

File No. 170104

Committee Item No. 4

Board Item No. _____

COMMITTEE/BOARD OF SUPERVISORS

AGENDA PACKET CONTENTS LIST

Committee: Budget & Finance Committee

Date February 23, 2017

Board of Supervisors Meeting

Date _____

Cmte Board

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

OTHER (Use back side if additional space is needed)

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Completed by: Linda Wong Date February 17, 2017

Completed by: Linda Wong Date _____

1 [Accept and Expend Grant - Public Health Foundation Enterprises, Inc. - Epidemiology and
2 Laboratory Capacity Gonorrhea Rapid Detection and Response Project- \$598,052.66]

3 **Resolution retroactively authorizing the Department of Public Health to accept and**
4 **expend a grant in the amount of \$598,052.66 from Public Health Foundation**
5 **Enterprises, Inc., to participate in a program entitled Epidemiology and Laboratory**
6 **Capacity Gonorrhea Rapid Detection and Response Project for the period of**
7 **August 1, 2016, through July 31, 2017.**

8
9 WHEREAS, Public Health Foundation Enterprises, Inc. is the recipient of a grant award
10 from Centers for Disease Control and Prevention supporting the Epidemiology and Laboratory
11 Capacity Gonorrhea Rapid Detection and Response Project grant; and

12 WHEREAS, With a portion of these funds, Public Health Foundation Enterprises, Inc.
13 has subcontracted with San Francisco Department of Public Health (DPH) in the amount
14 of \$598,052.66 for the period of August 1, 2016, through July 31, 2017; and

15 WHEREAS, As a condition of receiving the grant funds, Public Health Foundation
16 Enterprises, Inc. requires the City to enter into an agreement (Agreement), a copy of which is
17 on file with the Clerk of the Board of Supervisors in File No. 170104; which is hereby declared
18 to be a part of this Resolution as if set forth fully herein; and

19 WHEREAS, The purpose of this project will support, expand, and accelerate efforts to
20 combat antibiotic-resistant *Neisseria gonorrhoeae* (ARG) in San Francisco by developing and
21 implementing protocols for rapid identification and response to ARG cases, expanding
22 surveillance to additional clinic sites, populations including females and youth, and anatomic
23 sites of infection, and collaborating throughout the surrounding Bay Area region to provide
24 comprehensive rapid response to ARG cases; and

1 WHEREAS, A request for retroactive approval is being sought because DPH did not
2 receive notification of the award until October 26, 2016, for a project start date of
3 August 1, 2016; and

4 WHEREAS, The budget includes a provision for indirect costs in the amount
5 of \$99,866.13; now, therefore, be it

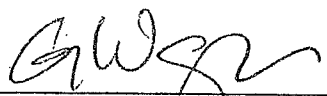
6 RESOLVED, That DPH is hereby retroactively authorized to accept and expend a grant
7 in the amount of \$598,052.66 from Public Health Foundation Enterprises, Inc.; and

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

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

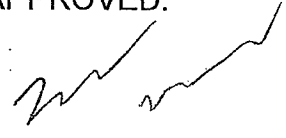
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RECOMMENDED:



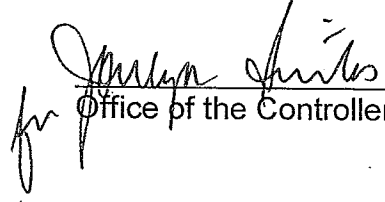
Barbara A. Garcia, MPA
Director of Health

APPROVED:



Office of the Mayor

for



Office of the Controller

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

Grant Resolution Information Form
(Effective July 2011)

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: **Epidemiology and Laboratory Capacity (ELC) Gonorrhea (GC) Rapid Detection and Response Project**
2. Department: **San Francisco Department of Public Health, Population Health Division, Disease Prevention and Control Branch**
3. Contact Person: **Susan Philip, MD, MPH** Telephone: **(628) 206-7638**
4. Grant Approval Status (check one):
 Approved by funding agency Not yet approved
5. Amount of Grant Funding Approved or Applied for: **\$598,052.66**
- 6a. Matching Funds Required: **N/A**
b. Source(s) of matching funds (if applicable): **N/A**
- 7a. Grant Source Agency: **Department of Health & Human Services, Centers for Disease Control and Prevention**
b. Grant Pass-Through Agency (if applicable): **Public Health Foundation Enterprises, Inc.**
8. Proposed Grant Project Summary:
In 2013, CDC identified antibiotic-resistant *Neisseria gonorrhoeae* (ARG) as an urgent public health threat requiring significant resources to detect and prevent cases in the United States. California (CA) and San Francisco (SF) are areas of particular concern. In 2014, CA had the most gonorrhea (GC) cases of any state. In 2015, there were 54,307 GC cases, and from 2011 to 2015 male cases ages 15-44 increased 113% and female cases ages 15-44 increased 67%. Furthermore, SF has the highest GC case rate in CA; in 2015, 4266 reported cases represented a 30% increase from 2014. In 2013, the SF case rate was 313.2/100,000, which exceeded the case rate for the Los Angeles metropolitan statistical area (MSA), the New York MSA, the state of CA, and the United States (US) as a whole. Prevention and control of GC are key responsibilities of state and local sexually transmitted disease (STD) programs and rely on timely and effective antibiotic treatment. However, GC has repeatedly developed resistance to antimicrobials including sulfonamides, penicillin, tetracyclines, and fluoroquinolones. Data from the CDC Gonococcal Isolate Surveillance Project (GISP) have shown that decreased antibiotic susceptibility to cephalosporins, the current mainstay of GC treatment, is more likely to be detected in specimens from the Western US compared to other US regions, and from men who have sex with men (MSM) compared to men who have sex with women (MSW). With large populations of MSM and high rates of GC, CA and SF are critical jurisdictions to implement effective surveillance and control of ARG.
Given California's increased epidemiologic risk for ARG, both the San Francisco Department of Public Health (SFDPH) and California Department of Public Health (CDPH) have established efforts to prepare for and respond to this public health threat. Our proposed California-San Francisco Rapid Detection and Response Project (CA-SF GC RDR) will support, expand, and accelerate efforts to combat ARG in San Francisco, by 1) developing and implementing protocols for rapid identification and response to ARG cases, 2) expanding surveillance to additional clinic sites, populations including females and youth, and anatomic sites of infection, and 3) collaborating throughout the surrounding Bay Area region to provide comprehensive rapid response to ARG cases. Rigorous data collection and evaluation of novel methods for GC surveillance, laboratory testing, and case investigation will inform preparedness for rapid ARG detection and response throughout California.

9. Grant Project Schedule, as allowed in approval documents, or as proposed:

Start-Date: **August 1, 2016**

End-Date: **July 31, 2017**

10a. Amount budgeted for contractual services: **\$25,000**

b. Will contractual services be put out to bid? **TBD**

c. If so, will contract services help to further the goals of the Department's Local Business Enterprise (LBE) requirements? **TBD**

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

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

b1. If yes, how much? **\$99,866.13**

b2. How was the amount calculated? **25% of Total Salaries and Fringes**

c1. If no, why are indirect costs not included?

Not allowed by granting 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 approval to accept and expend these funds retroactive to August 1, 2016. The Department received the notice of award on October 26, 2016.

GRANT CODE (Please include Grant Code and Detail in FAMIS): HCD141 - 1700

****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):

- | | | |
|--|---|---|
| <input checked="" type="checkbox"/> Existing Site(s) | <input checked="" type="checkbox"/> Existing Structure(s) | <input checked="" type="checkbox"/> Existing Program(s) or Service(s) |
| <input type="checkbox"/> Rehabilitated Site(s) | <input type="checkbox"/> Rehabilitated Structure(s) | <input type="checkbox"/> New Program(s) or Service(s) |
| <input type="checkbox"/> New Site(s) | <input type="checkbox"/> New Structure(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:

Matthew Valdez
(Name)

EEO Programs Manager, Office of Equal Employment Opportunity and Cultural Competency
(Title)

Date Reviewed: 11/09/16

[Signature]
(Signature Required)

Department Head or Designee Approval of Grant Information Form:

Barbara A. Garcia, MPA
(Name)

Director of Health
(Title)

Date Reviewed: 11/18/16

[Signature]
(Signature Required)

Public Health Foundation Enterprises
K6.AR-Gonorrhea: Rapid Detect and Resp Cap

Contract Term: 08/01/2016-07/31/2017
CFDA #:

Expenditure Type	Employee ID	Max # of Hours (if hourly employee)	(if available) Monthly Salary/Hourly Range (per budget)	Salary/Hourly Rate	Total % budgeted	Revised Total % budgeted	Months Position Budgeted	Original Budget
Epidemiologist								
TBD	0		\$ 6,794.00	\$ 39.20	100%		12	\$ 81,528.00
Health Worker								
TBD	0		\$ 4,788.00	\$ 27.62	100%		12	\$ 57,456.00
Microbiologist								
TBD	0		\$ 5,699.00	\$ 32.88	100%		12	\$ 68,388.00
Total Salaries								\$ 207,372.00
FB- Accrued Vacation								\$ 7,983.82
Fringe Benefits at 31.1%								\$ 66,075.68
Total Personnel								\$ 282,331.48
Equipment								
Equipment- Incubator								\$ 13,789.00
Equipment- Freezer-MDL								\$ 24,855.00
Equipment- Camera for Microscope								\$ 7,700.00
Total Equipment								\$ 46,344.00
Travel								
TC - Travel In State								\$ 19,560.00
TC- Out of State		(Rapid Detection and Response Capacity Meeting)						\$ 9,584.00
TC- Out of State		(Peer to Peer Travel)						\$ 28,692.00
TC- Out of State		(Infectious Disease Week)						\$ 4,782.00
TC- Out of State		(American Society for Microbiology)						\$ 3,858.00
Total Travel								\$ 66,256.00
Other Costs								
Office Supplies								\$ 9,000.00
Lab Supplies								\$ 66,121.00
Staff Development Training								\$ 800.00
Computers								\$ 10,100.00
CaREDIE/HIS Project Support								\$ 12,000.00
American Society of Microbiology								\$ 800.00
Notebook/Tablet								\$ 7,899.00
WiFi								\$ 300.00
Wireless Service								\$ 1,800.00
CAPTC-DIS Training Center Support								\$ 50,000.00
Background Check								\$ 180.00
Total Other Costs								\$ 158,800.00
Consortium/Contractual Cost								
Office Supplies								\$ 15,000.00 SFDPH
Office Furniture								\$ 2,000.00 SFDPH
A3 Thinking Training								\$ 50,000.00 SFDPH
IT Surveillance Systems Interoperability								\$ 20,000.00 SFDPH
Shipping								\$ 115,000.00 SFDPH
Database Development (EMERGE group)								\$ 18,000.00 EmERGE Group
Indirect for Contractual								\$ 114,615.00
Staff Development Training								\$ 1,000.00 SFDPH
Epidemiologist I/II								
TBD								\$ 130,745.00 (Hard Coded) SFDPH
Microbiologist								
TBD								\$ 119,413.00 (Hard Coded) SFDPH
Health Worker III								
TBD								\$ 170,801.00 (Hard Coded) SFDPH
Administrative Assistant								
TBD								\$ 37,700.00 (Hard Coded) SFDPH
Total Consortium/Contractual Cost								\$ 794,074.00
FA - Indirect								\$ 67,846.50
								\$ 67,846.50
Total Budget								\$ 1,415,651.98

Proposal/Approval Budget \$ 1,415,651.98
Difference \$ (0.00)

ELC GC RAPID DETECTION AND RESPONSE
August 1, 2016 TO JULY 31, 2017

BUDGET JUSTIFICATION

SALARIES AND FRINGES

\$399,464.53

Principal Investigator - S. Philip

\$9,128 biweekly x 26.1 pay periods = \$238,241 x .03 effort = No Salary Requested

This position serves as the Principal Investigator for the designated local jurisdiction for this project and will collaborate with the California Department of Public Health and other project PI's to ensure that the Project meets all the funding requirements. Dr. Philip is the San Francisco Department of Public Health Population Health Division Disease Prevention and Control Branch Director. She has over 8 years of experience in STD and HIV clinical care, epidemiology, and evaluation. She served previously as the Director for the SFDPH STD Prevention and Control Services Section and continues in her role as the City STD Controller. Key units/staff in DPC include San Francisco City Clinic, the Public Health Laboratory, and all SFDPH DIS staff. In both the STD Section and DPC Branch, quantitative and qualitative data are extensively used for evaluation and quality assurance of programs and activities, and shared with organizational and community partners.

