File No.

150893

Committee Item No. \_\_\_\_\_ &\_\_\_\_ Board Item No. \_\_\_\_\_ 31\_\_\_\_

## COMMITTEE/BOARD OF SUPERVISORS

AGENDA PACKET CONTENTS LIST

Committee: Budget & Finance Committee

Date September 30, 2015

Board of Supervisors Meeting

Date <u>October 4,2015</u>

## **Cmte Board**

		Motion
$\mathbf{X}$	$\nabla$	Resolution
$\square$	$\square$	Ordinance
		Legislative Digest
$\square$		Budget and Legislative Analyst Report
Π	$\Box$	Youth Commission Report
1 X	N	Introduction Form
Ŕ	$\overline{\mathbf{N}}$	Department/Agency Cover Letter and/or Report
Π	Ĩ,	MOU
$\overline{\mathbf{X}}$	X	Grant Information Form
$\overline{\mathbf{X}}$	R	Grant Budget
Π́.		Subcontract Budget
Ē	$\Box$	Contract/Agreement
X	X	Form 126 – Ethics Commission
$\overline{\mathbf{X}}$	<u>.</u>	Award Letter
Î	Ē	Application
Ħ	Ē	Public Correspondence
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Completed by:Linda WongDateSeptember 25, 2015Completed by:Linda WongDateOther

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FILE NO. 150893

#### **RESOLUTION NO.**

[Accept and Expend Grant - Centers for Disease Control and Prevention - Medical Monitoring Project - \$524,488]

Resolution retroactively authorizing the Department of Public Health to accept and expend a grant in the amount of \$524,488 from Centers for Disease Control and Prevention to participate in a program entitled Medical Monitoring Project for the period of June 1, 2015, through May 31, 2016.

WHEREAS, The Centers for Disease Control and Prevention (CDC) has agreed to fund Department of Public Health (DPH) in the amount of \$524,488 for the period of June 1, 2015, through May 31, 2016; and

WHEREAS, The full project period of the grant starts on June 1, 2015, and ends on May 31, 2020, with years two, three, four and five subject to availability of funds and satisfactory progress of the project; and

WHEREAS, As a condition of receiving the grant funds, CDC requires the City to enter into an agreement (Agreement), a copy of which is on file with the Clerk of the Board of Supervisors in File No. <u>150893</u>; which is hereby declared to be a part of this Resolution as if set forth fully herein; and

WHEREAS, The purpose of this project is to gather detailed information on HIVinfected patients receiving care in the United States; and

WHEREAS, An Annual Salary Ordinance amendment is not required as the grant partially reimburses DPH for three existing positions, one Manager I (Job Class No. 0922) at .25 FTE, one Health Program Coordinator III (Job Class No. 2593) at .40 FTE and one Health Program Coordinator II (Job Class No. 2591) at .15 FTE for the period of June 1, 2015 through, May 31, 2016; and

Supervisor Wiener BOARD OF SUPERVISORS Page 1

WHEREAS, The budget includes a provision for indirect costs in the amount of \$21,157; now, therefore, be it

RESOLVED, That DPH is hereby authorized to retroactively accept and expend a grant in the amount of \$524,488 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

ce of the Controller

#### Department Of Public Health BOARD OF SUPERVISORS

#### File Number:

(Provided by Clerk of Board of Supervisors)

#### Grant Information Form (Effective January 2000)

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: Medical Monitoring Project (MMP)
- 2. Department: Department of Public Health **Public Health Division (PHD)** Applied Research, Community Health Epidemiology, & Surveillance (ARCHES)
- 3. Contact Person: Maree Kay Parisi
- Grant Approval Status (check one):

[X] Approved by funding agency

[] Not yet approved

Telephone: 437-6253

5. Amount of Grant Funding Approved or Applied for: \$2,622,440 (Year 1 = \$524,488; Year 2 = \$524,488; Year 3 = \$524,488; Year 4 = \$524,488; Year 4 = \$524,488)

6a. Matching Funds Required: No

b. Source(s) of matching funds (if applicable): N/A

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:

The Medical Monitoring Project (MMP) is a comprehensive population-based project to gather detailed information on HIV-infected patients receiving care in the United States. San Francisco has been selected as one of the study sites. Information collected through patient interview and medical chart abstraction will enable us to estimate resource needs for treatment and other services for people infected with HIV in San Francisco as well as nationally. Data from the project can document who is receiving care and provide population-based estimates of clinical characteristics for persons with HIV and AIDS in care. This information can then be used to improve access to care and prevention by supporting funding requests for the Ryan White CARE Act and by informing the HIV prevention community planning process.

- 9. Grant Project Schedule, as allowed in approval documents, or as proposed: Approved Year 1 Project Start-Date: 6/01/2015 End-Date: 5/31/2016 **Full Project Period** Start-Date: 6/01/2015 End-Date: 5/31/2020
- 10a. Amount budgeted for contractual services: \$375,845 in Year 1

\$1,879,225 in the 5-year project period

- b. Will contractual services be put out to bid? No, existing services
- c. If so, will contract services help to further the goals of the Department's Local Business Enterprise (LBE) requirements? N/A

d. Is this likely to be a one-time or ongoing request for contracting out? On-going

11a. Does the budget include indirect costs? []No X Yes

b1. If yes, how much?	\$21,157 in Year 1
-	\$105,785 in the 5-year project period
b2. How was the amount ca	Iculated? 24.03% of Salaries

3518

c1. If no	, why are	indirect	costs n	ot included'
[]	Not allow	ed by gr	anting a	agency

[] To maximize use of grant funds on direct services

[] Other (please explain):

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

12. Any other significant grant requirements or comments:

We respectfully request for approval to accept and expend these funds retroactive to June 01, 2015. The Department received the letter of funding allocation on June 2, 2015.

#### Grant Code: HCAO05/15

\*\*Disability Access Checklist\*\*\*(Department must forward a copy of all completed Grant Information Forms to the Mayor's Office of Disability)

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

[X] Existing Site(s)	
[] Rehabilitated Site(s)	
[] New Site(s)	

[] Existing Structure(s) [] Rehabilitated Structure(s) [] New Structure(s)

[] Existing Program(s) or Service(s) [] New Program(s) or Service(s)

14. The Departmental ADA Coordinator 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 disability rights laws and regulations and will allow the full inclusion of persons with disabilities. These requirements include, but are not limited to:

1. Having staff trained in how to provide reasonable modifications in policies, practices and procedures;

2. Having auxiliary aids and services available in a timely manner in order to ensure communication access;

3. Ensuring that any service areas and related facilities open to the public are architecturally accessible and have been inspected and approved by the DPW Access Compliance Officer or the Mayor's Office on Disability Compliance Officers.

If such access would be technically infeasible, this is described in the comments section below:

Comments:

Departmental ADA Coordinator or Mayor's Office of Disability Reviewer:

Ron Weigelt (Name)

Director of Human Resources and Interim Director, EEO, and Cultural Competency Programs

(Title)

Date Reviewed:

(Signature Required)

Department Head or Designee Approval of Grant Information Form:

Barbara A. Garcia, MPA	·
(Name)	
Director of Health	
(Title)	$\left( \partial \left( D \right) \right) $
<sup>*</sup> Date Reviewed: 8/3/15	the for
	(Signature Required)
Date Reviewed0 /2 / 13	(Signature Required)

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#### AIDS Office - HIV Epidemiology Section Medical Monitoring Project (MMP) June 1, 2015 - May 31, 2016

Dept / Div: HPH-03 Fund Group: 2S/CHS/GNC ndex Code: HCHPDHIVSVGR Grant Code: HCAO05 Grant Detail: 1500

CATEGORY/LINE ITEM	Annual Salary		otal Annua al/Frin Be	% of Time	Monthly Rate	Mth	Salary Budget	Frin Ben Budget	Total Budget	Comments
PERSONNEL SEROEPIDEMIOLOGY										
1. Manager I 0923 2 S. Scheer	130,124	0	130,124	25%	10,844	۰ 12	32,531	14,639	47,170	
2. Health Program Coordinator III 2593 5 MK. Parisi	103,933	25,983	129,916	40%	8,661	12	41,573	16,629	58,203	
Health Program Coorindaor II 2591 V Delgado	92,927	23,232	116,158	15%	7,744	12	13,939	5,576	19,515	
4 2803 5 A. Hirozawa (.75 FTE)	79,135	0	79,135	11%	6,595	0	0	0	0	
ひ び い てのTAL SALARY/FRINGE	406,119	49,215	455,334				88,043	36,844	124,887	
00101 SALARIES 00103 FRNG BN SUB TOTAL								•	88,043 36,844 <b>124,887</b>	 -
TRAVEL 1. Local Travel (02301) 2. Out-of-Jurisdiction Travel(02101) Sub Total TRAVEL		•							2,600	One Meeting to Atlanta (fare \$600 +ground transportation \$100 + lodge \$200 x 3 nts) x 2 staff
EQUIPMENT 1. Computers (06061) Sub Total EQUIPM	<b>I</b> ENT					•		•	0 0	
MATERIALS AND SUPPLIES 1. Office supplies <b>(04951)</b> 2. Non-Inventoried Equipment Sub Total SUPPLI	ES								0 0 0	-
CONTRACTUAL SERVICES (02789) 1. PHFE 2. SFDPH-Public Health Laboratory Sub Total CONTR	ACTS						· .		375,845 0 375,845	

8/4/2015 1:3'

ept / Div: HPH-03 und Group: 2S/CHS/GNC Idex Code: HCHPDHIVSVGR rant Code: HCAO05 rant Detail: 1500

#### SAN FRANCISCO DEPARTMENT OF PUBLIC AIDS Office - HIV Epidemiology Section Medical Monitoring Project (MMP) June 1, 2015 - May 31, 2016

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ATEGORY/LINE ITEM		nual otal Annu n Ben ≩al/Frin Be	% OF TIME	Monthly Rate	Mth	Salary Budget	Frin Ben Budget	Total Budget	Comments	
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1. Rent support/mtg fac (03011)								0		
2. Telephone/Com (03241) 3. Postage (03561)								0		
4. Delivery/Courier srvc (03521)								0		
5. Reproduction/Photocopy								0		
a. Photocopier leasing (03131)							•	0	· · · · · · · · · · · · · · · · · · ·	
b. Photocopier maint (02931)								- 0		
c. Repro srvc (In House)(03551) 6. Print/Slide srvc (Outside)(03552)								0		
7. Promotion/Advertis (03599)	•					•		0		
8. Stipend (02783)		· •						õ		
9. Staff training (02201)								. 0		•
0. Other Prof. Svcs (02799)				•				0		
1. IRB fees (02799) Sub TOTAL OTHEI								0		
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2								,	•	•
		BUDGET	SUMMAR	Y						
<b>_</b>		BUDGET		Y				88 043		
A. SALARIES		BUDGET	SUMMAR	Y				88,043	· · ·	
<b>_</b>		BUDGET		Y				88,043 36,844	•	
A. SALARIES B. MANDATORY FRINGE		BUDGET		Y				36,844	• • •	
A. SALARIES		BUDGET		Ŷ					• • •	•
A. SALARIES B. MANDATORY FRINGE C. TRAVEL	· · ·	BUDGET		Ŷ				36,844 2,600		
A. SALARIES B. MANDATORY FRINGE		BUDGET		Υ.				36,844		
A. SALARIES B. MANDATORY FRINGE C. TRAVEL	LIES	BUDGET		Ŷ				36,844 2,600		
A. SALARIES B. MANDATORY FRINGE C. TRAVEL D. EQUIPMENT E. MATERIALS AND SUPP	LIES	BUDGET		Ŷ				36,844 2,600 0 0		
A. SALARIES B. MANDATORY FRINGE C. TRAVEL D. EQUIPMENT	LIES	BUDGET		Ŷ				36,844 2,600 0		
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A. SALARIES B. MANDATORY FRINGE C. TRAVEL D. EQUIPMENT E. MATERIALS AND SUPP F. CONTRACT / MOU G. OTHER DIRECT COSTS H. INDIRECT COST (24.03) TOTAL BUDGET		· ·		¥		•		36,844 2,600 0 375,845 0 503,332 21,157 <b>524,488</b>		· ·
A. SALARIES B. MANDATORY FRINGE C. TRAVEL D. EQUIPMENT E. MATERIALS AND SUPP F. CONTRACT / MOU G. OTHER DIRECT COSTS H. INDIRECT COST (24.03)		· ·		¥		•		36,844 2,600 0 375,845 0 503,332 21,157		

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### San Francisco Department of Public Health AIDS Office Applied Research, Community Health epidemiology, & Surveillance "Medical Monitoring Project (MMP)" PS09-93706CONT14 Grant #1U62PS004970-01 Revised Budget Summary

## June 1, 2015 - May 31, 2016

Α.	Salaries	\$88,043
В.	Mandatory Fringe	\$36,844
C.	Travel	\$2,600
D.	Equipment	\$0
	Materials and Supplies	\$0
F.	Contractual	\$375,845
G.	Other Expenses	\$0
	TOTAL DIRECT COSTS	\$503,332
н.	Indirect Costs (24.03% of Total Salaries)	\$21,157
	TOTAL BUDGET	\$524,488

#### Revised Detail Line-Item Budget and Justification: 6/1/2015 – 5/31/2016

#### A. PERSONNEL

B. MANDATORY FRINGE

Total Personnel	\$36,844 <b>\$124,887</b>
Fringe @ 41.85%	\$36,844 \$36,844
Total Salaries	\$88,043

 0922 – Manager I: Susan Scheer Director of ARCHES MMP Co-Principal Investigator

Annual Salary: \$130,124 x 0.25 FTE x 12 months = \$32,531

The Co-Principal Investigator will be responsible for ensuring that all MMP protocols are followed and that the necessary security and confidentiality standards are met. She will serve as the project liaison to the SFDPH HIV/AIDS core and incidence surveillance programs and make sure that MMP is integrated, to extent possible, with core surveillance. She will disseminate the MMP findings to the San Francisco Care Council, HIV Prevention Planning Council and other interested parties. She will be responsible for the fiscal management of MMP, all correspondence with the CDC, and will assist the MMP project coordinator with hiring of staff. She will oversee data collection, analysis interpretation, and dissemination.

 2593 - Health Program Coordinator III: Maree Kay Parisi MMP Project Coordinator Annual Salary: \$103,933 X 0.40 FTE x 12 months = \$41,573

The MMP Project Coordinator will coordinate MMP activities including developing, monitoring and overseeing MMP protocols and will provide administrative and technical. She will be responsible for searching lead-generating resources for contact information for participants, and recruitment of participants for MMP. She will continue to act as the main contact for San Francisco medical care providers. For example, drawing on her familiarity with medical care sites through core surveillance activities, she will assist in gaining access to medical records for abstraction, contact information for participants, and will be able to reassure MMP sites about security and confidentiality by relating it to the core surveillance guidelines. She will have direct supervision of four MMP staff members.

 2591 Health Program Coordinator II: Viva Delgado Annual Salary: \$92,927 x 0.15 FTE x12 months=\$13,939

The HIV core surveillance project coordinator will assist with MMP activities such as contacting and coordinating cross jurisdictional data exchange, locating, recruiting and

scheduling participants, and data management. She will manage sampled MMP patients who have moved outside of SF and will be the lead contact with other health departments to determine their policies around contacting, interviewing and conducting a medical record abstraction in their area.

#### C. TRAVEL

#### \$2,600

i. Out-of-Jurisdiction Travel \$2,600 This funding is to cover costs of domestic travel to CDC meetings for the principal investigator and project coordinator to attend the annual MMP meeting in Atlanta. Estimated costs are below.

