island Development Authority) on which an appointee of the City elective officer(s) identified on this form sits

Print Name of Board

Filer Information <i>(Please print clearly.)</i>	
Name of filer: Clerk of the SF Board of Supervisors	Contact telephone number: (415) 554-5184
Address: City Hall, Room 244 1 Dr. Carlton B. Goodlett Place	E-mail: Bos.Legislation@sfgov.org

Signature of City Elective Officer (if submitted by City elective officer)

Date Signed

Signature of Board Secretary or Clerk (if submitted by Board Secretary or Clerk)

Date Signed

**University of California, San Francisco (UCSF)
Board of Directors**

- William E. Oberndorf, Chair
- Arthur Kern, Vice Chair
- Barbara Bass Bakar
- Nancy Hellman Bechtle
- Lynné Benioff, Chair
- Faustino Bernadett, Jr., MD
- Zachary Bogue
- William K. Bowes
- T. Robert Burke
- Brook H. Byers
- Selina Gaw Cha
- William H. Davidow
- Dipanjan Deb
- Kenneth T. Derr
- Doris F. Fisher
- Nanci Bakar Fredkin
- Robert B. Friend
- Andrew S. Grove, PhD, Honorary Director
- Kathryn A. Hall
- Eve Epstein Jaffe
- F. Van Kasper
- Christine E. Lamond
- Mary Vaughan Lester
- Virginia Madden
- Leigh Sherwood Matthes
- Nan Tucker McEvoy
- Nion McEvoy
- Steven Merrill
- Ellen Magnin Newman, Chair Emeritus
- Catherine H. Podell
- Carmen Policy
- Jeanne Robertson
- Kenneth T. Rosen
- Richard M. Rosenberg
- Jaclyn Safier
- Chara Schreyer
- W. Clarke Swanson, Jr.
- Myron E. Ullman, III
- John S. Wadsworth, Jr.
- Amanda M. Wallis
- Debra Wetherby
- Diane B. Wilsey
- Andrew Woeber
- Gideon Yu

FORM SFEC-126:
NOTIFICATION OF CONTRACT APPROVAL
 (S.F. Campaign and Governmental Conduct Code § 1.126)

City Elective Officer Information <i>(Please print clearly.)</i>	
Name of City elective officer(s): Members, SF Board of Supervisors	City elective office(s) held: Members, SF Board of Supervisors

Contractor Information <i>(Please print clearly.)</i>	
Name of contractor: Public Health Foundation Enterprises, Inc.	
<i>Please list the names of (1) members of the contractor's board of directors; (2) the contractor's chief executive officer, chief financial officer and chief operating officer; (3) any person who has an ownership of 20 percent or more in the contractor; (4) any subcontractor listed in the bid or contract; and (5) any political committee sponsored or controlled by the contractor. Use additional pages as necessary.</i>	
<ol style="list-style-type: none"> 1. See Attached 2. Mark J. Bertler, President/CEO 3. N/A 4. N/A 5. N/A 	
Contractor address: 12801 Crossroads Parkway South, suite 200, City of Industry, CA 91746	
Date that contract was approved:	Amount of contract: \$239,056
Describe the nature of the contract that was approved: HIV Prevention	
Comments: PHFE is a 501 (c) 3 Nonprofit with a Board of Directors	

This contract was approved by (check applicable):

the City elective officer(s) identified on this form

a board on which the City elective officer(s) serves San Francisco Board of Supervisors
Print Name of Board

the board of a state agency (Health Authority, Housing Authority Commission, Industrial Development Authority Board, Parking Authority, Redevelopment Agency Commission, Relocation Appeals Board, Treasure Island Development Authority) on which an appointee of the City elective officer(s) identified on this form sits

Print Name of Board

Filer Information <i>(Please print clearly.)</i>	
Name of filer: Angela, Calvillo, Clerk of the Board	Contact telephone number: 415-554-5184
Address: City Hall, Room 244 1 Dr. Carlton B. Goodlett Place, San Francisco, CA 94102	E-mail: Board.of.Supervisors@sfgov.org

Signature of City Elective Officer (if submitted by City elective officer)

Date Signed

Signature of Board Secretary or Clerk (if submitted by Board Secretary or Clerk)

Date Signed

Public Health Foundation Enterprise

Board of Directors:

Bruce Y. Lai (chair)

Peter Jacobson

Teri A. Burley

Karen L. Angel

Michael Ascher

Loretta Davis

Susan DeSanti

Scott Filer

Gerald D. Jensen

Patrick M. Libbey

Erik D. Ramanathan

Edward Yip

Mark J. Bertler, CEO