Co-Principal Investigator - T. Aragon

\$9,141 biweekly x 26.1 pay periods = \$238,580 x .01 effort = No Salary Request

This position is the Co-PI for this project and will work with the other PI's to ensure that the Project meets all funding requirements, follows the standardized protocols and procedures and adheres to CDC's Data Security and Confidentiality Guidelines. They may participate in conference calls and/or attend mandatory project meetings. As the Director of the Population Health Division, this position has overall oversight and responsibility for all grants awarded to the Division and for the Program's compliance with funding requirements.

San Francisco Public Health Laboratory Director - G. Masinde

\$5,991 biweekly x 26.1 pay periods = \$156,365 x .01 effort = No Salary Request

This position provides Public Health Laboratory oversight and supervision as well as ensures compliance for this project. This position will work with the PI's and coordinator to ensure that all related laboratory testing follows the standardized protocols and procedures. He may participate in conference calls and/or attend mandatory project meetings.

ELC GC RAPID DETECTION AND RESPONSE
AUGUST 1, 2016 TO JULY 31, 2017

BUDGET JUSTIFICATION

HW IV - M. Lee

\$3,199 biweekly x 26.1 pay periods = \$83,494 x .10 effort = No Salary Requested

This position is responsible for coordinating the STD Screening Program, which includes oversight of GC screening and treatment needs at San Francisco City Clinic, private providers, and community-based health providers. The STD Screening Program has established relationships with community based health providers (e.g., 3rd Street Youth Center and Clinic) to facilitate the integration and expansion of STD screening into their practices; provides STD training and technical assistance to private providers and health clinics in the City; and performs facility visitations to screening sites as needed.

1.0 FTE - 2802 EPII - TBD

\$3,455 biweekly x 13.05 pay periods = \$45,087.75 x 1.00 FTE, plus 45% fringe

\$65,372.50

This position will provide epidemiological support for data collection and data management, including verifying, analyzing, interpreting, and summarizing data reports for this project. This position has a Masters Degree in Public Health and 4+ years experience in epidemiology and surveillance activities. They will be responsible for data management, analysis and dissemination, generation of program reports; providing technical assistance to participating health providers; providing epidemiological support for the staff performing interviews, partner services, and quality assurance of these data; cleaning, formatting, and transmitting data to CDPH and CDC within agreed upon timelines; and for dissemination of findings to appropriate stakeholders. They will also be responsible for responding to requests from the funder for data as well as participate on project conference calls and attend required project meetings as needed.

0.20 FTE - Epi II - T. Nguyen

\$4,197 biweekly x 26.1 pay periods = \$109,594 x 0.20 FTE, plus 45% fringe

\$31,767.09

This position will oversee all project activities to ensure compliance as well as performing QA of data reported through the various data collection streams and implement and adhere to protocol agreement for project activities.

0.20 FTE - Epi II - R. Kohn

\$4,197 biweekly x 26.1 pay periods = \$109,594 x 0.20 FTE, plus 45% fringe

\$31,767.09

This position will ensure implementation and quality assurance of data entry, data collection and data cleaning as well as oversee and maintain the electronic database and data system for this project.

ELC GC RAPID DETECTION AND RESPONSE
August 1, 2016 TO JULY 31, 2017

BUDGET JUSTIFICATION

0.40 FTE - 2802 Epi I - M. Mahersi (TBD start date)

\$2,706 biweekly x 26.1 pay periods = \$70,627 x 0.40 FTE, plus 45% fringe

\$40,963.43

This position will be responsible for data management, analysis and dissemination, generation of program reports; providing technical assistance to participating health providers; providing epidemiological support for the staff performing interviews, partner services, and qualitative data collection, including quality assurance of these data; cleaning, formatting, and transmitting data to CDPH and CDC within agreed upon timelines; and for dissemination of findings to appropriate stakeholders. They will also be responsible for responding to requests from the funder for data as well as participate on project conference calls and attend required project meetings.

HW IV - R. Shaw

\$3,199 biweekly x 26.1 pay periods = \$83,494 x .10 effort = No Salary Requested

This position is will be responsible for overseeing the field staff which will conduct the case investigations, including case reviews and monitoring of staff for this project.

Sr. Microbiologist - J. Carlson

\$4,375 biweekly x 26.1 pay periods = \$114,188 x .10 effort = No Salary Requested

This position provides supervision for the project microbiologist and ensures compliance for this project. This position is responsible for oversight of receiving and processing the project lab specimens, assisting lab staff with specimens, performing quality control testing of these tests and data-entry of results.

1.0 FTE - 2462 Microbiologist - TBD

Microbiologist - \$3,155 biweekly x 20.66 pay periods = \$65,196.55 x 1.00 FTE, plus 45% fringe

\$94,535.29

Under general supervision, conducts bacteriologic, parasitologic, serologic and related laboratory tests and examinations; and performs related duties as required. Requires responsibility for: performing scientific tests and investigations according to instructions and established methods and procedures; keeping complete and accurate records and submitting accurate reports on the results of investigations.

ELC GC RAPID DETECTION AND RESPONSE
August 1, 2016 TO JULY 31, 2017

BUDGET JUSTIFICATION

2.0 FTE - 2587 Health Worker III - TBD

Health Worker III - \$2,254 x 20.66 pay periods = \$46,572.11 x 2.00 FTE, plus 45% fringe \$135,059.13

These positions will provide case investigation, including provider-reported case and treatment information and partner follow-up for this project. One position will be located at SFCC as part of the STD Clinic Partner Services Team and provides case management and partner services (PS) for newly diagnosed gonorrhea cases with reduced susceptibility; conducts case investigations of sexual and social contacts of gonorrhea cases with reduced susceptibility; performs phlebotomy for syphilis and/or HIV partners and sexual network contacts; makes and verifies completion of referrals; performs follow up for patients who do not return for their test results or who are infected with gonorrhea and need treatment; and performs data entry in the STD database. One position will be initially trained at SFCC with the Partner Services Team, but will eventually be embedded at the 3rd Street Youth Center and Clinic in order to develop and implement PS protocols and best practices for youth. This embedded DIS will interview patients diagnosed with gonorrhea per established protocols; counsel and motivate patients to seek and notify partners, either directly or with Health Department assistance; perform on-site and field follow up of gonorrhea cases, contacts for referral to prevention, mental health and social services, as needed; document activities and entering data into the ISCHTR database as appropriate in a timely, accurate and comprehensive fashion per established protocols; and perform HIV and STD screening that may include collecting urine, rectal and pharyngeal specimens and drawing blood. These activities may be performed in the field, at health fairs and in other settings and may be held in the evening, nights or on weekends.

ELC GC RAPID DETECTION AND RESPONSE
August 1, 2016 TO JULY 31, 2017

BUDGET JUSTIFICATION

TRAVEL	\$19,456.00
Local Mileage - 2 HWIII, monthly & 4 ELC SF Staff to Richmond x 4 times	\$1,500.00
Per the K8 FOA, section v. Funding Strategy, funds are requested to attend the required annual ELC K8: Threat of Antibiotic-Resistant gonorrhoea: Rapid Detection & Response Capacity grantee meeting. Location TBD, but likely at CDC in Atlanta, GA. For 3 SFDPH staff: 3 staff x \$1,076.40 out-of-state airfare = \$3,229 3 staff x \$45 car rental x 5 days = \$675 3 staff x \$150 lodging x 4 nights = \$1,800 3 staff x \$15 parking x 5 days = \$225 3 staff x \$71 per diem x 5 days = \$1,065 3 staff x \$60 gas per travel = \$180	\$7,174.00
Travel to STD Conference (PHL Director/Epi)	\$4,782.00
Travel to Passport to Partner Services Training	\$6,000.00
OTHER COSTS	\$79,266.00
Funds are being requested to purchase general office supplies on behalf of the SFDPH contractor for staff to carry out daily activities of the program. Office supplies include pens, copy papers, toners, binders, folders, stapler etc.	\$2,666.00
Funds are being requested to purchase office furniture	\$2,000.00
Funds are being requested for an IT consultant to explore options for interoperability between the Integrated STD Electronic Data System or ISCHTR (SFDPH STD Program Database) and CalREDIE (State Database)	\$25,000.00

ELC GC RAPID DETECTION AND RESPONSE
AUGUST 1, 2016 TO JULY 31, 2017

BUDGET JUSTIFICATION

Funds are being requested by SFDPH for packaging and shipping of specimens per the protocols to the appropriate Antibiotic-Resistant Lab Network (ARLN) laboratory for confirmatory agar dilution and molecular characterization, such as whole genome sequencing. Funds are also being requested for packaging and shipping of samples of isolates to CDPH MDL for additional testing. Lastly, funds are being requested for courier service to properly transport specimens from testing facilities to SFDPH Lab. 228 courier deliveries, including dry ice at \$200 = \$45,600

\$45,600.00

Funds are being requested for staff development

\$4,000.00

INDIRECT COSTS

\$99,866.13

Indirect Costs = 25% of total salaries and fringes

TOTAL BUDGET

\$598,052.66

ELC GC RAPID DETECTION AND RESPONSE
AUGUST 1, 2016 TO JULY 31, 2017

BUDGET SUMMARY

SALARIES AND FRINGES	\$399,464.53
TRAVEL	\$19,456.00
OTHER COSTS	\$79,266.00
INDIRECT COSTS	\$99,866.13
TOTAL BUDGET	\$598,052.66



Public Health
Foundation
Enterprises
A 501 (c) 3 Nonprofit Organization

[SUBCONTRACT/SUBAWARD] AGREEMENT BETWEEN

PUBLIC HEALTH FOUNDATION ENTERPRISES, INC.

AND

**San Francisco Department of Public
Health**

This [Subcontract/Sub-Award] Agreement (this "Agreement") is made and entered into as of August 1, 2016 by and between PUBLIC HEALTH FOUNDATION ENTERPRISES, INC., a 501(c)(3) California nonprofit corporation (hereinafter referred to as "PHFE"), and the party identified in Section 1 below (hereinafter be referred to as "Subcontractor/Subawardee").

RECITALS

A: PHFE has been granted an award by DHHS-CDC (the "Funding Agency"), under contract number 5NUOCK000410-03 and (the "Funding Award CFDA# 93.323") under which PHFE and its subcontractors and subawardees will Provide services as outlined in Exhibit A.

B. Subcontractor/Subawardee has expertise in the areas as outlined in Exhibit A Scope of Work, which expertise can assist PHFE to perform its obligations under the Funding Award Agreement; and

C. PHFE desires to engage the services of Subcontractor/Subawardee to assist PHFE in the performance of certain of its obligations under the Funding Award Agreement as set forth herein.

AGREEMENT

1. IDENTITIES OF PARTIES.

SUBCONTRACTOR/SUBAWARDEE: Please complete:
 Legal Name of Subcontractor/Subawardee: San Francisco Department of Public Health
 DBA of Subcontractor/Subawardee: San Francisco Department of Public Health
 Type of Entity: Sole Proprietorship Partnership
 Corporation Limited Liability Company
 State of Organization (if an entity): California

Address: 25 Van Ness Avenue, Suite 500

City/State/Zip: San Francisco, CA 94102

Business Telephone: 628-206-7617

Social Security or Employer Identification Number:

License Number and Expiration Date, if any: _____

Email Address: Susan.Phillip@sfdph.org

Name of Principal Investigator/Project Coordinator: Susan Phillip MD, MPH

Phone Number of Principal Investigator/Project Coordinator: 628-206-7638

Is Subcontractor/Subawardee required to file a Single Audit with the Federal Government?
(Required for parties who receive Federal funds in the aggregate amount of \$500,000 or more): Please complete:

Yes No

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

Yes No

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

http://sfcontroller.org/sites/default/files/F__inetpub_wwwroot_fac_collect_auditReports_01669182.pdf

PHFE:

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

Program Name: K8: AR Gonorrhea Rapid Detect and Resp Cap

Program/CID #: 0187.4004

Contracts Manager Name: Rochelle McLaurin

Contracts Manager Email Address: RMcLaurin@phfe.org

Program Director Name: Cheryl Starling Telephone Number: 916.324.0336

Program Director Email: Cheryl.Starling@cdph.ca.gov

2. SCOPE OF SERVICES.

(a) Services. Subcontractor/Subawardee shall perform the services, duties and obligations set forth in the Statement of Work ("SOW") attached as Exhibit A hereto, which is made a part hereof and incorporated herein by reference (the "Services"). The Services relate to Sections Exhibit C and n/a of the Funding Award Agreement. Subcontractor/Subawardee shall perform the Services in accordance with the specifications, timetables and requirements set forth in the SOW and this Agreement. PHFE may, in its discretion, provide to Subcontractor/Subawardee a copy of the Funding Award Agreement or the relevant sections thereof. If Subcontractor/Subawardee is provided with a copy of the Funding Award Agreement or the relevant sections thereof, Subcontractor/Subawardee shall carefully review them and shall perform the Services in accordance with the specifications, timetables and requirements set forth therein.