	Airfare (\$600 x 2 staff) =	\$1,200
	Lodging (\$200/night x 3 nights x 2 staff) =	\$1,200
	Ground Transportation (\$100/person x 2 staff) =	<u>\$ 200</u>
	Total =	\$2,600
	•	. •
D	EQUIPMENT	<b>\$0</b>
E.	MATERIALS AND SUPPLIES	\$0
F.	CONTRACTUAL	\$375,845

1. Name of contractor: Public Health Foundation Enterprises, Inc. (PHFE)

**Method of Selection:** PHFE was selected through a Request for Qualifications process held in 2013 by the SFDPH Contracts Unit. PHFE will act as a fiscal intermediary for staff hired by SFDPH.

#### **Period of performance:** 6/1/2015 – 5/31/2016

**Description of activities:** PHFE will provide the staffing for data management and data dissemination; and field activities: including medical record abstraction and patient interview. They have demonstrated expertise in this area and have an established relationship with the SFDPH.

**Method of accountability:** The contractor will follow the CDC and HIV Epidemiology Section's procedures; will follow strict performance timelines; contractor's performance will be monitored and evaluated by the senior epidemiologist; payment to contractor will be based on fee for service.

Itemized budget with narrative justification:	\$375,845
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a) PHFE Personnel

b) PHFE Mandatory Fringe Benefits

Total Salaries

\$233,452

Mandatory Fringe @ 31.1% \$ 72,604 Total Personnel \$306,056

i. Research Associate: Amedeia Rector

Annual Salary: \$43,384 x 1.0 FTE for 10 months = \$36,153 \$44,685 x 1.0 FTE for 2 months = \$7,448

Under the supervision of the MMP project coordinator, the employee will be conducting interviews, recruiting participants and conducting chart abstraction in clinics, hospitals, and private medical provider's offices. She will be responsible for updating the DCC and the CAT with local MMP data.

ii. Research Associate: Maya Yoshida

Annual Salary: \$46,597 x 0.5 FTE for 10 months = \$19,415 \$47,995 x 0.5 FTE for 2 months = \$4,000

Under the supervision of the MMP project coordinator, the employee will be conducting interviews, recruiting participants and conducting chart abstraction in clinics, hospitals, and private medical provider's offices. She will be responsible for updating the DCC and the CAT with local MMP data.

 iii. Research Associate: Zachary Matheson Annual Salary: \$45,226 x 1.0 FTE for 10 months = \$37,688 \$46,583 x 1.0 FTE for 2 months = \$7,764

Under the supervision of the MMP project coordinator, the employee will be conducting interviews, recruiting participants and conducting chart abstraction in clinics, hospitals, and private medical provider's offices. He will be responsible for updating the DCC and the CAT with local MMP data and will assist in searching lead-generating resources in Accurint, Ishtar, ARIES and LINCS for patient contact information.

iv. Research Associate: Veronica Jimenez Annual Salary: \$43,384x 1.0 FTE for 10 months = \$36,153 \$44,685 x 1.0 FTE for 2 months = \$7,448

Under the supervision of the MMP project coordinator, the employee will be conducting interviews, recruiting participants and conducting chart abstraction in clinics, hospitals, and private medical provider's offices. She will be responsible for updating the DCC and the CAT with local MMP data.

v. Data Manager: Jennie Chin Annual Salary: \$86,509 x 0.20 FTE for 2 months = \$2,884

#### \$86,509 x 0.15 FTE for 7 months = \$7,570 \$89,104 x 0.15 FTE for 2 months = \$2,228

Principal duties include processing and managing the MMP sample, interview and abstraction data, patient and facility tracking systems, minimum dataset and SAS coding for analyses. She will serve as a back-up for the MMP Data Manager for securely transmitting data to the CDC and for communication with CDC regarding data management issues.

vi. Epidemiologist: Alison Hughes MMP Co-Principal Investigator/Data Manager Annual Salary: \$73,527 x 0.50 FTE for 3 months = \$9,191 \$73,527 x 1.0 FTE for 7 months = \$42,890 \$75,732 x 1.0 FTE for 2 months = \$12,622

The Co-Principal Investigator duties include processing and managing the MMP sampling frame, data management, databases for tracking information and systems to maintain collected MMP data (interviews, MRA, facility attributes, MDS and provider survey). She will be responsible for leading data analysis, interpreting, writing and disseminating findings. She will be responsible for forwarding data to the CDC and will be the point person for CDC regarding data management issues.

#### c) PHFE Travel

#### \$9,488

\$O

\$3,366

i. Local Travel (\$3,264)

Funds will cover local travel costs for Research Associates. Costs estimated at 68/muni pass x 4 staff x 12 months = 3,264

#### ii. Out-of-Jurisdiction Travel (\$6,224)

To cover costs of domestic travel to meetings for the data manger, the epidemiologist, and 3 research associates. Estimated costs are below.

RA MRA Meeting	
Airfare (\$600 x 2 staff) =	\$2,400
Lodging (\$200/night x 3 nights x 2 staff) =	\$2,400
Per Diem (\$64/day x 4 days x 2 staff) =	\$1,024
Ground Transportation (\$100/person x 2 staff) =	\$ 200
Total =	\$6,224

d) PHFE Equipment	
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e) PHFE Materials and Supplies

5.

#### i. Office Supplies (\$1,800)

Funds will cover costs for office supplies required by project staff. Costs include internet access in the field, basic office supplies, and fees to maintain a post office box. Costs are estimated as follows:

Office Supplies: \$150/month x 12 months = \$1,800

ii. IT Supplies (\$1,566)

Funds will cover costs for upgrading one computer, including software for project staff.

f) PHFE Contractual Services

\$0

g) PHFE Other Expenses

\$20,300

i. Participant Stipends (\$15,000)

Reimbursement provided to clients participating in the MMP. Participant will be given a cash stipend. 300 Participants x \$50 Stipend/Participant = \$15,000

ii. Medical Record Fees (\$5,000)

Cost associated with reimbursing out of jurisdiction providers for releasing, copying and over-night- courier of participant's medical records. 50 medical records x \$100= \$5,000

iii. Courier (\$300)

Cost associated with mailing program related documents and delivery of petty cash for stipends. Costs estimated at \$25 per month for 12 months.

H.	INDIRECT COST (24.03% of Total Salaries)	\$21,157	
•	TOTAL DIRECT EXPENSE:	\$503,332	
G.	OTHER	<b>\$0</b>	
	Total PHFE Budget:	\$375,845	
h)	Total PHFE Indirect Costs (@ 10.8% MTDC)	\$36,635	
	Total PHFE Direct Costs	\$339,210	

TOTAL BUDGET: \$524,488

#### BACKGROUND

HIV surveillance has expanded from monitoring the prevalence levels, trends, and characteristics of diagnosed persons during the early years of the epidemic to now include monitoring HIV incidence, behaviors among infected and at-risk persons, drug resistance, and HIV-related care. These surveillance methods were added to standard case reporting in response to improvements in laboratory technology and the clinical management of HIV disease. What was once a universally fatal condition has become a chronic disease that can be effectively managed with appropriate care and treatment and the use of prevention services to reduce the risk of co-morbidities that occur in higher rates among HIV-infected than uninfected persons. Since 2007 the Medical Monitoring Project (MMP) has provided important information at the national and local level about HIV-diagnosed persons receiving care. More recently, case surveillance based sampling (CSBS) for MMP has been successfully implemented in five pilot sites, including San Francisco. This approach involves sampling directly from the HIV case registry allowing for the selection of all diagnosed persons regardless of whether or not they are engaged in care and thereby provides a more comprehensive picture of the characteristics and outcomes of all diagnosed persons. Such data are essential at the national and local levels in order to prioritize, target, and apply evidence-based HIV prevention care and treatment responses.

#### APPROACH

#### PROBLEM STATEMENT

HIV, once a universally fatal condition, has become a chronic disease that can be effectively managed with appropriate care and treatment and the use of prevention services to reduce the risk of co-morbidities that occur in higher rates among HIV-infected than uninfected persons. Additionally, unequivocal evidence has demonstrated that not only does treatment improve the health of the HIV-infected individual, it also reduces HIV transmission by 96%. Data are needed at the national and local levels in order to prioritize, target, and apply evidence-based HIV prevention, care and treatment responses.

#### PURPOSE

Since 2007 the Medical Monitoring Project (MMP) has provided important information at the national and local level of HIV-diagnosed persons receiving care. More recently, case surveillance based sampling (CSBS) for MMP has been successfully implemented in five pilot sites, including San Francisco. This approach permits sampling diagnosed persons who are not engaged in care and thereby provides a more comprehensive picture of the characteristics and outcomes of all diagnosed persons. Such data are essential at the national and local levels in order to prioritize, target, and apply evidence-based HIV prevention, care and treatment responses.

#### OUTCOMES

The two main project outcomes to be achieved by the end of the project period are: 1) to inform local and national HIV prevention and treatment efforts with MMP data, and 2) to ensure that key local and national users have the MMP data they need and are using this data to inform budgeting, planning and service delivery decisions. In order to accomplish these

outcomes, we have created three specific aims: 1) to collect high quality data that is representative of persons infected with HIV in San Francisco, 2) conduct targeted data analysis and dissemination, and 3) collaborate with local and national partners responsible for HIV surveillance, prevention and treatment. Below we have outlined how we will accomplish these specific aims by creating benchmarks for each aim.

#### Specific Aims:

1. To collect high quality data on clinical and behavioral characteristics that is representative of persons infected with HIV in San Francisco.

Benchmarks:

- a. Draw patient sample by June 1st of each data collection cycle.
- b. Conduct first interview by July 1 of each data collection cycle.
- c. Conduct first medical record abstraction by September 1 of each data collection cycle year.
- d. Contact 95% of eligible sampled patients by October 1st of each data collection cycle.
- e. Achieve a patient-level response rate of at least 50% and increase patient response rate each cycle.
- f. Securely transmit interview data to CDC according to schedule.
- g. Conduct a medical record abstraction on 100% of the interviewed patients who have an accessible medical record.
- h. Conduct a minimum of 5% Quality Assurance (QA) on interviews and medical record abstractions.
- i. Extract minimum data set (MDS) on 100% of selected patients.
- j. Conduct Facility Attributes survey on 100% of facilities where sampled patients were seen for HIV care.
- k. Conduct provider survey per CDC guidance and achieve a minimum of 50% response rate.

#### 2. Conduct strong data analysis and dissemination targeted to local and national users. Benchmarks:

- a. Produce local MMP report published by SFDPH at least annually.
- b. Produce local MMP fact sheet updated annually.
- c. Create MMP data analysis and dissemination plan by June 1<sup>st</sup> of each cycle which will detail targeted dissemination at the local level. Feedback for this plan, including areas for analyses, will be solicited from individuals at SFDPH, CDC, the SF MMP Provider and Community Advisory Board, the HIV Prevention Planning Council (HPPC) and the HIV Care Council.
- d. Present MMP data annually to the SF HPPC, the HIV Care Council, the SF MMP PAB and CAB and at least one HIV medical care provider/facility. Submit at least one abstract annually to a scientific conference highlighting recent MMP analyses.
- 3. Collaborate with local and national partners responsible for HIV surveillance, prevention and treatment.

Benchmarks:

- Patients identified in MMP as not in HIV care will be referred to the SFDPH Linkage Integration, Navigation, and Comprehensive Services (LINCS) services.
  MMP will collaborate with core HIV surveillance to evaluate LINCS success in linkage or re-linkage to care for the patients identified through MMP as out of care. A minimum 80% of these patients with previous barriers to consistent care will be re-linked to care within 3 months.
- b. Information from MMP such as patient address and phone number, as well as missing opportunistic infection diagnoses and transmission risk will be uploaded into eHARS within two months of the end of each MMP data collection cycle. Information will be imported into eHARS on a minimum of 80% of the eligible patient sample.
- c. Maintain Provider and Community Advisory Boards. Meet with advisory boards semi-annually to update on MMP progress and solicit feedback about data collection and analysis.
- d. Meet with HIV Prevention and Planning Council and the HIV Care Council at least once annually to discuss how MMP data can be used to inform local HIV prevention, treatment and fiscal planning and incorporate these findings into Data Analysis and Dissemination Plan.
- e. Meet with the San Francisco Getting to Zero Coalition (a citywide coalition of representatives from SFDPH, community based organizations, medical providers, community members, the Mayor's office, and the Board of Supervisors working together to get to zero new infections, deaths from HIV and stigma in SF) at least once annually to present stigma information collected in MMP and other relevant MMP data as needed.

#### STRATEGY AND ACTIVITIES

#### Preparation

#### Regulatory Authority

All necessary regulatory approval to conduct MMP under surveillance authority has been obtained by the SFDPH. MMP was previously conducted as research covered by four local IRBs for the 2007 to 2011 data collection cycles. Starting in the 2012 MMP cycle, we applied for and were granted a non-research determination by all four governing IRBs. Since then MMP has operated under surveillance authority and the CSBS demonstration pilot has also been conducted as such in San Francisco (SF). Sampling, contacting, and recruiting participants from eHARS is allowed and has been successfully occurring as part of the CSBS demonstration project conducted in SF. HIV surveillance staff at the SFDPH have access to medical record data at a majority of HIV care facilities for core surveillance activities as well as MMP activities including the ability to look up patient locating information, next appointment time and place and medical record abstraction. In addition, eHARS is currently used to identify HIV-infected persons for partner services and to identify persons in need of linkage or re-linkage to HIV care. These activities are considered to be routine public health services and are not subject to local IRB approval.

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#### Development of local standard operating procedures

A standard operating procedure (SOP) was developed for the CSBS pilot demonstration and will be utilized and adapted in the upcoming cycle of MMP. The protocol for recruiting sampled persons includes sending a letter to the sampled person, followed by a phone call, and inperson recruitment either at a medical provider or the person's residence if needed. The SOP includes procedures for conducting telephone interviews. If during recruitment, or an interview, an adverse event takes place, staff will follow our local protocol which includes documentation of the event on forms provided by the CDC, and reporting the event to the CDC within 24 hours. In addition, the SFDPH Health Officer and SFDPH Privacy Officer would be contacted. In order to minimize adverse events during the project, MMP staff will participate in HIV Counseling and Testing trainings including disclosing HIV positive test results to persons previously unaware of their HIV status, core HIV surveillance security and confidentiality training and interviewing, de-escalation and sensitivity trainings. All trainings will take place within 45 days of hire and annually thereafter.

Sampled patients will be assigned a random unique non-identifying identification number for use in data collection and analysis. The SOP includes safeguards to preserve patient confidentiality. MMP and Core HIV Surveillance activities are fully integrated. MMP follows the same security and confidentiality guidelines as core surveillance and staff complete the same trainings. In addition, all HIV surveillance activities in the SFDPH follow additional SFDPH guidelines to protect patient confidentiality. Data collection will be performed on encrypted and password protected electronic devices. Electronic devices will be transported in the field in a locked brief case, and all work will be returned to the office at the end of the work day. Data analysis will be performed using procedures that meet security and confidentiality requirements. Data analysis will be conducted only on-site, in the secure HIV surveillance area using data files without patient name or address.

Since patients who are not in care may be sampled, we have developed protocols to refer them to the SFDPH Linkage Integration, Navigation, and Comprehensive Services (LINCS) program. As with MMP and CSBS in the past, MMP will continue to be closely aligned with the programmatic activities of LINCS to aid in linkage and re-linkage of HIV-infected persons to care. During recruitment and the interview, the MMP staff will identify participants in need of referral to medical services. A protocol for support service referral has been developed based on procedures currently conducted as part of the routine MMP interview process. SF's SOP also follows the guidelines provided by the CDC during the CSBS pilot demonstration pilot to conduct recruitment and data collection on cross-jurisdictional patients. SF's protocol also includes updating eHARS with information provided by other jurisdictions during cross-jurisdictional data collection.

In California, mandatory reporting of confirmed HIV-positive antibody, and all viral load tests has been in effect since July 2002 and CD4 test reporting has been in effect since September 2008. California law mandates that HIV-related laboratory tests be reported to local health officer within 7 days of result. All confirmed HIV-positive antibody, CD4 and viral load test results are reported by laboratories to SFDPH and imported into eHARS on a monthly basis for all persons with these laboratory tests in SF, including both residents of the city and persons

who reside outside of SF but receive care in the city. Approximately 10,000 laboratory reports are processed each month from a total of 29 laboratories, 17 of which report electronically. Laboratory reporting is highly complete in SF. For cases diagnosed with HIV/AIDS in 2012 in SF, 89% had a viral load or CD4 test within three months of diagnosis recorded in eHARS. Completeness and timeliness of laboratory reporting is routinely assessed. In 2011, completeness of electronic laboratory reporting at the public health laboratory was 92% and for one of the laboratories that submits hard copies, completeness was 77%. Among all electronically reported HIV test results from April 1, 2013 through March 31, 2014, the mean time from date of test to reporting to SFDPH was 11 days for HIV labs and 9 days for CD4 labs and 87% of all reportable HIV and CD4 lab tests were reported within 14 days.

#### Hiring and Training of professional staff

SF will continue to employee existing MMP staff for the next grant cycle. This includes four interviewer/chart abstractors who are also trained to recruit participants over phone, at medical appointments, or at residence. In addition, the current MMP PI, Data Manager and Project Coordinator will continue in their roles. We have also integrated Core surveillance staff with MMP, specifically utilizing the expertise of the HIV surveillance program manager who conducts "CDC checks" with CDC HIV surveillance using soundex, date of birth and gender to find a case in SF who may be reported in another jurisdiction, follow up with other jurisdictions, and Routine Interstate Duplicate Review (RIDR).

#### Cross jurisdictional data collection

The HIV core surveillance program manager who conducts routine HIV core surveillance activities with other surveillance jurisdictions nationally is part of the MMP team. As part of her core surveillance activities she performs CDC checks, follows up with other jurisdictions regarding case investigation and data sharing, and conducts RIDR. As such, she maintains a close and strong working relationship with other HIV surveillance jurisdictions. She has handled the CSBS cross jurisdictional data collection and makes contact with other jurisdictions regarding SF cases that have moved away into other jurisdictions. This established relationship has facilitated cross jurisdictional data collection and data sharing to the extent allowed by local laws and regulations.

We will closely adhere to each State and Territory Overall Responsible Party's policy on contacting SF participants who have moved out of jurisdiction and now reside in their area. We will update policies on cross jurisdictional data collection from other health departments when CDC informs us of changes in policy as needed. Local SF policy allows data collection on persons sampled in other project areas who have moved to SF. SF supports cross jurisdictional recruitment, interview, and medical record abstraction on all sampled persons who have migrated to SF.

#### Capacity for telephone interviewing

Telephone interviews will be offered to all participants during recruitment. Our staff has extensive training and experience interviewing by telephone. For example, 26% of interviews for 2013 MMP were conducted via telephone, and 38% of interviewed patients in the 2013 CSBS pilot were telephone interviews. We are also able to offer telephone interviews in Spanish

and English. When scheduling telephone interviews, staff will check to see if the participant has access to the internet during the interview. If so, they will be guided to the interview response cards via the interview. If not, the interview response cards will be mailed and the interview will be scheduled allowing for enough time for delivery of response cards. Protocols are in place for collecting a Release of Information (ROI) for the MRA from telephone respondents (see below in Data Collection) and for sending the stipend via mail. We have a secure and dedicated MMP telephone line in place and a post office box specifically set up for the return of ROI and for medical records that provider sites mail to us.

#### Operational document input

We will work closely with the CDC and other MMP sites to provide input on operational documents and data collection instruments. Based on our experience conducting MMP since 2007 and being one of the CSBS demonstration sites, we've developed MMP Standard Operating Procedures (SOP) for the 2014 cycle, and will continue working closely with the CDC to maintain and update as needed for the 2015 data collection cycle.

#### Sampling and Data Collection

#### **Sampling and Minimum Dataset**

Sample selection will be conducted by receiving a sample of eligible HIV-diagnosed persons from CDC that have been sampled from the National HIV Surveillance System (NHSS). Because personal identifiers are not contained in NHSS, we will run a SAS program developed in collaboration with CDC that will match sampled cases to our local eHARS in order to obtain patient identifiers such as name, address of most current residence, and phone number. This information will be uploaded in the Contacts Attempt Tracking (CAT) database for patient location and recruitment. After the sample has been drawn, we will monitor and track the sample quality. For example, we will identify the number and characteristics of cases that have moved away from SF, who have died or who are otherwise ineligible. Evaluation of the sample quality in this manner may identify possible modifications to future sample draw programs. Copies of local eHARS datasets will be saved in order to run other SAS programs to create a minimum dataset, or assist in weighting and quality assurance. Data extracted from local eHARS for these purposes will be securely transmitted to CDC via the Secure Access Management Services (SAMS) portal as requested.

#### Location, Contact and Recruitment

#### Locating patients

The original MMP sampling method only captured patients who were in care in SF, making them relatively easy to locate. Because the new sampling method captures these patients plus those who may be marginally in care, out-of-care, or who may have moved out of jurisdiction, the work of locating patients for the future of MMP will be more challenging. Based on our work during the CSBS pilot demonstration, we have developed a rigorous method for finding patients which we will implement in MMP. Our search algorithm is a 6-step process designed to track down accurate patient leads, such as patient phone number and address, emergency contacts, and medical provider. Each step represents a lead-generating resource (a particular

database or organization with access to a particular database) which helps us gather patient contact leads. Our resources are as follows, listed in the order we will run our sample through to gather contact leads:

- 1) eHARS: During patient sampling, information such as patient address, telephone and HIV provider will be extracted from eHARS to generate leads.
- Medical records: Since MMP and core HIV surveillance staff work closely together, MMP staff will have relatively easy access to patient medical records (physical and electronic records) at many medical provider sites around the city.
- Accurint (Lexis-Nexis): A rich, private repository of information on millions of people around the country. Originally developed for the legal profession, it has since been expanded for use by other organizations, such as businesses, law enforcement and local government.
- 4) ISHTAR: A database developed by our municipal STD clinic that tracks all STD clinic patients.
- 5) ARIES: A partner program with access to Ryan White databases.
- 6) LINCS: A partner program tracking patients accessing SFDPH linkage and navigation services and with access to a homeless patient information database.

Staff will search each resource until a lead is generated, at which point they will attempt to contact the patient (see *Contacting and Recruiting* section below). If the lead is a dead end (a wrong number, or a bad address) the process will continue, with staff running the patient through each subsequent resource until either the patient is recruited, or staff exhausts all leads and resources. One additional step is employed when we find a lead (such as an out of state address) that indicates that the patient has moved out of our jurisdiction. In these cases, leveraging our integration with core HIV surveillance and following cross jurisdictional data collection protocols, we will reach out to the jurisdiction in question for more information.

#### Contacting and recruiting patients

Contacting a patient will be a two-step process: reaching out to the HIV care provider, and reaching out to the patient. Because the sample drawn from NHSS will also be linked to our local eHARS, we will be able to find information on many patients' most recent HIV healthcare providers. We will contact these providers to verify and update the patient's contact information and to assess any perceived barriers to successfully recruiting the patient that we should be aware of, such as mental instability or a known objection to being interviewed. We will contact providers using a formalized letter that summarizes the study and includes a list of sampled patients believed to still be under their care. The letter will ask providers to respond within two weeks of receipt with any questions, leads, or objections. After the two week response period has elapsed, we will begin contacting the patient. We will contact patients using letters, phone calls, house visits and medical provider visits; contact and recruitment will be conducted in English and Spanish. We will always attempt to send a letter first. Anecdotal reports from patients who have participated in CSBS and MMP who received letters first suggests that receiving a letter lends legitimacy to phone calls received subsequently. Patients will have one week to respond to the letter before staff will follow up with phone calls and other contact methods. We anticipate that staff will make numerous callback attempts before

reaching a patient or determining that the lead is a dead end. Sending letters in advance should help to diminish this number to a degree. Based on prior experience, the bulk of patients will be recruited using phone calls. We will attempt to contact the patient in-person if phone call attempts have failed, either through a medical provider visit or a home visit. We will connect with a patient's medical provider to find out when the next HIV care appointment is, and if the medical provider gives us permission, we will have staff attempt in-person recruitment at the medical visit. A home visit will be attempted last if all other contact attempts have been unsuccessful.

Staff will recruit patients using the local patient-contact protocol, designed to ensure that patient privacy and confidentiality is preserved and informs patients of their rights and responsibilities as a participant in MMP. Staff is trained in cultural sensitivity and procedures that ensure that patient privacy and confidentiality are preserved. Staff will verify the patient's identity in two steps: the patient will confirm spelling of their last name and will verify their date of birth (month and year). The patient must do so with 100% accuracy and without assistance from a third-party. Once the patient's identity has been verified, staff will read them an information form that outlines the following: the purpose of the study; how the patient was selected; the patient's rights and responsibilities as a participant; the steps we take to ensure their privacy and confidentiality; the risks involved in participating; and the benefits of participating. If the patient agrees, an interview will be scheduled or conducted at time of recruitment.

#### Contact tracking

We will use local and national contact tracking databases that have been developed. The local tracking database (called the CAT Database) captures patient names, contact information, the methods used to contact the patients, the number of attempts to reach the patients, and final outcomes. The national tracking database (called the DCC) captures limited, non-identifying information (such as patient disposition, date of final contact, and date of interview) and includes a direct connection to the CDC, for secure monthly data transmission. The databases will be updated on a weekly basis.

#### Data Collection: Interview, MRA, Facility Attributes and Provider Survey

Data collection instruments will be designed in collaboration with CDC. Medical record abstraction and interviews will be conducted by SFDPH MMP staff who have completed data collection training from CDC and practiced interviewing and abstracting locally with their peers and supervisor. Data collection devices (laptops) will meet CDC and SFDPH security and confidentiality requirements and all data collection staff will be trained to maintain these standards. Data collected will be maintained in the secure HIV core surveillance section and securely transmitted to CDC on a regular basis.

#### Interview

After the patient has been successfully recruited, project staff will attempt to schedule an interview either by telephone, at the SFDPH MMP office, an affiliated site or at a place mutually agreed upon where privacy can be assured. Telephone interviews will be offered to everyone however SF is geographically small, facilitating in-person interviews. Telephone interviews are

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critical at gaining cooperation with patients who do not reside in SF or patients with time constraints. MMP staff may travel by public transit or car to locations outside of SF provided they are within two hours travel time to conduct an in-person interview. Interviews will be offered throughout the day including early morning, evening and weekends. When necessary, interviewers bilingual in English and Spanish will conduct interviews in Spanish. We anticipate conducting a large proportion of interviews via telephone. For example, 26% of interviews for 2013 MMP were conducted via telephone, and 38% of interviewed patients in the 2013 CSBS pilot were telephone interviews. Because the MMP sampling procedures will be conducted in the same way as the CSBS pilot, we anticipate having a similar sample of patients for future MMP cycles as we did for the CSBS pilot. In the 2013 CSBS cycle we conducted 84 interviews: 32 (38%) were telephone interview, 16 (19%) were participants who resided outside of SF and 6 (7%) were conducted in Spanish.

The interview session will begin by greeting the patient and then providing a Patient Information Form, which according to non-research determination procedures serves to inform the patient of study procedures. For telephone interviews, the Patient Information Form and interview response cards will be mailed to the study participant before the interview is conducted. The interviewer will review the information sheet with the participant to ensure that he or she understands the procedures and provides informed consent. Participants will be compensated \$50.00 for the interview. A standard local protocol for tracking appointments, scheduling interviews, making appointment reminder phone calls and conducting interviews and interview quality assurance, modeled on our current MMP protocol, will be followed in accordance with SFDPH confidentiality procedures.

Interview staff will complete all CDC interview trainings. Interview data will be collected using QDS software and computer-assisted-personal-interview (CAPI) files created by CDC will be used to collect the national standard interview. The standard interview will take approximately 60 minutes to conduct. A local interview will also be conducted and will be added onto the national standard interview using a separate but linked CAPI QDS file. The local interview will contain questions of local interest that are not administered in the national standard interview such as the Household Food Insecurity Access Scale (HFAIS) and will take approximately 5 minutes to conduct. To ensure that interviews are conducted according to protocol and in a culturally sensitive manner, 5% of interviews of all interview staff will be observed by a supervisor. Results and suggestions from observed interviews will be provided to the interviewer individually and common problem areas will be discussed with all interviewers.

#### Medical Record Abstraction

A Release of Information (ROI) form will be obtained for all interviewed participants to facilitate MRA for participants who receive care outside of SF or within SF but at one of the few facilities where we do not conduct active HIV core surveillance. For face-to-face interviews, participants will be asked to sign a ROI at the beginning of the interview session. An ROI will be mailed to telephone interview participants before the interview is conducted with a self-addressed-stamped envelope for the participant to sign and return to SFDPH. We will attempt to complete a MRA for all patients who agree to participate in the interview. The online electronic MRA platform provided by CDC will be used to collect MRA data. We will ask the participant for their

usual source of care and to sign a ROI for that site to identify medical charts for MRA. Obtaining an ROI for all patients will ensure that we will be able to procure medical records for patients who receive HIV care outside of SF. If a participant received care outside of SF, we will contact that medical facility, provide the signed ROI, and request that a hard copy of the medical chart be mailed to our MMP office following our Security and Confidentiality (S&C) guidelines for confidential information. If the medical facility is located in an area covered by another MMP site, we will ask MMP staff from that site to conduct the MRA for us.

During the 2013 CSBS cycle, we were able to complete 95 total MRAS: 90 were conducted at SF active surveillance facilities, 1 was conducted at a SF passive surveillance site, and 4 were conducted on medical charts obtained from outside of SF. SF MMP medical record abstractors are integrated with core HIV surveillance activities and have access to the electronic medical record system for all SFDPH clinical sites. As such, staff can complete MRAs from SFDPH clinical sites from our offices. All other sites are easily accessible by public transit or on foot.

A standard local protocol for tracking and scheduling MRAs will be modeled after our current MMP protocol and followed in accordance with SFDPH confidentiality procedures. A senior abstractor will re-abstract a 5% sample of MRAs and compare results to the original data to identify and correct discrepancies. These re-abstractions will occur throughout the data collection period to ensure problems are identified early and corrected and to look for protocol drift later in the data collection period. All staff will be informed of mistakes identified and when needed, additional training will be provided.