(b) Location(s) of Services. Subcontractor/Subawardee shall perform the Services at the following location(s): Please complete:

San Francisco City Clinic, 356-7th Street, SF, CA 94103

San Francisco Public Health Laboratory, 101 Grove Street, 4th Floor, SF, CA 94102

San Francisco Department of Public Health, 25 Van Ness Avenue, SF, CA 94102

(c) Subcontractor/Subawardee Principal Investigator/Project Coordinator. Subcontractor/Subawardee shall appoint the Principal Investigator/Project Coordinator (the "PI") identified above to be primary point of contact with PHFE and the Funding Agency with respect to the Services and to have primary responsibility within Subcontractor's/Subawardee's organization for the performance of the (technical or programmatic) aspects of the Services. Subcontractor/Subawardee shall not replace or reassign the PI without PHFE's and the Funding Agency's prior written approval.

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

(e) Performance Reporting. If requested by PHFE or the Funding Agency, Subcontractor/Subawardee shall submit a final technical or performance report, annual performance report, and quarterly performance reports. The final report shall be due 30 days after expiration or termination of this Agreement; annual reports and quarterly reports shall be due 30 days after the reporting period. Subcontractor/Subawardee shall also provide any other reports as may be requested by PHFE. Performance reports shall include a comparison of actual accomplishments with goals and objectives established for the period, findings of the PI, or both, as requested by PHFE. Where possible, quantitative output data should be related to cost data for computation of unit costs. Other pertinent information will include, when appropriate, the reasons why established goals were not met and an analysis. Subcontractor/Subawardee shall immediately

notify PHFE of developments that have a significant impact on the performance of the Services hereunder and of any problems, delays, or adverse conditions that materially impair its ability to meet the objectives of the Services, including providing a statement of the action taken or contemplated and any assistance needed to resolve the situation.

3. COMPLIANCE WITH FUNDING AWARD AGREEMENT AND LAWS AND REGULATIONS; FLOW DOWN PROVISIONS

(a) Compliance with Funding Contract. Subcontractor/Subawardee shall comply with, and shall ensure that all of its personnel and lower-tier subcontractors comply with, all of the rules, requirements and restrictions set forth in the Funding Award Agreement that are applicable to Subcontractor/Subawardee and Subcontractor's/Subawardee's activities.

(b) Flow Down Provisions. Without limiting the generality of Section 3(a) above, Subcontractor/Subawardee shall comply with, and shall ensure that all of its personnel and lower-tier subcontractors comply with, all of the flow-down provisions of the Funding Award Agreement applicable to Subcontractor/Subawardee set forth in Exhibit C attached hereto or otherwise made available to Subcontractor/Subawardee (including through links to website pages), which are made a part hereof and incorporated herein by reference (the "Flow Down Provisions"). Subcontractor/Subawardee represents and warrants that it has carefully reviewed all of the Flow Down Provisions and is able to comply with all of the Flow Down Provisions. In the event that the requirements set forth in the Flow Down Provisions are greater than the requirements set forth in this Agreement, or in the event of any conflict between the provisions of this Agreement and the Flow Down Provisions, the Flow Down Provisions shall control and Subcontractor/Subawardee shall comply with the requirements set forth in the Flow Down Provisions in accordance with Section 2(a).

(c) Laws and Regulations. Subcontractor/Subawardee shall also comply with all state and federal statutes and regulations applicable to Subcontractor/Subawardee, the Services or the Funding Award Agreement, in performing its obligations under this Agreement. Without limiting the generality of the foregoing, Subcontractor shall:

(i) unless exempt, comply with the requirements under 45 CFR Part 74, and the Public Health Service Grants Policy Statement;

(ii) unless exempt, comply with Executive Order 11246 entitled "Equal Employment Opportunity" as amended by Executive Order 11375 and as supplemental in Dept. of Labor regulations (41 CFR Part 60);

(iii) comply with (and not violate) all statutes, laws, rules and regulations relating to non-discrimination against any employees or applicants for employment, including, without limitation, Title VII of the Civil Rights Act of 1964, The Americans with Disabilities Act Amendments Act of 2008, and the California Fair Employment and Housing Act (if Subcontractor/Subawardee is located within California), and shall take affirmative action to ensure

that all employment related decisions are made in conformance with all such statutes, laws, rules and regulations; and

(iv) unless it is exempt from doing so, comply with 45 CFR Part 76, Appendix B-Certification Regarding Debarment, Suspension, and Ineligibility, Voluntary Exclusion-Lower Tier Covered Transactions.

(d) HIPAA Business Associate Agreement. If the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA") is applicable to the Services, Subcontractor/Subawardee shall execute and deliver PHFE's standard Business Associate Agreement as required by HIPAA.

(e) Lower-tier Subcontractors/Subawardees. Subcontractor/Subawardee shall incorporate all of the terms and conditions of this Agreement into all lower-tier subcontracts that Subcontractor/Subawardee may enter into in connection with this Agreement, and shall ensure that all such lower-tier subcontractors/subawardees and their personnel comply with all of the requirements of this Agreement applicable to Subcontractor/Subawardee, and all of the rules, requirements and restrictions set forth in the Funding Award Agreement, including the Flow Down Provisions, that are applicable to such lower-tier subcontractors'/subawardees' activities.

4. PAYMENT FOR SERVICES

(a) Budget. The total compensation and reimbursements payable to Subcontractor/Subawardee hereunder shall be as set forth in the detailed budget for the Services attached hereto as Exhibit B (the "Budget"), which is made a part hereof and incorporated herein by reference, which Budget is as set forth in the Funding Award Agreement. The maximum amount payable to Subcontractor/Subawardee hereunder shall not exceed the maximum amount set forth in the Budget.

(b) Must Stay Within Budget Time Periods. Subcontractor/Subawardee shall be compensated only for Services actually performed by Subcontractor/Subawardee and within the appropriate time period set forth in the Budget.

(c) Approval of Services by PHFE. All Services must be completed to the satisfaction of PHFE in order to be entitled to payment hereunder.

(d) Funds Available to PHFE. PHFE shall not be obligated to make payment under this Agreement unless the corresponding funds are disbursed to PHFE under the Funding Award Agreement. In the event that PHFE has made payment to Subcontractor/Subawardee under this Agreement and PHFE subsequently does not receive from the Funding Agency for any reason the corresponding payment for the Services performed by Subcontractor/Subawardee or expenses incurred by Subcontractor/Subawardee, then Subcontractor/Subawardee shall refund such payment to PHFE within ten (10) days after written notice from PHFE.

(e) Billing of Expenses and Costs. All expenses and costs shall be billed in accordance with the approved budget. Expenses incurred after the expiration or termination of this Agreement shall be disallowed. Subcontractor/Subawardee shall submit its final invoice no later than 30 days after the date of expiration of the term or termination of this Agreement.

(f) Budget Modifications. The Budget may be modified only by written agreement of PHFE and Subcontractor/Subawardee and the prior written approval of the Funding Agency.

5. INVOICING PROCEDURES

(a) Approval by Funding Agency. If required under the Funding Award Agreement, Subcontractor/Subawardee must first submit all timesheets and invoices to the Funding Agency for approval by the Funding Agency. After the Funding Agency has approved a timesheet and invoice submitted by Subcontractor/Subawardee, Subcontractor/Subawardee shall submit the same to PHFE.

(b) Address for Invoices. Subcontractor/Subawardee shall send all timesheets and invoices to the attention of the PHFE Project Director at the address set forth in Section 1 above.

(c) Invoicing Period. All invoices shall be submitted not more frequently than monthly, in arrears and must be submitted to PHFE within 30 days after the end of the applicable month or within 15 days after approval by the Funding Agency (if applicable), whichever is later. All final invoices must be received within 30 days of the expiration or termination of this Agreement or within such earlier time period as PHFE may require. If any invoices are not submitted within such time periods, Subcontractor/Subawardee waives (in PHFE's discretion) all rights to payment under such invoices.

(d) Formatting and Requirements of Invoices. All invoices shall be submitted in the form attached hereto as Exhibit D, as it may be modified by PHFE from time to time.

6. TERM AND TERMINATION

(a) Term. Unless earlier terminated as provided herein, the term of this Agreement shall be from August 1, 2016 to July 31, 2017(the "Term").

(b) Termination Without Cause. Without cause, PHFE may terminate this Agreement by giving 30 days prior written notice to Subcontractor/Subawardee of its intent to terminate this Agreement without cause.

(c) Termination for Cause. With reasonable cause, either party may terminate this Agreement effective immediately upon the giving of written notice of termination for cause. Reasonable cause shall include:

i. A material violation or breach of this Agreement by the other party which is not cured within 15 days after written notice from the terminating party;

ii. Any act of the other party that exposes the terminating party to liability to others for personal injury or property damage or any other harm, damage or injury; or

iii. If either party receives notice from the Funding Agency of the cancellation or termination of, or reduction of funding under, the Funding Award Agreement affecting the Services.

(d) Termination for Lack of Funding. PHFE may terminate this Agreement if for any reason the funding available under the Funding Award Agreement is withdrawn, limited, or impaired.

(e) Cessation Upon Termination. On the effective date of termination, Subcontractor/Subawardee shall cease all further Services under this Agreement, and Subcontractor/Subawardee shall cancel as many outstanding obligations as possible and not incur any additional obligations.

(f) Payment After Termination. Subject to the terms and conditions set forth in this Agreement, upon termination of this Agreement, provided, that PHFE has received the corresponding funds from the Funding Agency under the Funding Award Agreement, PHFE shall pay for any reasonable non-cancellable obligations properly incurred by Subcontractor/Subawardee under this Agreement and in accordance with the Budget prior to termination, and shall pay any amounts due to Subcontractor/Subawardee and properly invoiced under this Agreement for Services performed prior to termination; provided, that if PHFE has terminated this Agreement for reasonable cause under Section 6(c) above, then PHFE shall have the right to offset and deduct from any payments due to Subcontractor/Subawardee hereunder any damages or losses incurred by PHFE as a result of such violation or breach.

(g) Return of Materials. Upon the expiration or termination of this Agreement, Subcontractor/Subawardee shall immediately promptly return to PHFE all computers, cell phones, smart phones, computer programs, files, documentation, user data, media, related material and any and all other Confidential Information (as defined in below) of PHFE and all Work Product (as defined below). PHFE shall have the right to withhold final payment to Subcontractor/Subawardee until all such items are returned to PHFE.

(h) Surviving Provisions. The provisions of Sections 7 through 16, and any other sections that by their nature should or are intended to survive the expiration or termination of this Agreement shall survive and the parties shall continue to comply with the provisions of this Agreement that survive.

7. REPRESENTATIONS AND WARRANTIES. Subcontractor/Subawardee represents, warrants and covenants to PHFE as follows:

(a) Licenses and Permits. Subcontractor/Subawardee maintains and shall maintain during all relevant times under this Agreement all applicable federal, state and local business and other licenses, including any professional licenses or certificates, industrial permits and/or licenses, industry specific licenses, licenses required by the state(s) and/or locality(s) in which it does business, fictitious business names, federal tax identification numbers, insurance, and anything else required of Subcontractor/Subawardee as a business operator.

(b) Qualifications and Performance. Subcontractor/Subawardee (i) has the experience and skill to perform the Services hereunder, (ii) shall perform the Services in a good and workman like manner and in accordance with generally accepted professional standards and in an expeditious and economical manner consistent with sound professional practices, and (iii) is adequately financed to meet any financial obligation it may be required to incur hereunder.

(c) Not Debarred. Neither Subcontractor/Subawardee nor its principals or personnel are presently, nor will any of them be during the term of this Agreement, debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or funding agency.

8. INDEPENDENT CONTRACTOR STATUS

(a) Independent Contractor. Nothing in this Agreement is intended to place the parties in the relationship of employer-employee, partners, joint venturers, or in anything other than an independent contractor relationship. It is the parties' intention that Subcontractor/Subawardee shall be an independent contractor and not PHFE's employee or agent, and in conformity therewith, that Subcontractor/Subawardee shall retain sole and absolute discretion and judgment in the manner and means of carrying out Subcontractor/Subawardee's Services hereunder. Subcontractor/Subawardee is under the control of PHFE as to the results of Subcontractor/Subawardee's Services only, and not as to the means by which such results are accomplished.