#### Linkage to Care

MMP will be closely aligned with programmatic activities of LINCS to aid in linkage and relinkage of HIV-infected persons to care. During the interview, the MMP staff will identify participants in need of referral to medical and ancillary services. "Out of care" is defined locally by LINCS as not receiving HIV care for 6 months or more. As has been our experience with MMP and the CSBS pilot, we anticipate that most interviews will be conducted at our office. At the end of the interview, participants in need of HIV medical services will be introduced to a LINCS staff member in person who will assess the patient's needs, make active referrals to HIV care providers, assist with scheduling of care appointments, and direct persons to community agencies that assist in enrollment into public insurance/benefits and support programs. LINCS staff are conveniently located in our building. When needed or requested, LINCS staff will escort participants to appointments. For participants who are not interviewed in our offices, LINCS staff are the same whether these are offered in our offices or the field. A protocol for support service referral, such as dental care, mental health care, and food assistance, is already in place and currently conducted as part of the routine MMP interview process.

At the end of each cycle, we will measure the success of our linkage efforts by calculating the number of persons successfully linked to care within three months of contact with LINCS staff by reviewing the tracking database, by computer matching the MMP sample with the LINCS database, and reviewing eHARS and LDMS for evidence of laboratory test results.

#### Facility Attributes and Provider Survey

We maintain an HIV care facility sampling frame and update this frame as new HIV care facilities are identified through routine core HIV surveillance activities, or have been identified during CSBS as sites where patients have received HIV care. Because some sampled patients for MMP will be seen at sites that are outside SF, we also will maintain a list of these out of jurisdiction (OOJ) facilities. If the patient was seen in a state or jurisdiction currently participating in MMP, we will ask the project area if they have a facility code for that particular facility, and this code will be used in the MRA and in the facility sampling frame. We will collect the facility attributes data on facilities where patients in MMP were seen for HIV care, and submit the data electronically to CDC on a secure web portal.

We will support MMP provider survey activities in accordance with CDC guidance. We will create and maintain a provider sampling frame which will be used to randomly sample a selection of MMP providers for the provider survey. We will collect data via a provider survey instrument created by CDC. Due to demanding provider work schedules, we may face barriers with nonresponse of the provider survey. We will leverage our relationships with providers to increase the response rate of the provider survey and will persistently contact MMP providers for participation via telephone, letter and email. Data collected from provider survey will be transmitted to CDC via a secure web portal and will be maintained locally for data analysis and dissemination.

#### Data Management and Dissemination:

#### Data Management

Local protocols are in place to extract interview data daily from data collection laptops. Data collected for MMP purposes, such as interview, medical record abstraction, MDS, facility sampling frame, facility attributes and provider survey, will be maintained in the secure HIV surveillance section and securely transmitted to CDC by requested deadlines. Additionally, MMP data from the local questionnaire will not be sent to CDC but will be managed and cleaned locally. When weighted final interview data has been returned from CDC, the local interview questions will be appended to the standard interview datasets.

Routine data cleaning activities will be performed by the Data Manager. This includes running QA SAS programs that match tracking information from local tracking Access databases to tracking information on the Data Coordinating Center (DCC) portal to check and make sure there are no discrepancies. Locally developed interview and MRA data quality SAS programs will be run to periodically check data during the collection cycle, for instance to check "other specify" values in the interview and MRA data. Feedback based on these data quality checks will be shared with data collection staff in real-time so that future data collection activities will improve in quality. Additionally, the Data Manager will reconcile any data errors in a timely manner and work with the Technical Assistance Coordinator from the DCC to review and respond to any error messages on the Data Management Reports which are returned on a monthly basis.

Once final weighted data is returned to SF for analysis, the Data Manager will prepare the

various data files for analysis. This involves running SAS code that will substitute key variables in the dataset from complementary datasets. For instance, if the birth sex was not reported in the interview, this variable can be substituted from the Minimum Dataset (MDS). Next, the Data Manger will run a series of modification SAS programs that corrects errors to the QDS skip patterns in interview data and cleans data on HIV viral laboratory results from the MRA. Finally, the Data Manager will run a series of programs on the data that result in a set of "calculated variables" which are useful variables for analysis that are created by re-coding multiple variables from the interview and MRA datasets. An example of a calculated variable would be "most recent viral load test result" which is calculated by taking all viral load test results in the MRA and choosing the most recent value. Finally, when creating multi-cycle datasets for analysis, the Data Manager will re-calculate person weights. Copies of the original datasets and augmented data will be managed by the Data Manager and will be securely stored in the HIV surveillance registry on external hard-drives.

#### **Data Analysis and Dissemination**

We will continue our tradition of prioritizing analysis and dissemination of MMP data for local use and we will form a data dissemination plan each year and report to CDC on the dissemination events that have occurred. Information from MMP will augment data collected through core surveillance, incidence surveillance and behavioral surveillance and prior MMP cycles which did not include HIV-infected persons who were out-of-care. The new MMP sampling methodology has the potential to include persons who have never received care or who have fallen out of care. With the emphasis on diagnosing and treating all HIV-infected persons as a way to both reduce morbidity and mortality and to prevent transmission, linkage to and retention in care is essential. By accessing barriers to receiving HIV care, treatment and adherence, MMP has the ability to target interventions to increase uptake along the continuum of care to improve health outcomes and reduce transmission.

One major advantage of MMP data is the fact that the data are weighted to represent all diagnosed HIV infected persons in SF, and person weights can be applied to obtain population estimates. Data analyzed in this manner can be used to inform key decisions locally for budgeting, planning and service delivery. For example, using MMP data, population estimates for met and unmet needs for HIV ancillary services will be reported in an annual SF MMP Report, and can be utilized by health services to calculate how much funding should be allocated for each ancillary service. Results from this type of analysis would also fuel the importance of advocating for further expansion and funding for services with the greatest unmet need.

Local MMP data will be analyzed and presented to the provider and community advisory boards, local HIV care providers and community organizations, included in our HIV/AIDS Epidemiology Annual Report, presented at scientific conferences and peer-reviewed manuscripts. We are currently in the process of creating our first local SF MMP Report, which will be published by SFDPH annually and will include prevalence estimates of sociodemographic, behavioral and clinical factors. To date, we have two MMP manuscripts published in peer-reviewed journals, have had seven abstracts presented at scientific conferences and four of the annual SFDPH HIV Epidemiology Reports have highlighted information from MMP

#### [1-13].

#### Quality Assurance and Evaluation

#### Data security and confidentiality

All MMP data will continue to be maintained and handled using the same standards used for HIV core surveillance data as outlined in the CDC Program Collaboration and Service Integration (PCSI) Data Security Guidelines. MMP staff will complete all security and confidentiality training. as required by the SFDPH, the California Department of Public Health and the CDC for both MMP and core HIV surveillance activities annually. In terms of physical security, our workspace is within a secure area that only persons working on MMP and/or core HIV surveillance have access to with a unique door code. Paper forms (such as contact and recruitment tracking forms, MRA assignments or signed Patient Information Forms and ROIs) are kept in a locked cabinet in a locked dedicated MMP room within this secure workspace. Additional MMP data is stored in the "HIV surveillance registry" which is another secure room within the workspace of HIV core surveillance. The HIV surveillance registry room is outfitted with a security alarm and motion detectors which staff must first disarm to gain access. A safe, accessible to only limited MMP and core surveillance staff, holds the keys to the double-locked filing cabinets where MMP materials are stored. Once a final disposition has been reached for a MMP patient, or at the end of the cycle for all patients, all paperwork is moved into a permanent secure location in the HIV surveillance registry. We also store MMP data collection laptops and external harddrives containing MMP data in the HIV surveillance registry when they are not being using by staff. All laptops used for data collection will have PGP whole disk encryption in addition to a Windows logon and password. Likewise, external hard-drives containing MMP data are whole disk encrypted with PGP whole disk encryption. Data transferred from SF to CDC will be encrypted using PGP software and transmitted via a secure web portal such as the Data Coordination Center (DCC) or Secure Access Management Services (SAMS).

#### **Data Quality Assurance and Evaluation**

Training and meetings are imperative in order to maintain data quality. SF staff will participate in all required trainings, meetings, site visits, webinars and conference calls, including the MMP annual meeting as appropriate for their project roles.

Before beginning the MMP data collection cycle, interviewers will go through three training exercises, two as a team and one individually. For the first team exercise, interviewers and the project coordinator will meet together and read the interview guidelines out loud. This gives interviewers a chance to thoroughly review the guidelines and ask questions, and ensures that all staff have a full understanding of the guidelines. For the second team exercise, the project coordinator will interview one staff member while the group watches and codes the answers. Coding will be reviewed as a group and discrepancies in how interviewers coded responses will be discussed. This collaborative mock interview will give interviewers a sense of how to identify ambiguous responses and how to code them. For the individual exercise, each staff member will conduct at least one practice interview with a co-worker and will have a chance to review their responses with the project coordinator and their co-worker and discuss coding decisions.

To ensure that interviews are conducted according to protocol and in a culturally sensitive manner, 5% of interviews conducted by all interview staff will be observed by a supervisor. Results and comments from these observations will be provided to the interviewer individually and common problem areas will be discussed as a group with all interviewers.

To prepare abstractors for MRAs, the abstractors will conduct mock "dual-abstractions": one abstractor codes the answers on the paper MRA form, and a different abstractor enters the paper copy codes into the MRA database, checking for coding errors and discrepancies as they go. Discrepancies will be reviewed as a group among all abstractors. Additionally, a senior abstractor will re-abstract a 5% sample of MRAs and compare results to the original data to identify and correct discrepancies. Staff will be informed of mistakes and when needed, additional training will be provided.

The MMP Data Manager will perform evaluation of data quality on a monthly basis to ensure high data integrity. The Data Manager will work with DCC staff to reconcile monthly interview and MRA data management reports and will run local SAS programs to improve data quality. As an example, local SAS programs are run on a monthly basis to check for discrepancies in tracking data between the local Access database and the DCC tracking data and to check returned interview and MRA data files for responses to the "other specify" fields. Any errors made by MMP staff will be communicated back to them to avoid future mistakes in data collection and errors will be corrected either by updating databases or by entering information into the DCC data error logs. Other evaluations of data quality will be conducted as requested by CDC, such as performing enhanced data collection on deaths among sampled HIV-infected individuals, new data collection techniques such as qualitative interviews or web-based data collection instruments, different sampling techniques or methods, and process or data quality surveys.

#### Collaboration

San Francisco will continue to maintain a Community Advisory Board (CAB) representative and a Provider Advisory Board (PAB) representative to support and inform MMP. Both the current PAB and CAB representatives have agreed to continue in their roles and support the MMP project staff as needed. The CAB representative is a staff member at the Native American Health Center and is experienced with working with patients and clients from underrepresented minorities. He has had helpful suggestions on how best to present data to these groups and has suggested particular data analyses that the community is interested in. The PAB representative is the Director of Magnet, the largest organization offering sexual health services including HIV and STD testing for MSM in SF. He works closely with other local HIV medical providers and will continue to represent MMP as needed in these professional groups and answer questions and address concerns. Both advisory board members sit on the HIV Prevention Planning Council (HPPC), and give constructive input to MMP on data collection and data dissemination needs and are able to provide information to the HPPC about MMP.

MMP and Core HIV surveillance are in the same branch at SFDPH, ARCHES (Applied Research, Community Health Epidemiology, and Surveillance), and some staff have shared job responsibilities. For example, some core HIV surveillance staff work part-time on MMP

conducting MRAs in medical facilities where they have access to medical record systems for core surveillance and gathering additional locating information on sampled patients. Other core HIV surveillance work in-kind on MMP on these activities as needed. For example, core surveillance staff will assist by completing a MRA if the medical chart needs to be reviewed at a facility where they are routinely assigned.

We have created protocols, SAS code and data systems to update eHARS with data obtained through MMP. Information from MMP such as patient address and phone number, as well as missing clinical information like opportunistic infection diagnosis and missing information on transmission risk and race/ethnicity will be uploaded into eHARS at the end of each MMP cycle thereby strengthening NHSS.

MMP has an existing close partnership with the SFDPH LINCS program. Patients from MMP who are in need of assistance linking or re-linking to HIV care or changing medical providers are referred to LINCS services at the time of their interview. Data from core HIV surveillance are also routinely used by LINCS for routine data-to-care activities and to evaluate linkage success. Patients recruited in previous MMP and CSBS cycles have appreciated and responded positively to LINCS referrals and services. MMP staff are also trained to provide referral for local supportive services such as dental care, mental health care and food assistance when these needs are identified.

Additionally, SF collaborates with other MMP sites and CDC to improve and supplement data collection, analysis and dissemination efforts. For example, both CDC and other MMP sites have helped us develop our local-use interview modules. These modules collect data of interest locally and to other collaborators (for example medical marijuana use data is being collected by three MMP sites) to be collectively shared and analyzed. To date, SF MMP has participated in three conference presentations and two published manuscripts with other MMP sites and CDC collaborators and we are currently working on a third manuscript with MMP staff from Los Angeles, Chicago, Philadelphia and CDC [7,8,9].

#### EVALUATION AND PERFORMANCE MEASUREMENT PLAN

The Evaluation and Performance Measurement Plan (hereafter referred to as the 'Plan') will serve two primary purposes: it will be used to outline how we will monitor our MMP performance indicators (i.e. the quality of our work and benchmarks) and used to identify priority outcome questions from MMP that can be used to measure the effectiveness of national and local prevention, care, and treatment strategies and initiatives. To a large extent, the components of the Plan that evaluate the conduct of MMP including achievement of benchmarks, quality assessments, and continuing quality improvement activities will be determined collaboratively between SFDPH and CDC with input from partners solicited. For the overarching evaluation questions that we hope to answer using MMP data, we will solicit extensive input from stakeholders (the MMP/CSBS CAB, the Ryan White Care council, the HIV Prevention Planning Council, and providers in large HIV care practices). Using the benchmarks listed in the FOA and our proposed effectiveness outcome questions, we developed an evaluation plan that can be discussed and built upon through input from local, state, and national stakeholders. This can be found in the **Appendix**.

We will provide a number of mechanisms whereby stakeholders can participate in developing evaluation questions; their input can be provided by attending meetings, by completing surveys that will be sent via postal service and e-mail, and by participating in an interview. Stakeholder input will be obtained at the start of the project period and be updated when additional performance indicators are developed SFDPH or by CDC. In collaboration with stakeholders and the CDC we will agree upon the evaluation questions, type (process or outcome), measures (both local and national as determined by CDC), data sources (and methods and feasibility of collection), time lines and responsible party for the evaluation and analysis plan, the frequency and methods of reporting and disseminating findings to stakeholders, the CDC and the broader scientific and public health community. The evaluation questions and measures will include those that can provide evidence of effective prevention, care, or treatment strategies particularly in areas where high quality effectiveness data is limited such as outcomes of outreach programs for engaging or re-engaging patients in care.

Specific MMP outcome measures will be used by the MMP/CSBS team to continually track how well we achieve the benchmarks outlined in the FOA, additional benchmarks identified by CDC, and those developed to meet local needs. Through the Plan we will identify areas in need of quality improvement including ongoing monitoring of patient participation rates, quality of interviews and medical record abstractions, and linkage to and re-engagement in care activities with corrective action taken as needed as part of continuous quality improvement.

As part of our efforts to provide evidence for effective prevention care and treatment strategies we will conduct robust analysis of MMP data. SFDPH has a strong history of analysis and dissemination of HIV surveillance data including over 13 specific analysis using MMP/CSBS data that have been disseminated through scientific and public health meetings, the SFDPH HIV Epidemiology Annual Report, and publications in peer-reviewed scientific journals. Our data analysis portion of the Plan calls for continuing these robust analyses and widespread dissemination.

#### ORGANIZATIONAL CAPACITY

Ten staff members will make up the Medical Monitoring Project 2015 team. All of these staff currently work on MMP and/or the CSBS pilot study and have been trained in their respective current roles including extracting data from eHARS (the CSBS co-Principal Investigator (PI) and MMP data manager), interviewing (the four research associates), conducting MRAs (the four research associates) and recruiting from eHARS (the four research associates and the MMP project coordinator). They include the following staff listed here with the role they will perform in MMP: Dr. Susan Scheer (.25 FTE) MMP co-PI; Alison Hughes (1.0 FTE) co-PI and MMP data manager; Maree Kay Parisi (.50 FTE) MMP Project Coordinator; four Research Associates Zachary Matheson (1.0 FTE), Amadeia Rector (1.0 FTE), Maya Yoshida-Cervantes (1.0 FTE) and Veronica Jimenez (1.0 FTE) conducting interviews and MRA. Two of the Research Associates are bilingual in Spanish and English. Three additional staff from HIV core surveillance will be funded part time to assist with MMP project recruitment, eHARS data abstraction and data management (Viva Delgado, Jennie Chin and Anne Hirozawa respectively). As core HIV surveillance staff, they have extensive knowledge of eHARS and experience recruiting from and

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extracting information from eHARS. We will also leverage the integration of MMP with core HIV surveillance and have three additional research associates from HIV core surveillance work inkind to conduct MRA at their active surveillance sites. Dr. Scheer, Alison Hughes and Maree Kay Parisi will serve as key staff on the project.

Dr. Scheer, the co-MMP Principal Investigator, is also the Acting Director of the SFDPH Applied Research, Community Health Epidemiology and Surveillance (ARCHES) Branch. Both core HIV surveillance activities and MMP are conducted within the ARCHES Branch. Dr. Scheer, as ARCHES Director, can ensure core surveillance staff and resources are available to assist MMP, that MMP has full access to eHARS and that project activities are coordinated and integrated as needed. As MMP co-PI, she will be responsible for ensuring that all MMP protocols are followed, that the necessary security and confidentiality standards are met, and for monitoring these throughout the project period. She will be responsible for all correspondence with CDC and for developing the budget. She will oversee data collection, analysis interpretation, and dissemination. She has over 20 years experience conducting and overseeing epidemiologic studies, the majority of which have focused on HIV/AIDS research and surveillance. (see Dr. Scheer's CV in CV attachment).

Alison Hughes, the MMP co-Principal Investigator, is also an Epidemiologist for the ARCHES Branch. Alison has worked on MMP as Data Manager since 2010 and also currently serves as the CSBS Co-Principal Investigator and Data Manager. She has over 7 years of experience collecting, managing and analyzing data for HIV research, including international HIV behavioral research for the Ministry of Health in Cambodia, HIV microbicide research at UCLA, National HIV Behavioral Surveillance at Los Angeles County Department of Public Health, and core HIV surveillance and MMP at SFDPH. As part of her work with core HIV surveillance, Alison has access to eHARS and has extensive experience extracting data from eHARS. Alison worked closely with CDC in developing the SAS programs for CSBS sampling from eHARS and performed test runs of CDC CSBS pilot study sampling programs on SF eHARS before CDC finalized the SAS programs for release to other CSBS pilot sites. Her suggestions and edits were incorporated in those final sampling programs. Alison is also currently a PhD student in Epidemiology at UC Berkeley. She will oversee MMP sampling from eHARS, data management, databases for tracking information and systems to maintain collected MMP data (interviews, MRA, facility attributes, MDS and provider survey). She will be responsible for leading data analysis and dissemination. She will solicit feedback from stakeholders for data dissemination and will conceptualize and lead data analyses that will be used to inform HIV treatment and prevention as well as budgeting, planning and service delivery at a local and national level. To date, Alison has lead seven MMP related conference abstracts or manuscripts, including one national manuscript with co-authors from CDC. (see Alison Hughes' CV in CV attachment).

The current MMP Project Coordinator, Maree Kay Parisi, will continue to coordinate MMP activities including developing, monitoring and overseeing MMP protocols. Ms. Parisi will also work closely with Dr. Scheer and the SFDPH Contracts and Grants Branch to develop a budget that covers all MMP activities including in- and out-of-state travel, incentives for participants, costs of copying and sending medical records from out of jurisdiction if needed, and all other necessary equipment and software needed to conduct MMP. Ms. Parisi has over 20 years

experience preparing and monitoring project budgets. In addition, she has worked in some capacity on MMP since 2007 and for the last three years has served as the MMP Project Coordinator. She has worked in HIV surveillance for twenty five years, and has served as the HIV Surveillance Program Director for ten years giving her extensive expertise in HIV core surveillance including extensive experience with and knowledge of eHARS, working with other HIV surveillance jurisdictions including sharing cross-jurisdictional information and with negotiating and setting up MMP MRA access with SF medical providers. She works closely with the SFDPH LINCS program in data-to-care activities and has successfully integrated core HIV surveillance activities with MMP activities. Integrated activities involve sharing recruiting, locating and scheduling MMP participants and leveraging core surveillance staff with access to provider/facilities' medical record systems to assist with MMP medical record abstraction. As MMP Project Coordinator, she will work with sampled patients and their medical providers as needed if concerns or questions arise particularly around collecting patient locating information and medical record abstraction and access. She will supervise the Research Associates who conduct medical record abstraction and interviews and the core HIV surveillance field staff who also conduct medical record abstractions for MMP. She will present data to stakeholders and answers guestions from medical care providers, facilities and participants regarding MMP procedures and findings. (see Ms. Parisi's CV in CV attachment).

The four Research Associates who will be conducting interviews and medical record abstractions have been working on MMP between one to three years. They are expert at participant recruitment, interviewing both in-person and by telephone and conducting medical chart abstractions. They have experience conducting home visits to locate participants and have conducted interviews on the spot if the participant is home and willing. Two are bilingual in Spanish and English. They will participate in CDC bi-monthly interviewer and abstractor conference calls, CDC trainings, and all local trainings provided to SF MMP staff. The Research Associates are trained in HIV core surveillance security and confidentiality procedures and core surveillance activities including use of eHARS and the local laboratory tracking database.

We will leverage additional assistance from core HIV surveillance staff to assist with MMP activities such as contacting and coordinating cross jurisdictional data exchange, locating, recruiting and scheduling participants, and data management. The core surveillance staff currently assigned as the lead liaison between local, state and national surveillance for case deduplication (RIDR) will manage sampled MMP patients who have moved outside of SF and will be the lead contact with other health departments to determine their policies around contacting, interviewing and conducting a medical record abstraction in their area. Her familiarity of key staff in other health jurisdictions has facilitated smooth data sharing across jurisdictions during the CSBS pilot project as local laws and policies allowed.

In addition, the core HIV surveillance Data Manager will provide back-up and coverage for the MMP Data Manager. She will assist with processing and managing the MMP sample, interview and abstraction data, patient and facility tracking systems, minimum dataset and SAS coding for analyses. She will serve as a back-up for the MMP Data Manager for securely transmitting data to the CDC and for communication with CDC regarding data management issues. She has over 14 years experience in HIV surveillance and is an experienced SAS programmer and an expert in

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navigating eHARS. She has written SAS programs, developed procedures for processing electronic laboratory data and for updating eHARS cases and performs quality assurance and data cleanup on our local case registry and laboratory database.

We have a current representative for the CDC MMP Provider Advisory Board and a representative on the Community Advisory Board. These representatives have committed to staying on the Boards. No funding is needed to support these activities; if needed in-kind support will be obtained.

#### WORKPLAN

The following chart provides a detailed work plan for the first year of activities. Details on how the activities will be implemented are discussed in the Strategies and Activities Section above.

Preparation Activities	Dates of Activity	Persons Responsible
Obtain regulatory approvals	Completed by June 15, 2015	Co-Pl Susan Scheer
Develop local standard operating	Completed by June 15, 2015	Co-Pl Susan Scheer
procedures (includes linkage to		Co-Pl Alison Hughes
care plans and referrals)	· · · · · · · · · · · · · · · · · · ·	
Hire and train professional staff to	Completed by June 15, 2015	Co-PI Susan Scheer .
recruit participants and collect data		Co-PI Alison Hughes
		PC Maree Kay Parisi
Facilitate cross jurisdictional data	Complete by June 15, 2015 a plan to	Co-PI Susan Scheer
collection	allow data collection on persons moving	
	into SF project area	
	· ·	
• •	By May 1, 2015 complete all requests	PC Maree Kay Parisi
	for interview or MRA of all sampled	Health Coordinator Viva Delgado
	persons who have moved to another	
	jurisdiction in order to meet interview	
·	completion date of May 31 and MRA	
	completion date of June 30, 2015.	
Develop capacity for telephone	Complete development by June 15,	PC Maree Kay Parisi
interviewing; develop plan and	2015;	Research Associates*
protocol		
· · · · · ·		
Maintain capacity for telephone	Maintain capacity ongoing June 2015-	PC Maree Kay Parisi
interviewing; quality assurance	May 2016	Research Associates
activities and on-going training		
Provide input on operational	Ongoing as needed and requested June	All MMP staff as role requires
documents and data collection	2015-May 2016	
instruments	pulous and the medical record abstractions	

#### Project Year 1 (June 1, 2015 - May 31, 2016) Workplan:

\*Research Associates conduct the interviews and the medical record abstractions.

Sampling and Data Collection	Dates of Activity	Persons Responsible
Conduct Sampling	Complete by June 1, 2015	Co-PI Alison Hughes
		Data Management Assistant

		Jennie Chin
Locate, contact, and recruit sampled	Complete contact attempts on 95% of	Research Associates
persons	sample by October 1, 2015	PC Maree Kay Parisi
		Health Coordinator Viva Delgado
Manage and report contact tracking	Report up-to-date contact attempt data	Co-Pl Alison Hughes
data	biweekly to CDC	Data Management Assistant Jennie Chin
	Report de-identified recruitment	· ·
	summary to CDC twice per data	
	collection cycle (1 <sup>st</sup> report by Nov 30, 2015; 2 <sup>nd</sup> report by April 30, 2016)	
Interview sampled persons	Complete first interview by July 1, 2015	Research Associates
	Complete an interview on at least 50%	
	of sample by April 30, 2016	Research Associates
Conduct medical record abstraction	Compete first MRA by September 1,	Research Associates
(MRA) on sampled persons	2015	Assistance as needed by HIV
		core surveillance Research
		Associates (in-kind)
	Complete MRAs for all interviewed	Research Associates
· · · · ·	persons by June 30, 2016	Assistance as needed by HIV
		core surveillance Research
		Associates (in-kind)
Facilitate access to HIV care linkage	Submit plan to refer out of care	Co-Pl Susan Scheer
and retention services for	participants to SFDPH LINCS program to	
participants	CDC prior to June 1, 2015 and receive	
· .	their approval	
Extract NHSS data	Complete and send to CDC by May 31, 2016	Co-PI Alison Hughes
Collect HIV care facility data	Complete and send to CDC by May 31, 2016	Co-PI Alison Hughes
Support and conduct MMP provider	Complete as requested through the	Co-Pl Susan Scheer
survey activities	data collection cycle as requested by CDC	PC Maree Kay Parisi

Data Management and Dissemination	Dates of Activity	Persons Responsible
Manage and transmit data	Submit all required data to CDC via DCC portal or the Secure Access Management Services (SAMS) monthly or as required per protocols by CDC	Co-Pl/Data Manager Alison Hughes Data Management Assistant Jennie Chin
Analyze and disseminate data	By June 1, 2015, submit data analysis plan to CDC. Respond to requests for data and/or data presentations throughout the data collection cycle as needed.	Co-Pi Susan Scheer (design plan, analyze and disseminate data) Co-Pi Alison Hughes (design plan, analyze and disseminate data) Epidemiologist Anne Hirozawa PC Maree Kay Parisi

	Complete at least one surveillance	(disseminate data )
l	summary report each data collection	Research Associates
	cycie and publish in the SFDPH	(disseminate data)
	Epidemiology annual report	
	Annually, provide an MMP update to	1
	the SF HIV Prevention Planning Council	PC Maree Kay Parisi
	and HIV Care Council	
	By June 1, 2016, submit a report to CDC	
	of all data dissemination activities	Co-Pl Allson Hughes (summarize
•	conducted during the data collection	and submit report)
·	cycle.	
Quality Assurance and Evaluation	Dates of Activity	Persons Responsible
Maintain HIV data security and	Throughout data collection cycle,	Co-Pl Susan Scheer
confidentiality	maintain HIV data security and	Co-Pl Alison Hughes
Ň	confidentiality	PC Maree Kay Parisi
		All MMP Staff
	Annually, ensure and document that all	PC Maree Kay Parisi
	MMP staff complete data security and	Health Coordinator Viva Delgada
	confidentiality training	ficant coordinator tha beight
Attend trainings and other meetings	Throughout data collection cycle,	All MMP Staff as roles require
	attend all trainings and meetings as	
	required	
Conduct quality assurance activities	Throughout data collection cycle,	Co-PI Susan Scheer
· ·	conduct and participate in quality	Co-Pl Alison Hughes
	-assurance -	PC Maree Kay Parisi
		All MMP staff participation as
		required
Conduct evaluation activities	Annually, conduct evaluation of MMP	Co-Pl Susan Scheer
	procedures and activities	Co-PI Alison Hughes
······································		PC Maree Kay Parisi
	· · · · · · · · · · · · · · · · · · ·	
Collaboration	Dates of Activity	Persons Responsible
Maintain advisory boards	Identify representatives to serve of	Co-PI Susan Scheer
	Community Advisory Board (CAB) and	Co-PI Alison Hughes
	Provider Advisory Board (PAB) by June	PC Maree Kay Parisi
	15, 2015	•
		Co-Pl Susan Scheer
	Maintain representation on both CAB	LO-PLNISZO SCHOOL

		1
	Maintain representation on both CAB and PAB throughout data collection cycle	Co-Pl Susan Scheer Co-Pl Alison Hughes PC Maree Kay Parisi
Strengthen NHSS	Within two months of the end of data collection, input residency, laboratory test results, transmission risk and other data collected during MMP into eHARS	Assistant Data Manager, Jennie Chin Epidemiologist Anne Hirozawa
	Annually, provide status report on laboratory completeness in eHARS to	•

	CDC	Assistant Data Manager, Jennie Chin Epidemiologist Anne Hirozawa
Strengthen local collaborations including HIV core surveillance staff, other SFDPH surveillance and prevention staff (Including those funded by CDC and other sources) and other local HIV prevention programs, health care facilities and others	Throughout data collection cycle, initiate, maintain and strengthen collaborations as needed.	Co-Pl Susan Scheer Co-Pl Alison Hughes PC Maree Kay Parisi

Outcomes	Dates of Activity	Persons Responsible
Inform local HIV prevention and treatment efforts	Annually, provide an update of MMP data to date to local prevention and treatment programs and include MMP data summaries and analyses in the SFDPH HIV Epidemiology Annual Report for their use.	Co-PI Susan Scheer Co-PI Alison Hughes PC Maree Kay Parisi
Document how MMP data are used to inform local HIV prevention and treatment efforts	Annually, document data dissemination efforts to HIV prevention and treatment programs	Co-PI Alison Hughes PC Maree Kay Parisi

Subsequent Project Cycle Cycle Workplans: 2016-2017; 2017-2018; 2018-2019; 2019-2020 June

- Refine development of protocol and data collection instruments, including telephone interviews, and HIV care linkage and retention service referrals for participants.
- Obtain local regulatory approval
- Facilitate cross jurisdictional data sharing
- Hire and train staff
- Draw a sample of eligible persons from eHARS
- Begin locating, contacting and recruiting sampled persons

#### July

- First interview conducted on sampled person; continue interviewing through May 31 following year
- Facilitate access to HIV care linkage and retention services for participants out of care throughout data collection cycle

#### September

 First medical record abstraction conducted on interviewed person; continue medical record abstractions through June 30 following year

#### October

- Attempt contact recruitment on 95% of sampled persons completed in October
- May
- NHSS data extracted and submitted to CDC
- HIV facility data collected and submitted to CDC

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 Facilitate cross jurisdictional data collection on all sampled persons identified as migrating out of jurisdiction

June

- Submit data analysis plan to CDC
- Respond to requests for data presentations throughout data collection cycle as needed
- Complete MMP data summary report the SFDPH HIV Epidemiology report
- Present MMP data to HIV Prevention Planning Council and HIV Care Council

#### REFERENCES

1. Hughes A, Parisi MK, Williams L, *et al.* Unprotected anal intercourse with a discordant serostatus partner among men who have sex with men in care for HIV, San Francisco 2007-2008. 2011 Council for State and Territorial Epidemiologists Conference, Pittsburgh, Pennsylvania, June 2011.