(b) No Power to Bind PHFE. Without limiting the generality of the foregoing paragraph, this Agreement does not designate Subcontractor/Subawardee as the agent or legal representative of PHFE for any purpose whatsoever. Subcontractor/Subawardee is not granted any right or authority to assume or create any obligation or responsibility, or to make any promise or commitment regarding any work, on behalf of or in the name of PHFE or to bind it in any manner, or to make any contract or agreement on behalf of or in the name of PHFE, without the prior written consent from PHFE management. No sales, invoices nor orders for goods or services shall be valid and binding upon PHFE (whether as the provider or the recipient) unless and until accepted by PHFE, at its sole and absolute discretion, through its established channels. PHFE shall not be liable for any obligation incurred by Subcontractor/Subawardee.

(c) No Withholding. Except for tax withholdings that are required by law, neither federal, nor state, nor local income tax nor payroll taxes of any kind shall be withheld or paid by PHFE on behalf of Subcontractor/Subawardee or the employees of Subcontractor/Subawardee. Subcontractor/Subawardee and its personnel shall not be treated as employees or PHFE with

respect to the Services performed hereunder for federal or state tax purposes or for any other purposes.

(d) No Employee Benefits. Neither Subcontractor/Subawardee nor its personnel shall be eligible for, and shall not participate in, any of PHFE's retirement, health, or other fringe benefit plans.

(e) Workers' Compensation. No workers' compensation insurance shall be obtained by PHFE concerning Subcontractor/Subawardee or Subcontractor's/Subawardee's personnel. Subcontractor/Subawardee shall comply with all workers' compensation laws concerning Subcontractor/Subawardee and its personnel.

(f) Taxes. Subcontractor/Subawardee understands that Subcontractor/Subawardee is responsible to pay, according to law, Subcontractor's/Subawardee's income taxes. If Subcontractor/Subawardee is not an entity, Subcontractor/Subawardee further understands that Subcontractor/Subawardee may be liable for self-employment (social security) tax, to be paid by Subcontractor/Subawardee according to law. Subcontractor/Subawardee shall be solely responsible for the payment of all federal, state and local income taxes, social security taxes, federal and state unemployment insurance and similar taxes and all other assessments, taxes, contributions or sums payable with respect to Subcontractor/Subawardee or its employees as a result of or in connection with the Services performed by Subcontractor/Subawardee hereunder. Subcontractor/Subawardee represents and warrants and covenants that it shall report all income earned as a result of this Agreement and pay all federal, state and local income and self-employment taxes and other assessments required to be paid under applicable law. Subcontractor/Subawardee agrees to defend, indemnify and hold PHFE harmless from any and all claims made by federal, state and local taxing authorities on account of Subcontractor's/Subawardee's failure to pay any such federal, state or local income and self-employment taxes or other assessments due as a result of Subcontractor's/Subawardee 's Services hereunder.

(g) Sub-Tier Subcontractors/Subawardees. Subcontractor/Subawardee shall have control over the manner and means of Subcontractor/Subawardee's performance under this Agreement. However, PHFE is engaging Subcontractor/Subawardee for Subcontractor's/Subawardee's unique skills, knowledge, abilities and other attributes. Accordingly, Subcontractors/Subawardees may not use any lower-tier subcontractors/subawardees in the performance of its services hereunder without PHFE's prior written approval. Any lower-tier subcontractors/subawardees who are approved by PHFE must execute all agreements and documents required by PHFE prior to performing any work. Subcontractor/Subawardee shall ensure that all lower-tier subcontractors/subawardees comply with all of the terms and provisions of this Agreement and shall be responsible and liable for all acts and omissions of all lower-tier subcontractors/subawardees as if they were the acts or omissions of Subcontractor/Subawardee.

9. ASSIGNMENT OF WORK PRODUCT.

(a) Ownership of Work Product. Subcontractor/Subawardee agrees that, as between PHFE and Subcontractor/Subawardee, all discoveries, ideas, inventions, and information that Subcontractor/Subawardee may develop (either alone or in conjunction with others), information or work product developed wholly or partially by Subcontractor/Subawardee as part of or related to Subcontractor's/subawardee's retention by PHFE hereunder (including all intermediate and partial versions thereof) or the performance of the services hereunder or which existence Subcontractor/Subawardee may discover while retained by PHFE, including any software, platforms, all ideas, designs, marks, logos, and content relating thereto, whether or not subject to patent, copyright or trademark or other intellectual property protections including without limitation, any scripts, prototypes, other components (collectively the "Work Product"), shall be the sole property of PHFE upon its creation and (in the case of copyrightable works) upon its fixation in a tangible medium of expression.

(b) Assignment. Subcontractor/Subawardee hereby forever assigns to PHFE all right, title and interest in any Work Product designed and/or developed by Subcontractor/Subawardee or otherwise delivered to PHFE as part of or related to Subcontractor's/Subawardee's retention with PHFE. The Work Product shall be the sole property of PHFE, and all copyrightable and patentable aspects of the Work Product are to be considered "works made for hire" within the meaning of the Copyright Act of 1976, as amended (the "Act"), of which PHFE is to be the "author" within the meaning of such Act. All such copyrightable and patentable works, as well as all copies of such works in whatever medium fixed or embodied, shall be owned exclusively by PHFE on their creation, and Subcontractor/Subawardee hereby expressly disclaims any interest in any of them. In the event (and to the extent) that any Work Product or any part or element of them, is found as a matter of law not to be a "Work Made For Hire" within the meaning of the Act, Subcontractor/Subawardee hereby assigns to PHFE the sole and exclusive right, title and interest in and to all such works, and all copies of any of them, without further consideration, and, if such assignment is invalid, Subcontractor/Subawardee hereby grants PHFE a non-exclusive, worldwide, perpetual, fully paid-up, irrevocable, right and license to use, reproduce, make, sell, perform and display (publicly or otherwise), and distribute, and modify and otherwise make derivative works of Subcontractor/Subawardee's Work Product and to authorize third parties to perform any or all of the foregoing, including through multiple tiers of sublicenses.

(c) Moral Rights Waiver. For purposes of this subsection, "Moral Rights" means any rights of paternity or integrity, any right to claim authorship of the Work Product, to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, the Work Product, whether or not such would be prejudicial to Subcontractor's/Subawardee's honor or reputation, and any similar right, existing under judicial or statutory law of any country in the world, or under any treaty, regardless whether or not such right is denominated or generally referred to as a "Moral" right. Subcontractor/Subawardee hereby irrevocably transfers and assigns to PHFE any and all Moral Rights that Subcontractor/Subawardee may have in the Work Product. Subcontractor/Subawardee also hereby forever waives and agrees never to assert any and all Moral Rights it may have in the Work Product, even after termination of Subcontractor's/Subawardee's work on behalf of PHFE as part of or related to Subcontractor's/Subawardee's retention with PHFE.

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

(e) Assignment Documents. Subcontractor/Subawardee will cooperate with PHFE, with PHFE's approval and at PHFE's expense, in obtaining patent, copyright, trademark or other statutory protections for the Work Product in each country in which one or more is sold, distributed or licensed, and in taking any enforcement action, including any public or private prosecution, to protect PHFE's intellectual property rights in or to the Work Product. Subcontractor/Subawardee hereby grants PHFE the exclusive right, and appoints PHFE as attorney-in-fact, to execute and prosecute in Subcontractor's/Subawardee's name as author or inventor or in PHFE's name as assignee, any application for registration or recordation of any copyright, trademark, patent or other right in or to the Work Product, and to undertake any enforcement action with respect to any Work Product. With PHFE's approval and at PHFE's expense, Subcontractor/Subawardee will execute such other documents of registration and recordation as may be necessary to perfect in PHFE, or protect, the rights assigned to PHFE hereunder in each country in which PHFE reasonably determines to be prudent.

(f) No Infringement. Subcontractor/Subawardee represents and warrants that any Work Product delivered to PHFE hereunder will be developed by Subcontractor/Subawardee and shall not infringe or violate any patents, copyrights, trademarks, trade secrets or other proprietary rights of any third party.

(g) No Harmful Code. With respect to the website and any computer programs or software code ("Software") included in the Services hereunder, Subcontractor/Subawardee represents and warrants that: (i) the Software and its media shall contain no computer instructions or inappropriate functions whose purpose or result is to disrupt, damage or interfere with PHFE's or its affiliates' or their customers' use of or access to the Software or any of their data, programs or computer or telecommunications facilities and (ii) unless expressly authorized in writing by PHFE, such Software shall not contain any mechanism which electronically notifies Subcontractor/Subawardee of any fact or event, nor contain any key, node lock, time-out, logic bomb or other function, implemented by any means, which may restrict PHFE's or its affiliates' or customers' use of or access to the Software or any other programs, data or equipment.

(h) Rights of Funding Agency and Federal Government. All rights to the Work Product assigned or granted to PHFE hereunder shall be subject to any rights of the Funding Agency under the Funding Award Agreement and any rights of the United States Federal Government under applicable laws and regulations.

10. PUBLICATIONS

(a) Right to Publish Works. Subcontractor/Subawardee may, with PHFE's and the Funding Agency's prior written consent, publish articles written by Subcontractor/Subawardee in connection with the Services performed by Subcontractor/Subawardee hereunder. Subcontractor/Subawardee shall submit all such articles for review by PHFE and the Funding Agency at least 60 days prior to the proposed publication date.

(b) Acknowledgment in Publications. On any publication approved by PHFE and the Funding Agency as described above, Subcontractor/Subawardee shall place an acknowledgment of federal government support, and shall include a disclaimer, as appropriate, as follows: "The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of Public Health Foundation Enterprises, Inc. or [Name of Funding Agency]".

(c) Use of PHFE's or Funding Agency's Name. Subcontractor/Subawardee shall not use in any manner PHFE's name, logo or trademarks without PHFE's prior written consent. Subcontractor/Subawardee shall not use in any manner the Funding Agency's name, logo or trademarks without the Funding Agency's prior written consent.

11. INDEMNIFICATION

(a) By Subcontractor/Subawardee. Subcontractor/Subawardee hereby agrees to indemnify, hold harmless and defend PHFE, its board of trustees, officers, directors, agents, contractors and employees from any and all claims, causes of action, costs, demands, expenses (including attorney's fees and costs), losses, damages, injuries, and liabilities arising from (i) any accident, death, or injury whatsoever or however caused to any person or property arising out of the intentional action or negligence of Subcontractor/Subawardee (or its agents, subcontractors or employees), (ii) Subcontractor's/Subawardee's (or its agents', subcontractors' or employees') violation of any federal, state or local law or regulation, (iii) the breach by Subcontractor/Subawardee (or its agents, subcontractors or employees) of any its representations, warranties or agreements under this Agreement or (iv) any claims that the Work Product, or any element thereof, infringes the intellectual, privacy or other rights of any party.

(b) By PHFE. PHFE hereby agrees to indemnify, hold harmless and defend Subcontractor/Subawardee, its officers, directors, agents, contractors and employees from any and all claims, causes of action, costs, demands, expenses (including attorney's fees and costs), losses, damages, injuries, and liabilities arising from (i) any accident, death, or injury whatsoever or however caused to any person or property arising out of the intentional action or negligence of PHFE, (ii) PHFE's violation of any federal, state or local law or regulation or (iii) the breach by PHFE of any its representations, warranties or agreements under this Agreement.

12. INSURANCE

(a) Required Coverages. Subcontractor/Subawardee shall, unless otherwise agreed in writing by PHFE, maintain: (i) Workers' Compensation insurance, (ii) Professional Liability Insurance and Commercial General Liability Insurance (including broad form contractual and automobile liability coverage), with minimum limits of ONE MILLION DOLLARS (\$1,000,000) combined single limit per occurrence, and (iii) Automobile Liability on each automobile owned by him/her/it or his/her/its agents, subcontractors/subawardees or employees, which is used at any time to carry out Subcontractor's/Subawardee's duties hereunder, with minimum limits of \$100,000 per person

and \$300,000 per occurrence for bodily injury. If higher or additional coverages are required under the Flow Down Provisions, Subcontractor/Subawardee shall procure such coverages.

(b) Additional Insureds. All such insurance shall provide that Subcontractor's/Subawardee's insurance is primary and not contributory, shall protect Subcontractor/Subawardee, PHFE and the Funding Agency and their affiliates from claims for personal injury (including bodily injury and death) and property damage which may arise from or in connection with the performance of the Services hereunder, or from or out of any negligent act or omission of Subcontractor/Subawardee, its officers, directors, agents or employees. All such insurance shall be written by a responsible insurance company possessing B+ VII rating or better as listed in the Best Guide, shall name PHFE and the Funding Agency as additional insureds for Professional Liability, Commercial General Liability and Automobile Liability only, shall contain a waiver of subrogation with respect to the additional insureds, shall be written on an occurrence basis and shall provide that the coverage thereunder may not be reduced or canceled unless 30 days' prior written notice thereof is furnished to PHFE and the Funding Agency. Certificates of Insurance containing such waiver of subrogation or copies of policies shall be furnished to PHFE upon request.