2. Hughes A, Scheer S. Characteristics of HIV-infected adults who report discontinuation of antiretroviral therapy, San Francisco 2007-2009. 2011 International AIDS Society Conference, Rome, Italy, July 2011.

3. Hughes A, Scheer S. Congruence between self-report and medical record CD4 lymphocyte and HIV viral load test results among HIV-infected patients in care. 2012 Council for State and Territorial Epidemiologists Conference, Omaha, Nebraska, June 2012.

4. Hughes A, Scheer S. Using secondary data to identify HIV/AIDS cases and evaluate completeness of case reporting in San Francisco, California. 2012 Council for State and Territorial Epidemiologists Conference, Omaha, Nebraska, June 2012.

5. Hughes A, Chin C-S, Scheer S. Evaluating the number and proportion of out of jurisdiction HIV/AIDS cases receiving care in San Francisco, CA. 2012 Council for State and Territorial Epidemiologists Conference, Omaha, Nebraska, June 2012.

6. Hughes A, Scheer S. Is age associated with unmet need for supportive services among HIVinfected patients receiving HIV care? Results from the Medical Monitoring Project, San Francisco, California, United States; 2007-2010. 2012 International AIDS Conference, Washington D.C., United States, July 2012.

7. Benbow N, Scheer S, Wohl A, *et al.* Linkage, Retention, ART Use and Viral Suppression in Four Large Cities in the United States. 2012 International AIDS Conference, Washington D.C., United States, July 2012.

 Scheer S, Hughes AJ, Tejero J, et al. "HIV Patients in Care in California: Regional Differences among the California Medical Monitoring Project Sites 2007-2008." Open AIDS 2012; 6:188-195.
Hughes AJ, Mattson CL, Scheer S, Beer L, Skarbinski J. "Discontinuation of antiretroviral therapy among adults receiving HIV care in the United States." JAIDS 2014; 66: 80-89.

10. HIV Epidemiology Section, San Francisco Department of Public Health. HIV/AIDS Epidemiology Annual Report 2010, July 2011: 73-76.

11. HIV Epidemiology Section, San Francisco Department of Public Health. HIV/AIDS Epidemiology Annual Report 2011, August 2012:17.

12. HIV Epidemiology Section, San Francisco Department of Public Health. HIV/AIDS Epidemiology Annual Report 2012, June 2013: 15-16.

13. HIV Epidemiology Section, San Francisco Department of Public Health. HIV/AIDS Epidemiology Annual Report 2013, August 2014: 17.
Notice of Award

issue Date: 05/26/2015



COOPERATIVE AGREEM CNTS Department of Health and Human Services Centers for Disease Control and Prevention NATIONAL CENTER FOR HIV, VIRAL HEPATITIS, STDS AND TB PREVENTION

Grant Number: 1U62PS004970-01 FAIN: U62PS004970

Principal Investigator(s): Susan Scheer, PHD

Project Title: MEDICAL MONITORING PROJECT (MMP)

SAJID SHAIKH BUSINESS OFFICIAL 25 VAN NESS AVE, SUITE 500 **HIV STATISTICS & EPIDEMIOL SECT** SAN FRANCISCO, CA 94102

Budget Period: 06/01/2015 - 05/31/2016 Project Period: 06/01/2015 - 05/31/2020

Dear Business Official:

The Centers for Disease Control and Prevention hereby awards a grant in the amount of \$524,488 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH in support of the above referenced project. This award is pursuant to the authority of 307,317K2 PHSA,42USC241,247BK2,PL108 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,

Arthur Lusby Grants Management Officer Centers for Disease Control and Prevention

Additional information follows

## SECTION I - AWARD D. A - 1U62PS004970-01

Award Calculation (U.S. Dollars)	
Salaries and Wages	\$88,042
Fringe Benefits	\$36,844
Personnel Costs (Subtotal)	\$124,886
Travel Costs	\$2,600
Consortium/Contractual Cost	\$375,845
Federal Direct Costs	\$503,331
Federal F&A Costs	\$21,157
Approved Budget	\$524,488
Federal Share	\$524,488
TOTAL FEDERAL AWARD AMOUNT	\$524,488
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$524,488

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

02 \$524,488 03 \$524,488 04 \$524,488 05 \$524,488

Fiscal Information:	
CFDA Number:	93.944
EIN:	1946000417A8
Document Number:	004970PS15

IC	CAN	2015	2016	2017	2018	2019
PS	9391195	\$524,488	\$524,488	\$524,488	\$524,488	\$524,488

SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
1	\$524,488	\$524,488
2	\$524,488	\$524,488
3	\$524,488	\$524,488
4	\$524,488	\$524,488
5	\$524,488	\$524,488

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

#### CDC Administrative Data:

PCC: N / OC: 4151 / Processed; ERAAPPS 05/26/2015

## SECTION II - PAYMENT/HOTLINE INFORMATION - 1U62PS004970-01

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 - 1U62PS004970-01

This award is based on the application submitted to, and as approved by, CDC on the abovetitled 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.

This award has been assigned the Federal Award Identification Number (FAIN) U62PS004970. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

#### Treatment of Program Income: Additional Costs

SECTION IV - PS Special Terms and Conditions - 1U62PS004970-01

Funding Opportunity Announcement (FOA) Number: PS15-1503 Award Number: 1 U62 PS004970-01

Award Type: Cooperative Agreement

Applicable Regulations: 45 Code of Federal Regulations (CFR) Part 75, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards

45 CFR 75 Supersedes regulations 45 CFR 92 and 74

#### AWARD INFORMATION

Incorporation: The Centers for Disease Control and Prevention (CDC) hereby incorporates Funding Opportunity Announcement number PS15-1503, entitled Medical Monitoring Project, and application dated January 8, 2015, as may be amended, which are hereby made a part of this Non-Research award hereinafter referred to as the Notice of Award (NoA). The Department of Health and Human Services (HHS) grant recipients must comply with all terms and conditions outlined in their NoA, including grants policy terms and conditions contained in applicable HHS Grants Policy Statements, and requirements imposed by program statutes and regulations and HHS grant administration regulations, as applicable; as well as any requirements or limitations in any applicable appropriations acts. The term grant is used throughout this notice and includes cooperative agreements.

Approved Funding: Funding in the amount of <u>\$524,488.00</u> is approved for the Year FY15 budget period, which is <u>June 1, 2015</u> through <u>May 31, 2016</u>. All future year funding will be based on satisfactory programmatic progress and the availability of funds.

Note: Refer to the Payment Information section for draw down and Payment Management System (PMS) subaccount information.

Award Funding: Not funded by the Prevention and Public Health Fund

**Objective/Technical Review Statement Response Requirement**: The 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/Grants Management Officer (GMS/GMO) noted in the Staff Contacts section of this NoA, no later than 30 days from the budget period start date. Failure to submit the required information by the due date, July 1, 2015, will cause delay in programmatic progress and will adversely affect the future funding of this project.

**Program Income**: Any program income generated under this grant or cooperative agreement will be used in accordance with the Addition alternative.

Addition alternative: Under this alternative, program income is added to the funds committed to the project/program and is used to further eligible project/program objectives.

Note: The disposition of program income must have written prior approval from the GMO.

#### FUNDING RESTRICTIONS AND LIMITATIONS

Administrative Restriction(s): Indirect cost in the amount of \$21,157.00 is restricted and cannot be spent until a current approved indirect cost rate agreement reflecting the proposed rate for the period 6/1/2015 through 5/31/2016 is submitted to and approved, in writing, by the Grants Management Officer. If the information is not provided by the end of the budget period, the above amount must be reported on the Federal Financial Report as unobligated funds.

**Indirect Costs:** Approval pending submission of a current approved indirect cost rate agreement to match the propose rate.

Cost Limitations as Stated in the Consolidated and Further Continuing Appropriations Act, 2015 (Items

## A through E)

*c*.

A. Cap on Salaries (Sec. 203): None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II.

Note: The salary rate limitation does not restrict the salary that an organization may pay an individual working under an HHS contract or order, it merely limits the portion of that salary that may be paid with Federal funds.

B. Gun Control Prohibition (Sec. 217): None of the funds made available in this title may be used, in whole or in part, to advocate or promote gun control.

C. Lobbying Restrictions (Sec. 503):

- 503(a): No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation of the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government itself.
- 503 (b): No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than normal and recognized executive legislative relationships or participation by an agency or officer of an State, local or tribal government in policymaking and administrative processes within the executive branch of that government.
- 503(c): The prohibitions in subsections (a) and (b) shall include any activity to advocate or promote any proposed, pending or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale of marketing, including but not limited to the advocacy or promotion of gun control.

For additional information, see Additional Requirement 12 at <u>http://www.cdc.gov/grants/additionalrequirements/index.html</u> and Anti Lobbying Restrictions for CDC Grantees at <u>http://www.cdc.gov/grants/documents/Anti-Lobbying Restrictions for CDC Grantees July 2012.pdf</u>

D. Needle Exchange (Sec. 521): Notwithstanding any other provision of this Act, no funds appropriated in this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

E. Blocking access to pornography (Div. H, Title V, Sec. 526): (a) None of the funds made available in this Act may be used to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography; (b) Nothing in subsection (a) shall limit the use of funds necessary for any Federal, State, tribal, or local law enforcement agency or any other entity carrying out criminal investigations, prosecution, or adjudication activities.

**Rent or Space Costs**: Grantees 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, including 45 CFR Part 75, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards. The grantee also has a responsibility to ensure sub-recipients expend funds in compliance with applicable federal laws and regulations. Furthermore, it is the responsibility of the grantee to ensure rent is a legitimate direct cost line item, which the grantee 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 grantee must provide a narrative justification, which describes their prescribed policy to include the effective date to the assigned Grants Management Specialist (GMS) identified in the CDC Contacts for this award.

**Trafficking In Persons**: This award is subject to the requirements of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. Part 7104(g)).

**Cancel Year**: 31 U.S.C. Part 1552(a) Procedure for Appropriation Accounts Available for Definite Periods states the following, On September 30<sup>th</sup> of the 5<sup>th</sup> fiscal year after the period of availability for obligation of a fixed appropriation account ends, the account shall be closed and any remaining balances (whether obligated or unobligated) in the account shall be canceled and thereafter shall not be available for obligation or expenditure for any purpose. An example is provided below:

Fiscal Year (FY) 2015 funds will expire September 30, 2019. All FY 2015 funds should be drawn down and reported to Payment Management Services (PMS) prior to September 30, 2019. After this date, corrections or cash requests will not be permitted.

#### REPORTING REQUIREMENTS

Annual Federal Financial Report (FFR, SF-425): The Annual Federal Financial Report (FFR) SF-425 is required and must be submitted through eRA Commons no later than 90 days after the end of the calendar quarter in which the budget period ends. The FFR for this budget period is due to the GMS/GMO by September 30, 2016. Reporting timeframe is June 1, 2015 through May 31, 2016.

The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data. All Federal reporting in PMS is unchanged.

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, the grantee is

required to contact the G is Officer listed in the contacts section of the stice before the due date.

FFR (SF-425) instructions for CDC Grantees are available at

<u>http://grants.nih.gov/grants/forms.htm</u>. For further information, contact <u>GrantsInfo@nih.gov</u>. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the <u>eRA Commons</u> Support Page: <u>http://grants.nih.gov/support/</u>.

**Performance Reporting:** The Annual Performance Report is due no later than 120 days prior to the end of the budget period, **February 1, 2016**, and serves as the continuing application. This report should include the information specified in the FOA.

In addition to the annual performance report, awardees must submit a detailed evaluation and performance measurement plan within the first six months of the project. Performance measures report as specified in the FOA.

#### Audit Requirement :

Domestic Organizations: An organization that expends \$750,000 or more in a fiscal year in Federal awards shall have a single or program-specific audit conducted for that year in accordance with the provisions of 45 CFR Part 75. The audit period is an organization's fiscal year. The audit must be completed along with a data collection form (SF-SAC), and the reporting package shall be submitted within the earlier of 30 days after receipt of the auditor's report(s), or nine (9) months after the end of the audit period. The audit report must be sent to:

Federal Audit Clearing House Internet Data Entry System <u>Electronic Submission</u>: <u>https://harvester.census.gov/facides/(S(0vkw1zaelyzjibnahocga5i0))/account/login.aspx</u>

#### AND

#### Procurement & Grants Office, Risk Management & Compliance Activity Electronic Copy to: PGO.Audit.Resolution@cdc.gov

After receipt of the audit report, CDC will resolve findings by issuing Final Determination Letters.

<u>Audit requirements for Subrecipients</u>: The grantee must ensure that the subrecipients receiving CDC funds also meet these requirements. The grantee must also ensure to take appropriate corrective action within six months after receipt of the subrecipient audit report in instances of non-compliance with applicable Federal law and regulations (45 CFR 75 Subpart F and HHS Grants Policy Statement). The grantee may consider whether subrecipient audits necessitate adjustment of the grantee's own accounting records. If a subrecipient is not required to have a program-specific audit, the grantee is still required to perform adequate monitoring of subrecipient activities. The grantee shall require each subrecipient to permit the independent auditor access to the subrecipient's records and financial statements. The grantee must include this requirement in all subrecipient contracts.

Note: The standards set forth in 45 CFR Part 75 Subpart F will apply to audits of fiscal years beginning on or after December 26, 2014.

#### Federal Funding Accountability and Transparency Act (FFATA):

#### 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.

Pursuant to A-133 (see Section\_.205(h) and Section\_.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.

#### FFATA: www.fsrs.gov.

#### Reporting of First-Tier Sub-awards

Applicability: Unless you are exempt (gross income from all sources reported in last tax return is under \$300,000), 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 sub-award to an entity.

Reporting: Report each obligating action of this award term to www.fsrs.gov. For sub-award 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). You must report the information about each obligating action that the submission instructions posted at www.fsrs.govspecify.

Total Compensation of Recipient Executives: You must report total compensation for each of your five most highly compensated executives for the preceding completed fiscal year, if:

- The total Federal funding authorized to date under this award is \$25,000 or more;
- In the preceding fiscal year, you received-
  - 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 Part 170.320 (and sub-awards); and
  - \$25,000,000 or more in annual gross revenues from Federal procurement ο contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR Part 170.320 (and sub-awards); and
  - The public does not have access to information about the compensation of the 0 executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. Part 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?explorer.event=true).