13. CONFIDENTIALITY

(a) Confidential Information. Subcontractor/Subawardee agrees that during the course of this Agreement, Subcontractor/Subawardee may be exposed to and become aware of certain unique and confidential information and special knowledge (hereinafter "Confidential Information") provided to or developed by PHFE. Said Confidential Information includes, but is not limited to, the identity of actual and potential clients of PHFE, client lists, particular needs of each client, the manner in which business is conducted with each client, addresses, telephone numbers, and specific characteristics of clients; financial information about PHFE and/or its clients; client information reports; mailing labels; various sales and marketing information; sales report forms; pricing information (such as price lists, quotation guides, previous or outstanding quotations, or billing information); pending projects or proposals; business plans and projections, including new product, facility or expansion plans; employee salaries; contracts and wage information; mailing plans and programs; technical know-how; designs; products ordered; business methods; processes; records; specifications; computer programs; accounting; and information disclosed to PHFE by any third party which PHFE is obligated to treat as confidential and/or proprietary. This Confidential Information derives independent actual or potential economic value from not being generally known to the public or to other persons, who can obtain economic value from its disclosure or use, is not readily available through any source other than PHFE and is the subject of reasonable efforts to maintain secrecy. Since Subcontractor/Subawardee may be exposed to and become aware of said Confidential Information and, because of its unique and confidential nature, the parties hereto desire to afford PHFE protection against its unauthorized use or its use in any manner detrimental to PHFE. Therefore, Subcontractor/Subawardee shall not disclose in any manner whatsoever any of the aforesaid Confidential Information, directly or indirectly, or use it in any way whatsoever, either during this Agreement or at any time thereafter, except as required in the course of Subcontractor's/Subawardee's work with PHFE or except as otherwise provided in this Agreement. Further, Subcontractor/Subawardee shall develop and maintain procedures and

take other reasonable steps in furtherance of PHFE's desire to maintain the confidentiality of its Confidential Information.

(b) Funding Agency Confidentiality. Subcontractor/Subawardee shall also comply with all confidentiality obligations imposed by the Funding Agency in the Funding Award Agreement or otherwise.

(c) Return of Documents. All documents and other items which might be deemed the subject of or related to Confidential Information of PHFE's business, whether prepared, conceived, originated, discovered, or developed by Subcontractor/Subawardee, in whole or in part, or otherwise coming into Subcontractor's/Subawardee 's possession, shall remain the exclusive property of PHFE and shall not be copied or removed from the premises of PHFE without the express written consent of PHFE. All such items, and any copies thereof, shall be immediately returned to PHFE by Subcontractor/Subawardee upon request at any time and upon termination of this Agreement.

14. NON-SOLICITATION OF EMPLOYEES

During the Term of this Agreement and for two years following the termination of this Agreement, Subcontractor/Subawardee shall not induce, encourage, or advise any person who is employed by or is engaged as an agent or independent contractor by PHFE to leave the employment or engagement of PHFE or otherwise raid the employees of PHFE. Nothing contained in this paragraph shall constitute a waiver by PHFE of any rights it may have if Subcontractor/Subawardee engages in actionable conduct after the two year period referred to above.

15. RECORD RETENTION AND ACCESS TO RECORDS

Subcontractor/Subawardee shall grant to PHFE, the Funding Agency and the U.S. Comptroller General and their respective authorized representatives upon demand, access to any books, documents, papers and records of Subcontractor/Subawardee relating to this Agreement or the Services for audit, examination, excerpt and transcription. Subcontractor/Subawardee shall retain all such records for seven (7) years (or longer if required under PHFE's record retention policy, under the Funding Award Agreement or by law, including under Circular A-110, Subpart C, Post-Award Requirements and FAR Subpart 4.7 Contractor Records Retention - 4.703 Policy) after final payment is made under this Agreement and all pending matters are closed, unless extended by an audit, litigation, or other action involving the records, whichever is later.

16. GENERAL TERMS

(a) Amendments. Amendments to this Agreement shall be in writing, signed by the party to be obligated by such amendment and attached to this Agreement.

(b) Governing Law; Venue. This Agreement is entered into in Los Angeles County, California. This Agreement shall be interpreted, construed and governed by, in accordance with

and consistent with the laws of the State of California without giving effect to its conflicts of laws principals. Such laws shall apply in all respects, including statutes of limitation, to any disputes or controversies arising out of or pertaining to this Agreement. The sole, exclusive and proper venue for any proceedings brought to interpret or enforce this Agreement or to obtain a declaration of the rights of the parties hereunder shall be Los Angeles County, California. Each of the parties hereto submits to the exclusive personal jurisdiction of the courts located in Los Angeles County, California and waives any defense of forum non conveniens.

(c) Equitable Relief. In light of the irreparable harm to PHFE that a breach by Subcontractor/Subawardee of Sections 9, 10, 13 and 14 of this Agreement would cause, in addition to other remedies set forth in this Agreement and other relief for violations of this Agreement, PHFE shall be entitled to enjoin Subcontractor/Subawardee from any breach or threatened breach of such Sections, to the extent permitted by law and without bond.

(d) Binding Agreement. All terms, conditions and covenants to be observed and performed by the parties hereto shall be applicable to and binding upon their respective agents, employees, heirs, executors, administrators, affiliates, subsidiaries, associates, employees, successors and assigns.

(e) Captions. All captions (section headings) set forth herein are inserted only as a matter of convenience and for reference, and shall not affect the interpretation of this Agreement.

(f) Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which, when taken together, shall constitute one and the same document.

(g) Additional Documents. The parties hereto each agree that they shall execute and, if appropriate, acknowledge any and all additional and other documents, instruments and writings which may be reasonably requested by the other party in order to fully carry out the intent and purpose of this Agreement.

(h) Attorneys' Fees; Costs. In the event that any suit in law or equity, arbitration or other formal proceeding is instituted by any party to enforce or interpret any part of this Agreement, or to recover damages for breach thereof, the prevailing party shall, in addition to any such other relief available to such party, be entitled to recover costs of suit incurred therein, and to also recover as an element of such costs (but not as damages) reasonable attorneys' fees incurred by such prevailing party.

(i) Entire Agreement. This Agreement, and all documents referred to in it, or incorporated in it, is an integrated document containing and expressing all terms, covenants, conditions, warranties and agreements of the parties relating to the subject matter hereof. No other or prior agreements or understandings, written or oral, pertaining to the same shall be valid or of any force or effect.

(j) Facsimile or Email Transmissions. A facsimile transmission or transmission by Email of the executed signature page of this Agreement shall be accepted as, relied upon as, and deemed to be, an original.

(k) Fair Interpretation. The language appearing in all parts of this Agreement shall be construed, in all cases, according to its fair meaning in the English language, and not strictly construed for or against any party hereto. This Agreement has been prepared jointly by the parties hereto after arms length negotiations and any uncertainty or ambiguity contained in this Agreement, if any, shall not be interpreted or construed against any party, but according to its fair meaning applying the applicable rules of interpretation and construction of contracts.

(l) No Waiver. No failure or delay by any party in exercising a right, power or remedy under the Agreement shall operate as a waiver of any such right or other right, power or remedy. No waiver of, or acquiescence in, any breach or default of any one or more of the terms, provisions or conditions contained in this Agreement shall be deemed to imply or constitute a waiver of any other or succeeding or repeated breach or default hereunder. The consent or approval by any party hereto to or of any act of the other party hereto requiring further consent or approval shall not be deemed to waive or render unnecessary any consent or approval to or of any subsequent similar acts.

(m) Notices. Any notice, demand, consent or other communication required or permitted to be given hereunder shall be made in the English language and shall be so given by personal delivery, by (i) registered or certified (return receipt) or First Class United States Postal Service mail, postage pre-paid, or (ii) recognized overnight national courier service, or (iii) facsimile transmission confirmed by letter sent by First Class United States Postal Service mail, postage pre-paid, or (iv) by email confirmed by letter sent by First Class United States Postal Service mail, postage pre-paid, addressed to the recipient of such notice at the following address or facsimile number, as the case may be, or any other address or facsimile number or email address provided by a party in the manner described hereinabove:

In the case of PHFE, addressed to:

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

Attention: Peter Dale, Director Contracts and
Grants

Facsimile: 562.692.6950

Email: PHFEContracts@phfe.org

In the case of Subcontractor, addressed to:

San Francisco Department of Public Health

25 Van Ness Avenue, Suite 500

San Francisco, CA 94102

Attention: Lorna Garrido

Facsimile: none

Email: Lorna.garrido@sfdph.org

Any such notice shall be deemed to have been received by the addressee, and service thereof shall be deemed effective, five (5) days following deposit thereof with the United States Postal Service, or upon actual receipt, whichever first occurs, unless the address for delivery is not within one of the United States or its territories or possessions, in which case service shall be effective seven (7) days following deposit, or upon actual receipt, whichever first occurs.

(n) Remedies Non-Exclusive. Except where otherwise expressly set forth herein, all remedies provided by this Agreement shall be deemed to be cumulative and additional and not in lieu of or exclusive of each other or of any other remedy available to the respective parties at law or in equity.

(o) Severability. If any term, provision, condition or other portion of this Agreement is determined to be invalid, void or unenforceable by a forum of competent jurisdiction, the same shall not affect any other term, provision, condition or other portion hereof, and the remainder of this Agreement shall remain in full force and effect, as if such invalid, void or unenforceable term, provision, condition or other portion of this Agreement did not appear herein.

(p) Limitation of Liability. Except for a breach of sections 9 and 13 above and except to the extent included in a party's indemnification obligations under Section 11 above, in no event shall any party be liable to the other for any indirect, special, incidental, punitive or consequential damages, whether based on breach of contract, tort (including negligence), or otherwise, and whether or not that party has been advised of the possibility of such damage.

(q) Non-Assignability. None of the parties shall assign, transfer, sell, encumber, hypothecate, alienate or otherwise dispose of this Agreement, or any right, title or interest to or in this Agreement, nor shall a party delegate any duty or obligation to be performed hereunder, without the express written consent of the other party having been first obtained, except that any party may assign this Agreement without the consent of the other party in the case of a reorganization, merger, consolidation, or sale of all or substantially all of its assets so long as the assignee expressly assumes all of the obligations of the assignor under this Agreement. Notwithstanding the foregoing, PHFE may assign this Agreement to an affiliate of PHFE without the

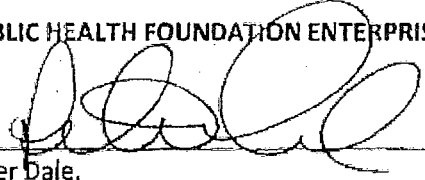
consent of the other party. Any attempt to assign this Agreement other than as permitted above shall be null and void.

(r) Signing Person. The individuals signing this Agreement on behalf of an entity represents and warrants that he/she has authority to bind such entity to this Agreement.

[Signatures follow on next page]

The undersigned have caused this Subcontract/Subaward Agreement to be executed as of the date first set forth above:

PUBLIC HEALTH FOUNDATION ENTERPRISES, INC.


By: 
Peter Dale,
Director, Contracts and Grants

10/29/16
Date

SUBCONTRACTOR/SUBAWARDEE

Name: Tomás J. Aragón,
MD, DPH

10/20/16
Date

Signature: 
Print Name, Title [If any entity]

**EXHIBIT A
TO SUBCONTRACT/SUBAWARD AGREEMENT**

Scope of Work (SOW)

Attached



ELC Project K8

Threat of Antibiotic-Resistant Gonorrhea: Rapid Detection and Response Capacity

Navigation

Click the name of a section below while holding the control key to jump to specific sections of this document.

Awardee Jurisdiction

Strategy 1

Strategy 2

Strategy 3

Evaluation and Performance Measurement Strategy

Guidance

The following work plan will outline the awardee's plans, milestones, and expected outcomes related to the project described in attachment Antibiotic-Resistant Gonorrhea of the ELC 2016 Application. Please review this guidance prior to completing this application.

If there are any questions or concerns while completing this application, please contact the ELC or Program POC to address and resolve the issue.

When completing the form, it is important to note that this is a locked document and only specific form fields and sections are editable. Please do not attempt to edit or alter sections of the form that are not available for edit as it could delay and hinder the ability to review the application.

Spell Check: You can run a spelling check by clicking the button below.

Spell Check

Track Changes: You may use track changes with this document by clicking the buttons below.

Turn Track Changes On/Off

Accept All Changes

Document ID: ELC-2016-Antibiotic-Resistant Gonorrhea 1111111111

Awardee Jurisdiction

Please select your Awardee jurisdiction.

States: Alabama through
Mississippi (Alphabetical)

California

States: Missouri through West
Virginia (Alphabetical)

Select One

Wisconsin, Wyoming and Non-
State Applicants (By Type)

Select One

Project Approach

Problem Statement

In completing this section, reference the component projects 'Problem Statement' within the funding opportunity guidance and articulate its applicability and special considerations to the applicant jurisdiction. *Please limit the response to this section to half a page - This section is unrestricted to allow entry of additional materials beyond text (including graphics, pictures, etc.) as necessary.*

In 2013, CDC identified antibiotic-resistant *Neisseria gonorrhoeae* (ARG) as an urgent public health threat requiring significant resources to detect and prevent cases in the United States. California (CA) and San Francisco (SF) are areas of particular concern. In 2014, CA had the most gonorrhea (GC) cases of any state. In 2015, there were 54,307 GC cases, and from 2011 to 2015 male cases ages 15-44 increased 113% and female cases ages 15-44 increased 67%. Furthermore, SF has the highest GC case rate in CA; in 2015, 4266 reported cases represented a 30% increase from 2014. In 2013, the SF case rate was 313.2/100,000, which exceeded the case rate for the Los Angeles metropolitan statistical area (MSA), the New York MSA, the state of CA, and the United States (US) as a whole. Prevention and control of GC are key responsibilities of state and local sexually transmitted disease (STD) programs and rely on timely and effective antibiotic treatment. However, GC has repeatedly developed resistance to antimicrobials including sulfonamides, penicillin, tetracyclines, and fluoroquinolones. Data from the CDC Gonococcal Isolate Surveillance Project (GISP) have shown that decreased antibiotic susceptibility to cephalosporins, the current mainstay of GC treatment, is more likely to be detected in specimens from the Western US compared to other US regions, and from men who have sex with men (MSM) compared to men who have sex with women (MSW). With large populations of MSM and high rates of GC, CA and SF are critical jurisdictions to implement effective surveillance and control of ARG.



**Epidemiology and Laboratory Capacity (ELC) –Building and Strengthening
Epidemiology, Laboratory and Health Information Systems Capacity 2016**

Purpose

Describe in 2-3 sentences specifically how the application will address the project’s problem as described in the component project’s ‘Problem Statement.’

Given California’s increased epidemiologic risk for ARG, both the San Francisco Department of Public Health (SFDPH) and California Department of Public Health (CDPH) have established efforts to prepare for and respond to this public health threat. Our proposed California-San Francisco Rapid Detection and Response Project (CA-SF GC RDR) will support, expand, and accelerate efforts to combat ARG in San Francisco, by 1) developing and implementing protocols for rapid identification and response to ARG cases, 2) expanding surveillance to additional clinic sites, populations including females and youth, and anatomic sites of infection, and 3) collaborating throughout the surrounding Bay Area region to provide comprehensive rapid response to ARG cases. Rigorous data collection and evaluation of novel methods for GC surveillance, laboratory testing, and case investigation will inform preparedness for rapid ARG detection and response throughout California.

Applicant Capacity

The below table provides some specific questions regarding gonorrhea morbidity and Public Health Lab capacity. Following the table is a free-response section for you to provide more information about your capacity.

Selection of a Local Health Jurisdiction	
If your organization is <u>not</u> a local health department, name the local health jurisdiction with whom you plan to partner to implement programmatic activities:	San Francisco Department of Public Health
Does the jurisdiction currently receive and electronically/automatically processes electronic lab reports (ELR)?	Yes, at state and local levels
Presence of a Categorical STD Clinic (a clinic whose primary mission is to provide diagnosis, treatment, counseling, and sex partner notification for STDs.)	
Provide the name(s) and location(s) of categorical STD clinics that serve the selected jurisdiction. If you will perform activities in only a select number of STD clinics, please denote the selected clinics:	San Francisco City Clinic 356 7 th Street San Francisco, CA 94103
Does/do the categorical STD clinic(s) that you proposed to work with utilize electronic medical records (EMR)?	Yes, All
If only some of the categorical STD clinics that you	

propose to work with utilize EMR, please indicate which clinics use EMR and which do not:	
Gonorrhea Morbidity	
How many cases of gonorrhea (GC) were reported in 2015 in the selected local jurisdiction?	<p>Female: 372</p> <p>Male (Overall): 3829</p> <p>-- Male (Men who have sex with men): 3067</p> <p>-- Male (Men who have sex with women only): 140</p> <p>Non-Hispanic White: 1887</p> <p>Non-Hispanic Black: 387</p> <p>Hispanic: 631</p> <p>Other races: 1352</p>
How many cases of GC were reported in 2015 from the categorical STD clinic(s) where you plan to implement activities? <i>Note: This program requires that at least one categorical STD clinic must diagnose at least 200 GC cases per year.</i>	<p>Number: 790</p> <p>Proportion of total GC cases reported in the selected jurisdiction diagnosed by the categorical clinic(s): 18.50%</p>
How many cases of GC from the selected local jurisdiction were cultured and tested for antibiotic susceptibility in 2015?	<p>Number: 273</p> <p>Proportion of total GC cases reported in the selected jurisdiction (i.e., not limited to the categorical clinics above): 6.40%</p>
Laboratory Capacity	
Please provide the name and location of the state/local public health laboratory that will be performing antibiotic susceptibility testing for the project	<p>Name: San Francisco Public Health Laboratory</p> <p>Location: 101 Grove Street, Room 419</p> <p>San Francisco, CA 94102</p>
Does the selected public health lab currently culture GC specimens for antibiotic susceptibility testing or diagnostic purposes?	Yes
If the selected public health lab currently cultures GC, please provide information on how many specimens the lab cultured and tested for antibiotic susceptibility in 2015 by test type.	<p>Agar dilution:</p> <p>Disc diffusion:</p> <p>E-testing: 73</p>

<p>If the selected public health lab currently cultures GC, please provide information on the mean time and range (in days) between specimen collection and the results being returned to the provider.</p>	<p>Other:</p> <p>Mean time (days): 3</p> <p>Range (high side, in days): 15</p> <p>Range (low side, in days): 1</p>
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Address the jurisdiction's current capacity to successfully implement the proposed strategies and activities (including describing staff and other infrastructure already in place that you will build upon) to meet project period outcomes. *Please limit the response to this section to 1 page - This section is unrestricted to allow entry of additional materials beyond text (including graphics, pictures, etc.) as necessary.*

The SF Department of Public Health (SFDPH) Population Health Division (PHD) is a longtime leader in STD prevention, and contains the premier categorical STD clinic in CA, San Francisco City Clinic (SFCC). SFCC has been a CDC GISP site for 30 years; for the first half of 2015, 203 cases of gonococcal urethritis were diagnosed at SFCC, 126 of which were submitted to the regional GISP laboratory via SFDPH Public Health Laboratory (PHL), itself a state-of-the-art microbiology laboratory with demonstrated excellence in both standard and innovative GC testing, including being among the first to utilize GC NAAT. Sequence analysis of SFCC GC specimens at PHL in 2008 demonstrated the presence of two previously undescribed penA alleles associated with elevated cephalosporin MICs. PHL implemented Etest in 2011 to provide susceptibility data 2-3 weeks before GISP results were available on specimens from four public health clinics across CA (including SFCC). Susceptibility data from PHL and GISP are stored in the SFDPH STD data system (ISCHTR - Integrated Surveillance and Clinical Health Tracking Registry), a robust data management system that enables timely analyses for continuous quality improvement.

The California Department of Public Health (CDPH) STD Control Branch (STDCB) coordinates STD prevention and control across CA and is creating an advanced data management system to track California GISP isolates and any suspected GC treatment failures or ARG cases. STDCB has worked with LHJs to not only respond to GC outbreaks, treatment failures and ARG but also to conduct many successful enhanced GC projects, including Etest and an evaluation of an alternative GC culture medium (InTray GC) with SFDPH, a test of cure study with San Mateo, a collaboration with San Luis Obispo to evaluate a cluster of disseminated gonococcal infections, and partner services for patients with GISP alerts (through which, in 2015, SFDPH interviewed 12 of 14 patients with reduced susceptibility). Additionally, CA and SF collaborated to analyze partner services data from SF and neighboring Bay Area counties, which revealed that 41% of sexual partnerships in a large network of early syphilis cases in the SF-Bay Area region were between persons who resided in different counties, reinforcing the importance of collaborative disease control efforts. In late 2015, STDCB began working

closely with the CDPH Microbial Diseases Laboratory Branch (MDL) to build capacity for GC culture and antimicrobial susceptibility testing (AST). MDL is available to perform whole genome sequencing and provide subject matter expertise on molecular diagnostics. Both CDPH and SFDPH receive funding for the STD Surveillance Network (SSuN) to conduct enhanced population-based GC surveillance.

The CA-SF GC RDR leadership team has extensive STD experience. **Dr. Susan Philip, MD, MPH**, the SFDPH PHD Disease Prevention and Control (DPC) Branch Director, and STD Controller for SF, will serve as the SF Principal Investigator for this project. She has over 13 years of experience in STD and HIV clinical care, epidemiology, research and evaluation. Key units in DPC include SFCC, PHL, and all SFDPH DIS staff. **Dr. Trang Nguyen, PhD, MPH** is a senior epidemiologist with extensive knowledge of the STD surveillance and program activities. She will work closely with the CA-SF GC RDR staff to meet objectives, assisting them in engaging all key stakeholders and staff to develop and implement the evaluations. **Dr. Mark W. Pandori, PhD, HCLD(ABB)** is the interim Director for PHL. He is a national expert in public health laboratory methods for GC and other STDs, and led many of the PHL innovations in GC testing described above. **Dr. Heidi Bauer, MD, MS, MPH** is the Chief of the CDPH STDCB and will serve as the CDPH Principal Investigator for this project; she has over 15 years of experience in STD prevention program development, epidemiology, research, and evaluation. **Dr. Juliet Stoltey, MD, MPH** is Chief of the Office of Science and Policy and the Public Health Medical Officer of CDPH STDCB; she has expertise in infectious diseases and STDs, 6 years of experience in STD and HIV clinical care, serves as the lead for ARG efforts at STDCB, and will work closely with the CA-SF GC RDR staff to meet objectives. **Dr. Vishnu Chaturvedi, PhD** is a board-certified laboratory director for MDL and recognized academic scientist, educator, editor and subject matter expert with an eighteen-year track record in managing people and processes that ensure the highest quality public health laboratory operations.





Strategy 1

Strategy: Strengthen local resistant GC threat coordination and epidemiological capacity

Add New Activity

Strategy 1: New Activity #1

Name (500 Character Maximum):

Designate an epidemiologist coordinator responsible for local resistant GC activities

Implementation Plan (1000 Character Maximum):

The San Francisco Department of Public Health (SFDPH) will define a scope of work and hire a GC Epidemiologist Coordinator (EC). This coordinator will be the primary person responsible for the activities of the CA-SF GC RDR in San Francisco. Additionally, CDPH will hire a Regional GC RDR Coordinator (RDRC). Named partners of SF cases come from both inside and outside SF and historically STD outbreaks in CA have involved multiple independent jurisdictions. Thus, a regional effort is necessary for both capacity building and surveillance to facilitate inter-jurisdictional coordination, data-sharing, and partner follow-up to provide a comprehensive public health infrastructure and capacity for detection and response, and to better characterize sexual transmission networks. This position will provide overall epidemiologic support and coordination with SFDPH and other regional and statewide partners.