Report executive total compensation as part of your registration profile at http://www.sam.gov. Reports should be made at the end of the month following the month in which this award is made and annually thereafter.

Total Compensation of Sub-recipient Executives: Unless you are exempt (gross income from all sources reported in last tax return is under \$300,000), for each first-tier sub-recipient under this award, you must report the names and total compensation of each of the sub-recipient's five most highly compensated executives for the sub-recipient's preceding completed fiscal year, if:

- In the sub-recipient's preceding fiscal year, the sub-recipient received-
  - 80 percent or more of its annual gross revenues from Federal procurement 0 contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR Part 170.320 (and sub-awards); and
  - \$25,000,000 or more in annual gross revenues from Federal procurement 0 contracts (and subcontracts), and Federal financial assistance subject to the Transparency Act (and sub-awards); and
  - The public does not have access to information about the compensation of the o executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. Part 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).

You must report sub-recipient executive total compensation to the grantee by the end of the month following the month during which you make the sub-award. For example, if a sub-award is obligated on any date during the month of October of a given year (i.e., between October 1st and 31st), you must report any required compensation information of the sub-recipient by November 30th of that year.

Definitions:

- Entity means all of the following, as defined in 2 CFR Part 25 (Appendix A, Paragraph(C)(3)):
  - o Governmental organization, which is a State, local government, or Indian tribe;
  - o Foreign public entity;
  - o Domestic or foreign non-profit organization;
  - o Domestic or foreign for-profit organization;
  - Federal agency, but only as a sub-recipient under an award or sub-award to a non-Federal entity.
- Executive means officers, managing partners, or any other employees in management positions.
- Sub-award: a legal instrument to provide support to an eligible sub-recipient for the
  performance of any portion of the substantive project or program for which the grantee
  received this award. The term does not include the grantees procurement of property and
  services needed to carry out the project or program (for further explanation, see 45 CFR
  Part 75). A sub-award may be provided through any legal agreement, including an
  agreement that the grantee or a sub-recipient considers a contract.
- Sub-recipient means an entity that receives a sub-award from you (the grantee) under this award; and is accountable to the grantee for the use of the Federal funds provided by the sub-award.
- Total compensation means the cash and non-cash dollar value earned by the executive during the grantee's or sub-recipient's preceding fiscal year and includes the following (for more information see 17 CFR Part 229.402(c)(2)):
  - o Salary and bonus
  - 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.
  - 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.
  - Change in pension value. This is the change in present value of defined benefit and actuarial pension plans.
  - o Above-market earnings on deferred compensation which is not tax-qualified.
  - 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.

#### GENERAL REQUIREMENTS

**Travel Cost**: In accordance with HHS Grants Policy Statement, travel costs are only allowable where such travel will provide direct benefit to the project or program. There must be a direct benefit imparted on behalf of the traveler as it applies to the approved activities of the NoA. To prevent disallowance of cost, the grantee is responsible for ensuring that only allowable travel reimbursements are applied in accordance with their organization's established travel policies and procedures. Grantees approved policies must meet the requirements of 45 CFR Part 75, as applicable.

**Food and Meals**: Costs associated with food or meals are allowable when consistent with federal regulations, HHS Federal regulations, Program Regulations, HHS policies and guidance. In addition, costs must be proposed in accordance with grantee approved policies and a

determination of reason sness has been performed by the grantees antee approved policies must meet the requirements of 45 CFR Part 75, as applicable.

**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 identified in the CDC Roles and Responsibilities section of this NoA.

**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 NoA. The grantee must submit these requests by February 1, 2016 or no later than 30 days prior to this budget period's end date. 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.

#### The following types of requests require prior approval.

- Use of unobligated funds from prior budget period (Carryover)\*
- Lift funding restriction, withholding, or disallowance
- Redirection of funds
- Change in scope
- Implement a new activity or enter into a sub-award that is not specified in the most recently approved budget
- Apply for supplemental funds
- Change in key personnel
- Extensions
- Conferences or meetings that exceed cost threshold -

Note: Awardees may request up to 75 percent of their estimated unobligated funds to be carried forward into the next budget period.

Templates for prior approval requests can be found at: <u>http://www.cdc.gov/grants/alreadyhavegrant/priorapprovalrequests.html</u>

**Key Personnel:** In accordance with 45 CFR Part 75.308, CDC grantees must obtain prior approval from CDC for (1) change in the project director/principal investigator, business official, authorized organizational representative or other key persons specified in the FOA, application or award document; and (2) the disengagement from the project for more than three months, or a 25 percent reduction in time devoted to the project, by the approved project director or principal investigator.

**Inventions:** Acceptance of grant funds obligates grantees to comply with the standard patent rights clause in 37 CFR Part 401.14.

**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 Grant or Cooperative Agreement Number, 1U62PS004970-01, funded by 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 or the Department of Health and Human Services.

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 grantees of Federal research grants, shall clearly state:

- percentage of the total costs of the program or project which will be financed with Federal money
- dollar amount of Federal funds for the project or program, and

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 percentage and lar amount of the total costs of the project c. ogram that will be financed by non-governmental sources.

**Copyright Interests Provision:** This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

**Disclaimer for Conference/Meeting/Seminar Materials:** Disclaimers for conferences/meetings, etc. and/or publications: If a conference/meeting/seminar is funded by a grant, cooperative agreement, sub-grant and/or a contract the grantee 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 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.

Logo Use for Conference and Other Materials: Neither the Department of Health and Human Services (HHS) nor the CDC logo may be displayed if such display would cause confusion as to the funding source or give false appearance of Government endorsement. Use of the HHS name or logo is governed by U.S.C. Part 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. Part 1320b-10. The appropriate use of the HHS logo is subject to review and approval of the HHS Office of the Assistant Secretary for Public Affairs (OASPA). Moreover, the HHS Office of the Inspector General has authority to impose civil monetary penalties for violations (42 CFR Part 1003). Accordingly, neither the HHS nor the CDC logo can be used by the grantee without the express, written consent of either the CDC Project Officer or the CDC Grants Management Officer. It is the responsibility of the grantee 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.

**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 grantee 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 it vn property management standards and pr dures, provided it observes provisions of in applicable grant regulations and 45 CFR Part 75.

**Federal Information Security Management Act (FISMA):** All information systems, electronic or hard copy, that contain federal data must be protected from unauthorized access. This standard 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, PL 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 these data, subject to all applicable laws protecting security, privacy, and research. If/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: <a href="http://frwebgate.access.gpo.gov/cgi-lite.com">http://frwebgate.access.gpo.gov/cgi-lite.com</a>

bin/getdoc.cgi?dbname=107 cong public laws&docid=f:publ347.107.pdf

**Pilot Program for Enhancement of Contractor Employee Whistleblower Protections:** Grantees are hereby given notice that the 48 CFR section 3.908, implementing section 828, entitled "Pilot Program for Enhancement of Contractor Employee Whistleblower Protections," of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2013 (Pub. L. 112-239, enacted January 2, 2013), applies to this award.

#### Federal Acquisition Regulations

As promulgated in the Federal Register, the relevant portions of 48 CFR section 3.908 read as follows (note that use of the term "contract," "contractor," "subcontract," or "subcontractor" for the purpose of this term and condition, should be read as "grant," "grantee," "subgrant," or "subgrantee"):

3.908 Pilot program for enhancement of contractor employee whistleblower protections.

3,908-1 Scope of section.

(a) This section implements 41 U.S.C. 4712.

(b) This section does not apply to-

(1) DoD, NASA, and the Coast Guard; or

(2) Any element of the intelligence community, as defined in section 3(4) of the National Security Act of 1947 (50 U.S.C. 3003(4)). This section does not apply to any disclosure made by an employee of a contractor or subcontractor of an element of the intelligence community if such disclosure-

(i) Relates to an activity of an element of the intelligence community; or

(ii) Was discovered during contract or subcontract services provided to an element of the intelligence community.

3,908-2 Definitions.

As used in this section-

"Abuse of authority" means an arbitrary and capricious exercise of authority that is inconsistent with the mission of the executive agency concerned or the successful performance of a contract of such agency.

"Inspector General" means an Inspector General appointed under the Inspector General Act of 1978 and any Inspector General that receives funding from, or has oversight over contracts awarded for, or on behalf of, the executive agency concerned.

3.908-3 Policy.

(a) Contractors and sub *u*ractors are prohibited from discharging, de. ing, or otherwise discriminating against an employee as a reprisal for disclosing, to any of the entities listed at paragraph (b) of this subsection, information that the employee reasonably believes is evidence of gross mismanagement of a Federal contract, a gross waste of Federal funds, an abuse of authority relating to a Federal contract, a substantial and specific danger to public health or safety, or a violation of law, rule, or regulation related to a Federal contract (including the competition for or negotiation of a contract). A reprisal is prohibited even if it is undertaken at the request of an executive branch official, unless the request takes the form of a non-discretionary directive and is within the authority of the executive branch official making the request.

(b) Entities to whom disclosure may be made.

(1) A Member of Congress or a representative of a committee of Congress.

(2) An Inspector General.

(3) The Government Accountability Office.

(4) A Federal employee responsible for contract oversight or management at the relevant agency.

(5) An authorized official of the Department of Justice or other law enforcement agency.

(6) A court or grand jury.

(7) A management official or other employee of the contractor or subcontractor who has the responsibility to investigate, discover, or address misconduct.

(c) An employee who initiates or provides evidence of contractor or subcontractor misconduct in any judicial or administrative proceeding relating to waste, fraud, or abuse on a Federal contract shall be deemed to have made a disclosure.

#### 3.908-9 Contract clause.

Contractor Employee Whistleblower Rights and Requirement to Inform Employees of Whistleblower Rights (Sept. 2013)

(a) This contract and employees working on this contract will be subject to the whistleblower rights and remedies in the pilot program on Contractor employee whistleblower protections established at <u>41 U.S.C. 4712</u> by section 828 of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112-239) and FAR <u>3.908</u>.

(b) The Contractor shall inform its employees in writing, in the predominant language of the workforce, of employee whistleblower rights and protections under <u>41 U.S.C. 4712</u>, as described in section <u>3.908</u> of the Federal Acquisition Regulation.

(c) The Contractor shall insert the substance of this clause, including this paragraph (c), in all subcontracts over the simplified acquisition threshold.

#### PAYMENT INFORMATION

Automatic Drawdown (Direct/Advance Payments): 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.

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

Director, Payment Management Services P.O. Box 6021 Rockville, MD 20852 Phone Number: (877) 614-5533 Email: <u>PMSSupport@psc.gov</u> Website: http://www.dpm.psc.gov/help/help.aspx?explorer.event=true

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

- University a Non-Profit Payment Branch: <u>http://www.dpm.psc.gov/contacts/dpm\_contact\_list/univ\_nonprofit\_aspx?explorer.event=tr\_ue</u>
- Governmental and Tribal Payment Branch;

http://www.dpm.psc.gov/contacts/governmental and tribal.aspx?explorer.event=true

Cross Servicing Payment Branch;

http://www.dpm.psc.gov/contacts/cross\_servicing.aspx?explorer.event=true

International Payment Branch:

Bhavin Patel (301) 492-4918\_ Email: <u>Bhavin.patel@psc.hhs.gov</u>

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:

U.S. Department of Health and Human Services Division of Payment Management 7700 Wisconsin Avenue, Suite 920 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.

**Payment Management System Subaccount**: Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC setup payment subaccounts within the Payment Management System (PMS) for all grant awards. Funds awarded in support of approved activities have been obligated in a newly established subaccount in the PMS, herein identified as the "P Account". A P Account is a subaccount created specifically for the purpose of tracking designated types of funding in the PMS.

All award funds must be tracked and reported separately. Funds must be used in support of approved activities in the FOA and the approved application.

The grant document number and subaccount title (below) must be known in order to draw down funds from this P Account.

Grant Document Number: 004970PS15 Subaccount Title: PS151503MEDMONPROJ15

Acceptance of the Terms of an Award: By drawing or otherwise obtaining funds from the grant Payment Management Services, the grantee 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 within thirty (30) days of receipt of this award notice.

**Certification Statement**: By drawing down funds, the grantee 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. Recipients must comply with all terms and conditions outlined in their NoA, including grant policy terms and conditions contained in applicable

HHS Grant Policy Statements, and requirements imposed by program statutes and regulations and HHS grants administration regulations, as applicable; as well as any regulations or limitations in any applicable appropriations acts.



#### CLOSEOUT REQUIRE. NTS

Grantees must submit closeout reports in a timely manner. Unless the Grants Management Specialist/Grants Management Officer (GMS/GMO) approves a deadline extension the grantee must submit all closeout reports within 90 days after the last day of the final budget period. Reporting timeframe is June 1, 2015 through May 31, 2020. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

All manuscripts published as a result of the work supported in part or whole by the cooperative grant must be submitted with the progress reports.

An original plus two copies of the reports must be mailed to the GMS for approval by the GMO by the due date noted. Ensure the Award and Program Announcement numbers shown above are on the reports.

The final and other programmatic reports required by the terms and conditions of the NoA are the following.

**Final Performance Report:** An original and two copies are required. At a minimum, the report should include the following:

- Statement of progress made toward the achievement of originally stated aims.
- Description of results (positive or negative) considered significant.
- List of publications resulting from the project, with plans, if any, for further publication.

**Final Federal Financial Report (FFR, SF-425):** The FFR should only include those funds authorized and actually expended during the timeframe covered by the report. The Final FFR, SF-425 is required and must be submitted through <u>eRA Commons</u> no later than 90 days after the end of the project period. This report must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. Should the amount not match with the final expenditures reported to the Department of Health and Human Services' Payment Management Services (PMS), you will be required to update your reports to PMS accordingly. Remaining unobligated funds will be de-obligated and returned to the U.S. Treasury.

If the final reports (FFR and Final Progress Report) cannot be submitted within 90 days after the end of the project period, in accordance with 45 CFR Part 75.381 (Closeout), the grantee must submit a letter requesting an extension that includes the justification for the delay and state the expected date the CDC Procurement and Grants Office will receive the reports. All required documents must be mailed to the business contact identified in Staff Contacts.

**Equipment Inventory Report:** An original and two copies of a complete inventory must be submitted for all major equipment acquired or furnished under this project with a unit acquisition cost of \$5,000 or more. The inventory list must include the description of the item, manufacturer serial and/or identification number, acquisition date and cost, percentage of Federal funds used in the acquisition of the item. The grantee should also identify each item of equipment that it wishes to retain for continued use in accordance with 45 CFR Part 75. These requirements do apply to equipment purchased with non-federal funds for this program. The awarding agency may exercise its rights to require the transfer of equipment purchased under the assistance award referenced in the cover letter. CDC will notify the grantee if transfer to title will be required and provide disposition instruction on all major equipment. Equipment with a unit acquisition cost of less than \$5,000 that is no longer to be used in projects or programs currently or previously sponsored by the Federal Government may be retained, sold, or otherwise disposed of, with no further obligation to the Federal Government. If no equipment was acquired under this award, a negative report is required.

**Final Invention Statement:** An original and two copies of a Final Invention Statement are required. Electronic versions of the form can be downloaded by visiting <u>http://grants1.nih.gov/grants/hhs568.pdf</u>. If no inventions were conceived under this assistance award, a negative report is required. This statement may be included in a cover letter.