2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1 Hire SFDPH GC Epidemiology Coordinator	Susan Philip and Trang Nguyen	Aug 2016	Nov 2016
2 Hire CDPH Regional GC RDR Coordinator	Heidi Bauer and Julie Stoltey	Aug 2016	Nov 2016
3		Select One	Select One

Strategy 1: New Activity #2

Name (500 Character Maximum):

Develop flow charts and definitions detailing case reporting, laboratory testing, and epidemiologic investigation and analysis

Implementation Plan (1000 Character Maximum):

The SFDPH GC EC will identify protocols, data systems, and staff associated with GC case reporting, laboratory testing, and epidemiologic investigation and analysis to develop a plan to meet project deliverables. The GC EC will work with key staff to develop the timeline for expanded GC culture and AST to include female and extragenital specimens of SFCC patients, and from the 3rd Street Youth Center and Clinic (a high volume youth clinic primarily serving African Americans in the highest adolescent STD prevalence area). The CDPH Regional GC RDRC will work closely with the SFDPH GC EC

to develop updated workflows that: link to regional GC efforts; facilitate data sharing on partners and for regional and state epidemiologic analyses; and ensure collaboration with other CA GC partners (e.g., Los Angeles). CDPH and SFDPH will conduct a SF-Bay Area meeting with key local health jurisdiction partners to develop an ARG Regional Strategic Plan that includes best practices for ARG response.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Catalog of existing and newly developed case surveillance, epidemiology, and laboratory protocols with flow charts and definitions	Trang Nguyen until SFDPH GC Epidemiologist Coordinator hired	Sep 2016	Jul 2017
2	CA-SF GC RDR strategic plan for expansion of GC specimen collection and AST beyond SFCC GISP specimens	SFDPH GC Epidemiologist Coordinator	Oct 2016	Jul 2017
3	SF-Bay Area ARG Regional Strategic Plan	CDPH Regional GC RDR Coordinator	Oct 2016	May 2017

Strategy 1: New Activity #3

Name (500 Character Maximum):

Hire needed staff (such as surveillance and field epidemiologists, laboratorians, case investigators, and data entry personnel) to support local coordination and capacity

Implementation Plan (1000 Character Maximum):

SFDPH will additionally hire CA-SF GC RDR: microbiologist responsible for GC culture and AST, developing protocols including expanded culture and testing of new specimen sources and from new media (e.g., InTray from 3rd Street Youth Center and Clinic (YCC)); and 2 health workers to conduct partner services (PS) (one at SFCC, one embedded at 3rd St YCC to develop, implement, and evaluate PS protocols for youth). CDPH will additionally hire CA-SF GC RDR: regional health worker responsible for case investigation and partner follow-up of GC cases with reduced susceptibility outside SF, training and technical assistance to LHJs for investigations on ARG GC cases; and microbiologist to perform AST of GC isolates, communicate results to staff and LHJs, and initiate and coordinate the collection and storage of a repository of ARG isolates. CDPH/SFDPH will develop training protocols and evaluation methods.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Post and hire SFDPH positions	Susan Philip and Trang Nguyen	Aug 2016	Feb 2017
2	Post and hire CDPH positions	Heidi Bauer and Julie	Aug 2016	Feb 2017

	Stoltey		
3 CA-SF GC RDR staff training protocols and evaluation plans	SFDPH GC Epidemiologist Coordinator and CDPH Regional GC RDR Coordinator	Nov 2016	Feb 2017

Strategy 1: New Activity #4

Name (500 Character Maximum):

Advance workforce development and training related to rapid response for resistant GC (optional)

Implementation Plan (1000 Character Maximum):

SFDPH and CDPH staff with a role in ARG detection and response must be proficient in continuous quality improvement methods and standardized, applied problem solving. These skills are fundamental to every proposed ARG response activity and will increase SFDPH and CDPH workforce capacity for innovation by teaching standardized problem solving and evaluation to improve efficiency. CA-SF RDR hired and in-kind staff, as well as select SFDPH and CDPH clinicians, laboratorians, and health workers with roles in ARG detection and response, will undergo training on A3 Thinking to learn a common 'language' of problem solving. This method has already been taught at the SFDPH clinics and hospitals that will be partners in expanded GC culture efforts – proving further usefulness of ensuring this standard. Also, the CA STD/HIV Prevention Training Center (CAPTC), DIS Training Center (DISTC) will develop training materials for DIS on rapid response case investigation and partner services of ARG cases.

2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1 Final A3 Thinking training schedule, contract, and staff attendee list	Susan Philip with Heidi Bauer	Aug 2016	Jul 2017
2 Identify CDPH or SFDPH staff to attend national STD and microbiology conferences for workforce development	Heidi Bauer and Susan Phillip	Aug 2016	Mar 2017
3 Training materials on rapid response case investigations and field services of ARG cases	CDPH Regional GC RDR Coordinator and CAPTC-DISTC	Oct 2016	Jul 2017

Strategy 2

Strategy: Enhance timely surveillance for detection of resistant GC threats

Strategy 2: New Activity #1

Name (500 Character Maximum):

Establish local lab capacity and protocols for implementing e-test for timely antibiotic susceptibility testing

Implementation Plan (1000 Character Maximum):

In collaboration with the SFDPH GC EC, the SFDPH interim PHL Director Dr. Mark Pandori will work with the newly hired CA-SF GC RDR Microbiologist to update existing protocols for Etest for timely antibiotic susceptibility testing and protocols for providing results to clinicians in short time frames. PHL implemented Etest in 2011 and recently tested approximately 70 isolates per month for all CA GISP sites, but results have not yet been used to inform patient care. Again, the models of change and evaluation the lab staff, epidemiologists and DIS will be trained in will guide how this effort will be designed and evaluated. The CDPH MDL will continue to build capacity to conduct GC culture and AST with Etest. MDL will provide subject matter expertise and serve as a back-up and reference laboratory for additional testing of isolates from SFDPH. MDL will also maintain stock and surveillance cultures of notable ARG isolates for any future testing.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Catalog of existing and necessary protocols for Etest at PHL of SFCC GISP samples	Mark Pandori until SFDPH Microbiologist hired	Aug 2016	Oct 2016
2	Validated GC culture and Etest at CDPH MDL laboratory	Vishnu Chaturvedi until CDPH Microbiologist is hired	Aug 2016	Dec 2016
3	Number of antibiotic-resistant gonorrhea isolates archived at MDL	Vishnu Chaturvedi until CDPH Microbiologist is hired	Aug 2016	Jul 2017

Strategy 2: New Activity #2

Name (500 Character Maximum):

Develop processes for rapid communication of e-test results to surveillance and field epidemiology staff

Implementation Plan (1000 Character Maximum):

Importation of PHL results, including susceptibility data, into ISCHTR occurs routinely. Using the proposed training in standardized, applied problem solving, these processes will be automated and alerts developed to ensure timely use of critical Etest results for action (e.g., case investigation, verification of treatment to evaluate potential treatment failures). In collaboration with the CDPH Regional GC RDRC, the SFDPH GC EC will work with related SFDPH PHL, SFCC, epidemiology staff, and

CDPH staff to develop protocols and templates for rapid reporting of Etest results to appropriate SF and CA health workers and providers. The CDPH Regional GC RDRC will coordinate discussions to facilitate interoperability across SFDPH and CDPH IT systems to ensure seamless state and local data exchange and will work to operationalize real-time data transfer between CDPH MDL information systems and the existing CDPH ARG database.

2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1 Catalog of protocols and templates for rapid reporting of Etest results to SFDPH health workers and local providers	SFDPH GC Epidemiologist Coordinator	Oct 2016	Jul 2017
2 Catalog of protocols and templates for communication of Etest results to CDPH regional health worker and regional providers	CDPH Regional GC RDR Coordinator	Oct 2016	Jul 2017
3 Average turn-around-time for the collection and rapid reporting of ARG data fields from CDPH MDL laboratory information system to CDPH ARG database	CDPH Regional GC RDR Coordinator	Dec 2016	Jul 2017

Strategy 2: New Activity #3

Name (500 Character Maximum):

Increase and improve timeliness of reporting and complete capture of data relevant to antibiotic-resistant GC surveillance and epidemiology in electronic surveillance systems. These may include: treatment date and regimen, anatomic site of infection, gender of sexual partners

Implementation Plan (1000 Character Maximum):

The SFDPH GC EC, in collaboration with the CDPH Regional GC RDRC, will finalize a list of key variables (e.g., treatment date and regimen, anatomic site of infection) to assess and prioritize projects to improve reporting timeliness and completeness, including the evaluation of sending electronic patient and laboratory data messages from providers such as the SFDPH outpatient clinics for importation to ISCHTR. The CDPH Regional GC RDRC will work within CDPH to facilitate SF providers' use of the California integrated communicable disease surveillance system, CalREDIE provider portal for rapid reporting and retrieval of GC treatment, and other relevant clinical data; evaluate a mechanism for rapid data exchange between CalREDIE and ISCHTR, including susceptibility data from PHL and MDL, and case/partner data for PS outside SF; and work to improve completeness of electronic laboratory reporting. This activity is linked to meeting requirements for Strategy 2: Activity #8.

2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
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- | | | | | |
|---|--|--|------------|------------|
| 1 | List of key variables for ARG surveillance and epidemiology; timeline for evaluating and finalizing mechanisms to improve data completeness and timeliness | SFDPH GC Epidemiologist Coordinator with IT consultant | Sep 2016 | Jul 2017 |
| 2 | Determine the interoperability between SFDPH and CDPH electronic data systems to facilitate real-time sharing of relevant clinical data fields (i.e., treatment date and regimen, anatomic site of infection, gender of sexual partners) | CDPH Regional GC RDR Coordinator | Oct 2016 | Jul 2017 |
| 3 | | | Select One | Select One |

Strategy 2: New Activity #4

Name (500 Character Maximum):

Establish a plan for expanded collection of GC culture and performance of GC antibiotic susceptibility testing (e.g., collection of specimens from clinical sites outside of the STD clinic, collection of culture from female GC cases, collection of culture from extragenital sites of GC cases)

Implementation Plan (1000 Character Maximum):

The SFDPH GC EC will collaborate with the CDPH Regional GC RDRC to create a timeline and protocols for collecting additional specimens at SFCC from females and extragenital sites (males and females) and at the 3rd Street YCC (with InTray) to attempt to isolate cultures and conduct Etests. During Year 1, SFDPH will increase the number of non-GISP specimens to culture from SFCC and 3rd St YCC, eventually trying to successfully culture isolates from an additional estimated 200 urethral, 50 cervical, 100 pharyngeal, and 100 rectal specimens, based on likely eligible patients using 2015 clinic data. Also, SFDPH will develop mechanisms to identify potential treatment failures and providers to target for expanded GC culture. Analyzing case report data might identify providers who should routinely collect cultures at the original and follow-up GC tests. CDPH MDL will provide GC culture and AST for Bay Area partners named by SF cases.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Number of GC culture and Etest of non-GISP specimens from SFCC and 3rd St YCC	SFDPH GC Epidemiologist Coordinator	Nov 2016	Mar 2017
2	Catalog of protocols for Etest at PHL of SFCC and 3rd St YCC non-GISP specimens	Mark Pandori until SFDPH Microbiologist hired	Jan 2017	Jul 2017
3	Number of GC culture and Etest specimens tested from populations outside SF boundaries	Vishnu Chaturvedi until CDPH Microbiologist is hired	Jan 2017	Jul 2017

Strategy 2: New Activity #5

Name (500 Character Maximum):

Pilot novel approaches to detect resistance in non-STD clinic settings, including but not limited to public health detailing to distribute culture media plates (InTray GC™) to high-volume providers that do not routinely perform culture-based testing due to lab capacity issues.

Implementation Plan (1000 Character Maximum):

CDPH led an evaluation of InTray GC to culture male urethral specimens at SFCC and found that the InTray GC system was 87.5% sensitive for GC culture. SFDPH will collect specimens using InTray GC at the 3rd St YCC, benefitting from lessons learned to create protocols and an evaluation plan. Symptomatic female youth will be initially prioritized for culture; in 2015, 71 GC tests were conducted among symptomatic females ages <=25 (24 GC tests among symptomatic male youth). CA-SF GC RDR staff will analyze the yield of culture by InTray and the proportion of cultures that underwent AST with Etest, using results to plan expansion to other clinics. Additionally, the CDPH Regional GC RDRC will meet with large regional medical groups to discuss InTray GC/AST, and academic partners to explore piloting novel molecular assays to detect GC resistance.

2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1 Eligibility criteria and evaluation plan for GC culture collection using InTray and conducting Etest of 3rd St YCC specimens	SFDPH GC Epidemiologist Coordinator	Nov 2016	Mar 2017
2 Catalog of protocols for InTray specimen collection at 3rd St YCC	Mark Pandori until SFDPH Microbiologist hired	Jan 2017	Jul 2017
3 Number of meetings conducted with regional medical providers to discuss InTray GC and AST	CDPH Regional RDR Coordinator	Oct 2016	Jul 2017

Strategy 2: New Activity #6

Name (500 Character Maximum):

Package and ship specimens per protocols to the appropriate Antibiotic-Resistant Lab Network (ARLN) laboratory for confirmatory agar dilution and molecular characterization, such as whole genome sequencing.

Implementation Plan (1000 Character Maximum):

SFDPH is committed to packaging and shipping of specimens per protocol to the appropriate Antibiotic-Resistant Lab Network (ARLN) laboratory for confirmatory testing and molecular characterization. Having participated in GISP since its inception, SFDPH has extensive experience in preparing inoculated culture plates from SFCC to the PHL for processing and shipment of frozen isolates to regional laboratories. SFDPH will be readily able to update existing protocols for shipment to

an ARLN laboratory for additional testing. While SFDPH will collaborate with CDC and other funded GC RDR sites on finalizing protocols and the proportion or types of specimens to send to an ARLN laboratory, SFDPH has estimated the proportion of GISP and non-GISP cultures from SFCC and 3rd St YCC that will be isolated and available for shipment to the ARLN, and its related costs. SFDPH will also package and ship a small number of isolates to CDPH MDL for additional reference testing.