#### CDC ROLES AND RESPONSIBILITIES

**Roles and Responsibilities:** Grants Management Specialists/Officers (GMO/GMS) and Program/Project Officers (PO) work together to award and manage CDC grants and cooperative agreements. From the pre-planning stage to closeout of an award, grants management and program staff have specific roles and responsibilities for each phase of the grant cycle. The GMS/GMO is responsible for the business management and administrative functions. The PO is responsible for the programmatic, scientific, and/or technical aspects. The purpose of this factsheet is to distinguish between the roles and responsibilities of the GMO/GMS and the PO to provide a description of their respective duties.

Grants Management Officer: The GMO is the federal official responsible for the business and other non-programmatic aspects of grant awards including:

- Determining the appropriate award instrument, i.e.; grant or cooperative agreement
- Determining if an application meets the requirements of the FOA
- Ensuring objective reviews are conducted in an above-the-board manner and according to guidelines set forth in grants policy
- Ensuring grantee compliance with applicable laws, regulations, and policies
- Negotiating awards, including budgets
- Responding to grantee inquiries regarding the business and administrative aspects of an award
- Providing grantees with guidance on the closeout process and administering the closeout of grants
- Receiving and processing reports and prior approval requests such as changes in funding, carryover, budget redirection, or changes to the terms and conditions of an award
- Maintaining the official grant file and program book

The GMO is the only official authorized to obligate federal funds and is responsible for signing the NoA, including revisions to the NoA that change the terms and conditions. The GMO serves as the counterpart to the business officer of the recipient organization.

GMO Contact: See Staff Contacts below for the assigned GMO

**Grants Management Specialist:** The GMS is the federal staff member responsible for the dayto-day management of grants and cooperative agreements. The GMS is the primary contact of recipients for business and administrative matters pertinent to grant awards. Many of the functions described above are performed by the GMS on behalf of the GMO.

#### GMS Contact: See Staff Contacts below for the assigned GMS

**Program/Project Officer:** The PO is the federal official responsible for the programmatic, scientific, and/or technical aspects of grants and cooperative agreements including:

- The development of programs and FOAs to meet the CDC's mission
- Providing technical assistance to applicants in developing their applications e.g. explanation of programmatic requirements, regulations, evaluation criteria, and guidance to applicants on possible linkages with other resources
- Providing technical assistance to grantees in the performance of their project
- Post-award monitoring of grantee performance such as review of progress reports, review of prior approval requests, conducting site visits, and other activities complementary to those of the GMO/GMS

Programmatic Contact: Christine Mattson, Project Officer Centers for Disease Control National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

# Page 15 of 16

1600 Clifton Road NE; E-46 Atlanta, GA 30329 Telephone: 404-639-8572\_ Fax: 404-639-8640\_ Email: ggi8@cdc.gov

## STAFF CONTACTS

Grants Management Specialist: Gladys T Gissentanna Centers for Disease Control and Prevention Procurement and Grants Office 2920 Brandywine Road, Mailstop K-70 Atlanta, GA 30341 Email: gcg4@cdc.gov Phone: 770.488.2741 Fax: 770.488.2670

#### Grants Management Officer: Arthur Lusby Centers for Disease Control and Prevention (CDC) Procurment and Grants Office 2920 Brandywine Road, MS E-15 Atlanta, GA 30341

Email: alusby@cdc.gov Phone: (770) 488-2865 Fax: 770-488-2868

#### SPREADSHEET SUMMARY GRANT NUMBER: 1U62PS004970-01

## INSTITUTION: SAN FRANCISCO DEPT OF PUBLIC HEALTH

and the second	•				
Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	\$88,042				
Fringe Benefits	\$36,844				· · ·
Personnel Costs (Subtotal)	\$124,886	1		1	
Travel Costs	\$2,600				
Consortium/Contractual Cost	\$375,845				
TOTAL FEDERAL DC	\$503,331	\$524,488	\$524,488	\$524,488	\$524,488
TOTAL FEDERAL F&A	\$21,157				1
TOTAL COST	\$524,488	\$524,488	\$524,488	\$524,488	\$524,488

# SUMMARY STATEMENT FUNDING OPPORTUNITY ANNOUNCEMENT CDC-FOA PS15-1503 "Medical Monitoring Project"

**Date of Review:** February 4, 2015 **Applicant Name:** San Francisco Department of Public Health **Recommendation:** Approved

## **RECOMMENDATIONS:**

None noted,

## **OTHER RELEVANT COMMENTS:**

- Given the Applicant's history of doing this work, it is expected to see more originality in its proposal.
- Would like to see what lessons were learned from its previous history doing this kind of work?

#### CRITERIA

1. Approach

Summary of Strengths:

- The Applicant responds to every component of FOA and has a solid application.
- Applicant has a history of conducting MMP. In addition, Applicant is one of the sites where case based surveillance sampling was a demonstration project, and it has an extensive history of linking HIV positive individuals to a linkage and navigation program through the HIV case registry. The Applicant's involvement in a research study, data-to-care activities, and its previous history as an MMP site has prepared it to be successful in this endeavor.
- The Applicant provides a clear strategy that supports two main project outcomes---local and national HIV prevention and treatment efforts informed by MMP data; and key users having MMP data for budgeting, planning and service delivery decisions.
- Benchmarks are provided for three specific aims related to collecting high quality, representative data; targeting data analysis and dissemination; and promoting collaboration among partners representing surveillance, prevention and treatment.
- Timelines are specific, reasonable, and aligned with project activities.
- The Applicant provides a detailed 1-year work plan outlining activities, dates of activities, and persons responsible. (pages 19-23)
- A high level activities plan is provided for subsequent annual project cycles (page 22)
- Evidence-based activities and methods are described in detail and appear achievable and appropriate for the project outcomes. For example, the Applicant specifies that patients identified as not in care will be referred to the the Applicant Linkage Integration, Navigation, and
  - Comprehensive Services (LINCS) and that 80% will be re-linked to care within 3 months. (page 3) The Applicant cites specific stakeholders who will be involved in these activities including Provider

and Community Advisory Boards, the HIV Prevention and Planning Council, HIV Care Council, and San Francisco Getting to Zero Coalition. (page 3)

- All regulatory approvals have been obtained including those related to sampling, contacting and recruiting participants from eHARS. eHARS is currently used to identify HIV-infected persons for Partner Services and in need of linkage or re-linkage to care. (page 3)
- Standard Operating Procedures (SOP) are developed for the CSBS pilot and are now in place (page 4). These procedures protect patient confidentiality; ensure secure data files and analysis; support recruitment and data collection on cross-jurisdictional patients (updating eHARS accordingly); timely and complete CD4 and viral load reporting (89% in 2012); address Routine Interstate Duplicate Review (RIDR); and facilitate handling of interview response cards via internet or mail. (page 6)
- Sampling and data collection procedures are described in detail including sample selection and minimum dataset (e.g., Contacts Attempt Tracking, sample quality); location, contact and recruitment (including a rigorous 6-step search algorithm to track down patient leads (pages 6-7); contacting and recruiting patients (including local patient-contact protocol and 2-step process developed during CSBS pilot for reaching out to the HIV care provider and patient); contact tracing, using local and national databases that have been developed.
- Data collection methods specify details regarding the interview approach (including 5% of interviews observed by a supervisor); medical record abstraction (MRA); linkage to care with referrals to prevention services as needed; and facility attributes and provider survey. (pages 9-11)
- Data management, analysis, and dissemination protocols and activities---including quality assurance---are clearly defined and in place. Monitoring and evaluation procedures are appropriate. The applicant describes how evaluation and performance measurement will be used for project planning, implementation and reporting. A detailed evaluation plan and proposed performance measures are provided. (pages 23-24)
- A Community Advisory Board (CAB) and Provider Advisory Board (PAB) will continue to support and inform MMP. The applicant proposes to engage key stakeholders including the MMP/CSBS CAB, the Ryan White Care Council, the HIV Prevention Planning Council, and providers in large HIV care practices. Stakeholders will be engaged though meetings, surveys, and interviews. An MMP advisory board will be involved in evaluation activities. (page 24)
- Applicant proposes a data dissemination plan that will be developed with input from individuals at SFDPH, CDC, SF MMP Provider and Community Advisory Board, the HIV Prevention Planning Council, and the HIV Care Council.
- Applicant's plan to meet the outcomes is feasible.
- Proposed use of funds is consistent with project activities and appears reasonable.

## Summary of Weaknesses:

- The minimum sample size of 400 is not mentioned aside from in the budget.
- Applicant does not describe the core information relative to the problem for the jurisdictions or populations it serves.

## 2. Evaluation and Performance Management

#### **Summary of Strengths:**

• The Applicant describes an evaluation plan that clearly identifies key evaluation questions. The evaluation plan appears feasible and methodologically sound. It describes how evaluation and

performance measurement will contribute to developing an evidence base where needed, e.g., The plan ... "will be used to identify areas in need of quality improvement including ongoing monitoring of patient participation rates, quality of interviews and medical record abstractions, and linkage to and re-engagement in care activities with corrective action taken as needed." (page 16)

- The evaluation plan will seek to provide evidence of effective prevention, care, or treatment strategies particularly in areas where high quality effectiveness data is limited.
- The Applicant notes its intent to work with stakeholders and CDC to further articulate key evaluation questions (page 16), address benchmarks (including proposed effectiveness outcome questions), and conduct quality assessments and continuing quality improvement activities. (page 15)
- The plan describes generally how various types of evaluation activities will be conducted including data collection and analysis. It specifies sample performance measures, data sources and feasibility (page 24).
- In Appendix A the Applicant describes in detail the types of evaluations to be conducted, how and by whom evaluation will be conducted, data collection and analysis plans, how data will be reported, and how evaluation and performance measurement findings will be used to demonstrate the outcomes of the FOA and for continuous program quality improvement.
- The application is complete.
- The plan cites the Project Coordinator and Project Director as the Responsible Party. Support for evaluation activities (i.e., related to benchmarks for sampling and data collection; data management and dissemination; collaboration; and use of MMP data to inform HIV prevention and treatment programs) will be provided by the co-principal investigators, research associates, and data manager.
- The Applicant proposes to engage key stakeholders including the MMP/CSBS CAB, the Ryan White Care Council, the HIV Prevention Planning Council, and providers in large HIV care practices. Stakeholders will be engaged though meetings, surveys, and interviews. An MMP advisory board will be involved in evaluation activities. (page 24)
- The Applicant proposes robust analysis of MMP data and cites its strong history of analysis and dissemination of HIV surveillance data. This includes over 13 specific analyses using MMP/CSBS data (page 23), findings from which have been disseminated through scientific and public health meetings, the SFDPH HIV Epidemiology Annual Report, and publications in peer-reviewed scientific journals.

#### Summary of Weaknesses:

• None noted

## 3. Applicant's Organizational Capacity to Implement the Approach Summary of Strengths:

- The Applicant includes a work plan (pages 19-22) that describes who is doing what and when.
- The Applicant has experience conducting MMP since 2007 and was a CSBS pilot site. Standard Operating Procedures are in place. The Applicant provides a staffing plan and project management structure that appears sufficient to meet project goals. Staff roles are clearly defined. Based on prior experience and staffing, the applicant demonstrates the management, administrative, and technical experience and capacity needed to achieve the project goals.
- The Applicant will continue to employ existing MMP staff for the next grant cycle. This includes 10 staff members all of whom have been trained in their current staff roles including eHARS data

extraction (CSBS Co-PI and MMP Data Manager), interviewing (4 research associates), conducting MRAs (4 research associates), and recruiting from eHARS (4 research associates and MMP Project Coordinator). (pages 16-17) The HIV core surveillance program manager who conducts routine HIV core surveillance is on the MMP team. She works closely with other jurisdictions regarding case investigation and data sharing.

- The Co-MMP PI is also Acting Director for the SFDPH Applied Research, Community Health Epidemiology and Surveillance (ARCHES) Branch within which MMP and HIV surveillance activities are conducted. She will oversee data collection, analysis and interpretation---and has over 20 years of experience in this area. (page 17)
- Staff has extensive training and experience with telephone interviewing, including in Spanish. (page 5)
- Appropriate trainings for staff has been noted (e.g., security and confidentiality, sensitivity).
- The Applicant demonstrates organizational and management capacity for implementing project activities including monitoring and evaluation.
- Leveraging the integration of MMP with CORE surveillance will enable the addition of 3 additional staff members.
- The MMP Project Coordinator has worked on MMP for the past seven years in some capacity.

## Summary of Weaknesses:

- There is no organizational chart.
- 4. Budget Comments
- None noted

Print Form	
<u>Introduction Form</u> By a Member of the Board of Supervisors or the Mayor	
I hereby submit the following item for introduction (select only one):	Time stamp or meeting date
1. For reference to Committee. (An Ordinance, Resolution, Motion, or Charter Amendm	ent)
2. Request for next printed agenda Without Reference to Committee.	
3. Request for hearing on a subject matter at Committee.	
4. Request for letter beginning "Supervisor	inquires"
<ul> <li>5. City Attorney request.</li> </ul>	
6. Call File No. from Committee.	
7. Budget Analyst request (attach written motion).	
8. Substitute Legislation File No.	
9. Reactivate File No.	
10. Question(s) submitted for Mayoral Appearance before the BOS on	
ase check the appropriate boxes. The proposed legislation should be forwarded to the follow Small Business Commission Youth Commission Ethics Com	
Planning Commission     Building Inspection Commission	
Note: For the Imperative Agenda (a resolution not on the printed agenda), use a Imperativ	e Form.
Sponsor(s):	
Scott Wiener	
Subject:	
Accept and Expend Grant – Medical Monitoring Project - \$524,488	
The text is listed below or attached:	•
Resolution authorizing the San Francisco Department of Public Health to retroactively accept ar the amount of \$524,488 from Centers for Disease Control and Prevention to participate in a pro- Monitoring Project for the period of June 1, 2015, through May 31, 2016.	¥ 0 1
Signature of Sponsoring Supervisor:	Cher
For Clerk's Use Only:	

#### FORM SFEC-126: NOTIFICATION OF CONTRACT APPROVAL F. Campaign and Governmental Conduct Code & 1 126)

City Elective Officer Information (Please print clearly.)	
Name of City elective officer(s):	City elective office(s) held:
Members, Board of Supervisors	Members, Board of Supervisors
· ·	
Contractor Information (Please print clearly.)	
Name of contractor:	· · · · ·
Public Health Foundation Enterprises, Inc. (PHFE)	
financial officer and chief operating officer; (3) any person	ard of directors; (2) the contractor's chief executive officer, chief who has an ownership of 20 percent or more in the contractor; (4) political committee sponsored or controlled by the contractor. Use
See attachment	
Charles 11	
Contractor address: 12801 Crossroads Parkway South, Suite 200, City of Industr	ry, CA 91746-3505
Date that contract was approved: (By the SF Board of Supervisors)	Amount of contracts: \$375,845 in one year
Describe the nature of the contract that was approved: PHFE will provide the staffing for data management and dat abstraction and patient interview	ta dissemination; and field activities: including medical record
Comments: PHFE is a 501 ( c ) 3 Nonprofit with a Board of Directors	
Comments:	

□the City elective officer(s) identified on this form

☑ a board on which the City elective officer(s) serves: <u>San Francisco Board of Supervisors</u> 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 (Please print clearly.)	
Name of filer:	Contact telephone number:
Angela Calvillo, Clerk of the Board	(415) 554-5184
Address:	E-mail:
City Hall, Room 244, 1 Dr. Carlton B. Goodlett Pl., San Francisco, CA 94102	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

PHFE Board of Directors 2015-16

Officers:

Erik D. Ramanathan, Chair Tamara Joseph, Vice Chair Delvecchio Finley, Secretary Robert R. Jenks, Treasurer Blayne Cutler, Ph.D., M.D, CEO

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