2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1 Shipment protocols to ARLN	SFDPH GC Epidemiologist Coordinator	Oct 2016	Jul 2017
2 Number of PHL staff trained on ARLN shipment protocols	SFDPH Microbiologist	Dec 2016	Jul 2017
3		Select One	Select One

Strategy 2: New Activity #7

Name (500 Character Maximum):

Electronically submit associated data to ARLN for addition of whole genome sequencing data, and for ultimate submission to CDC.

Implementation Plan (1000 Character Maximum):

Having a longstanding history of sending associated GC case and laboratory data to CDC as part of the GISP protocol, SFDPH will be readily able to update existing protocols and programming for electronic submission of required data to ARLN. SFDPH anticipates collaborating with CDC and other funded GC RDR sites on protocols and definitions. SFDPH will also continue to submit data to CDPH, per current protocols.

2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1 Data definitions and protocols for required GC RDR data to send to ARLN and CDC	SFDPH GC Epidemiologist Coordinator	Oct 2016	Jul 2017
2 Data programming to send associated data to ARLN and CDC	SFDPH GC Epidemiologist Coordinator	Dec 2016	Jul 2017
3		Select One	Select One

Strategy 2: New Activity #8

Name (500 Character Maximum):

Enhance local health department capacity to appropriately record antibiotic susceptibility testing data

(e.g., date of test, test type, and MIC results by drug tested) in the state/local information system.

Implementation Plan (1000 Character Maximum):

Given its experience with Etest, the SFDPH PHL has a database for capturing all relevant AST data. These data were routinely uploaded and stored in ISCHTR. GISP results from the regional GISP laboratory are sent to SFDPH and stored in ISCHTR. The PHL database and ISCHTR will be evaluated and enhanced for interoperability and facile data exchange with CDPH as discussions with CDC and CDPH about testing and results variables lead to definitions and protocols for data-entry and quality assurance to implement. CDPH and SFDPH will evaluate mechanisms for sharing these data readily with surveillance and DIS. AST results will be added to existing state electronic laboratory reported data streams. Relevant ARG data fields (e.g., MIC) will be added to CalREDIE, and the existing CDPH ARG data system. CDPH will lead data system interoperability efforts across ISCHTR, CalREDIE, MDL laboratory information system and existing CDPH ARG database (in alignment with meeting Strategy 2: Activity #3).

2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1 Updated database used by PHL for Etest and other AST results	SFDPH GC Epidemiologist Coordinator	Oct 2016	Mar 2017
2 AST results added to ELR data streams; relevant project data fields added to CalREDIE	CDPH Regional GC RDR Coordinator	Oct 2016	Jul 2017
3 Determine the interoperability between SFDPH and CDPH data systems to facilitate real-time data sharing of relevant laboratory data fields (i.e., date of test, test type, and MIC results by drug tested)	CDPH Regional GC RDR Coordinator	Oct 2016	Jul 2017

Strategy 2: New Activity #9

Name (500 Character Maximum):

Evaluate time-to-clearance among persons tested and treated for GC who return for a test-of-cure (optional)

Implementation Plan (1000 Character Maximum):

San Francisco City Clinic has experience implementing an evaluation of GC molecular test of cure in men who have sex with men. Existing experience, protocols, and remaining questions will be built upon in future years of this grant to expand the evaluation of GC time to clearance in youth, females, and heterosexual males. Additional clinical sites would be considered within San Francisco and in other CA public health STD clinics (e.g., Orange County, San Diego). In addition, AST with Etest would also be considered to address correlation between time to clearance and antibiotic susceptibility profile. The

CDPH Regional GC RDR Coordinator would be responsible for planning the evaluation and coordinating with SF and other clinical sites in Year 1, to pursue the evaluation in subsequent project years.

2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1 List of potential additional clinical sites within San Francisco to participate in time-to-clearance evaluation	SFDPH GC Epidemiologist Coordinator	Feb 2017	Jul 2017
2 GC time-to-clearance project plan	CDPH Regional GC RDR Coordinator	Nov 2016	Jul 2017
3		Select One	Select One

Strategy 3

Strategy: Enhance GC case investigations to identify transmission dynamics of emerging resistant GC threats

Add New Activity

Strategy 3: New Activity #1

Name (500 Character Maximum):

With CDC guidance, funded sites will draft and implement an unified case investigation guide for resistant GC cases or GC cases with reduced susceptibility that encompasses areas of interest (e.g., travel history, anatomic sites of exposure)

Implementation Plan (1000 Character Maximum):

Based on the combination of the long history of SFDPH and CDPH participation in SSuN, SFDPH experience in interviewing GISP/Etest alert cases, and a CDPH draft protocol and instrument for ARG case investigation, CA-SF GC RDR will contribute extensive lessons learned and best practices to discussions with CDC and other RDR funded sites to finalize a unified case investigation guide for resistant GC cases or GC cases with reduced susceptibility. Our historic data collection from patients with GC, particularly with those who were contacted because of a GISP/Etest alert, will inform discussions on the quality and completeness of variables of interest, as well as how best to discuss public health concerns about antibiotic resistance in order to maximize the potential for new ARG cases to provide high quality information. The unified case investigation guide will be shared and built upon at a planned regional Bay Area meeting of ~20 key state and LHJ partners working on GISP and ARG efforts.

2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
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1	Data tables of relevant SFDPH SSuN and GISP data variables to inform discussion on a unified case investigation guide for resistant GC cases or GC cases with reduced susceptibility	SFDPH GC Epidemiologist Coordinator	Nov 2016	Jan 2017
2	Data tables of relevant CDPH SSuN and GISP data variables to inform discussion on a unified case investigation guide for resistant GC cases or GC cases with reduced susceptibility	CDPH Regional GC RDR Coordinator	Nov 2016	Jan 2017
3	Unified GC ARG case investigation guide	SFDPH GC Epidemiologist Coordinator and CDPH Regional GC RDR Coordinator	Nov 2016	Jul 2017
4			Select One	Select One
5			Select One	Select One

Strategy 3: New Activity #2

Name (500 Character Maximum):

Rapidly (within 2 days) interview all GC cases found through laboratory diagnostics or clinical presentation (e.g. unsuccessful treatment) to be infected with a strain of reduced-susceptibility GC.

Implementation Plan (1000 Character Maximum):

In San Francisco through 2015, all patients found to have an MIC above a GISP or Etest alert value were assigned for further interview, assessment of travel and antibiotic use, re-testing and partner notification. In 2015, all 14 cases with GISP alert values were assigned for interview within 24 hours; 10 of 14 cases were interviewed within 7 days, 4 of which were interviewed within 2 days. Local protocols will be evaluated and compared to CA GISP interview protocols to identify mechanisms that could be evaluated to increase timeliness and completeness of interviews. The CDPH regional health worker will rapidly interview all ARG cases that reside outside SF. Case assignment will initially begin with GC cases with reduced susceptibility or antibiotic resistance, but productivity and completeness of interviews will be continually monitored to determine how best to prioritize assigning other GC cases for interview (e.g., by gender of sex partner, HIV status, history of STD).

2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1 Protocol for alerting staff of any cases requiring CA-SF GC RDR case investigation and partner services	Trang Nguyen until SFDPH GC Epidemiologist Coordinator hired	Aug 2016	Jul 2017

2	Evaluation plan to assess different modalities for CA-SF GC RDR case investigation and partner services	SFDPH GC Epidemiologist Coordinator and CDPH GC RDR Coordinator	Oct 2016	Jan 2017
3	Proportion of ARG cases residing in SF that were interviewed within 2 days among total number of ARG cases in SF	SFDPH Health Workers	Oct 2016	Jul 2017
4	Proportion of ARG cases residing outside of SF referred to CDPH regional health worker for interview within 2 days among total number of cases that reside outside of SF that are referred to the CDPH health worker for interview	CDPH Regional GC RDR Coordinator	Oct 2016	Jul 2017
5	Proportion of ARG cases residing outside SF that were interviewed within 2 days of assignment among total number of ARG cases residing outside SF that were assigned	CDPH Regional Health Worker	Oct 2016	Jul 2017

Strategy 3: New Activity #3

Name (500 Character Maximum):

Conduct investigations of sexual and social contacts and develop methods for describing social and sexual networks of interviewed cases.

Implementation Plan (1000 Character Maximum):

SFDPH has extensively enhanced its DIS program to integrate STD and HIV priorities and outcomes. Existing PS protocols for the CA-SF GC RDR will be enriched with CDPH expertise from other successful LHJ PS protocols. SFDPH will also develop a PS protocol for partners of youth at 3rd St YCC. Case and partner data are stored in ISCHTR in a way that has enabled actionable analysis of sexual networks. SFDPH will evaluate and enhance the way susceptibility and partnership data are collected, stored, and analyzed to assess different methods for describing social and sexual networks of GC cases. The CDPH regional health worker will provide PS for ARG cases outside SF, and CA and SF will build on existing expertise and analyses to characterize the regional sexual networks in order to enhance collaborative disease control efforts.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Partner services protocol for GC cases with reduced susceptibility or antibiotic-resistant strains within SF	Trang Nguyen until SFDPH GC Epidemiologist Coordinator	Aug 2016	Feb 2017

2	Evaluation of ISCHTR data needs for enhancing social and sexual network analysis of GC cases with reduced susceptibility or antibiotic-resistant strains; updated data collection and routine analysis (ensuring continuous quality improvement) of social and sexual networks of GC cases with reduced susceptibility or antibiotic-resistant strains	Trang Nguyen until SFDPH GC Epidemiologist Coordinator	Aug 2016	Jul 2017
3	Proportion of interviews of partners of ARG cases that reside in SF among total number of partners of ARG cases identified in SF	SFDPH Health Workers	Nov 2016	Jul 2017
4	Partner services protocol for GC cases with reduced susceptibility or antibiotic-resistant strains outside SF, and across the SF-Bay Area Region	CDPH Regional GC RDR Coordinator	Oct 2016	Feb 2017
5	Proportion of interviews of partners of ARG cases that reside outside of SF among total number of partners of ARG cases identified outside of SF	CDPH Regional Health Worker	Nov 2016	Jul 2017

Strategy 3: New Activity #4

Name (500 Character Maximum):

Analyze phenotypic susceptibility testing, sociodemographic, risk behavior, and whole genome sequencing data (where available) concurrently to improve understanding of local GC epidemiology and transmission dynamics of emerging resistant GC threats.

Implementation Plan (1000 Character Maximum):

Existing SFDPH and CDPH systems will be updated to store Etest and ARLN data, including whole genome sequencing. SFDPH and CDPH will develop analytic plans in collaboration with CDC to determine the data elements and methods that will be useful to improving the local and regional epidemiology and transmission dynamics of emerging ARG threats. Because most GC patients for whom ARG data are available will have been identified through SFCC, we will have a rich dataset of sociodemographic and risk behavior data collected through medical care visits. Those patients able to be interviewed will have provided additional detail about risk behaviors, sexual partnerships, travel history, recent antibiotic use and meeting locations that will enrich the analyses. We anticipate having laboratory STD testing and AST results and sociodemographic data from a proportion of named contacts that we are able to reach, interview, and test, through SFDPH or CDPH PS and any MDL reference testing.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	List of data that will be reported from ARLN and added to local data systems	SFDPH GC Epidemiologist Coordinator	Jan 2017	Jul 2017
2	Analysis plan and draft table shells for SF epidemiology of emerging GC resistance	SFDPH GC Epidemiologist Coordinator and CDPH	Mar 2017	Jul 2017
3	Analysis plan and draft table shells for SF-Bay Area regional epidemiology of emerging GC resistance	Regional GC RDR Coordinator in collaboration with regional bay area counties	Mar 2017	Jul 2017
4			Select One	Select One
5			Select One	Select One

Strategy 3: New Activity #5

Name (500 Character Maximum):

Report all antibiotic susceptibility results and awardee-required variables to state health department and CDC and all susceptibility results demonstrating reduced susceptibility to state health department and CDC within 24 hours of testing.

Implementation Plan (1000 Character Maximum):

SFDPH has an extensive history with reporting data to CDPH and CDC in different formats, with reports using different visualizations and layouts (e.g., line lists, table summaries, pivot tables), and utilizing various mechanisms (e.g., CDC Secure Access Management Services, NETSS, CDPH secure file transfer), often in automated or routine modalities. ISCHTR already stores antibiotic susceptibility results provided by the regional GISP laboratory and Etest results from PHL. SFDPH routinely sends associated GC case and laboratory data to CDC as part of the GISP protocol. SFDPH will be readily able to update ISCHTR fields and update/prepare protocols and programming for electronic submission of required data to CDPH and CDC. SFDPH and CDPH will collaborate with CDC and other funded GC RDR sites to finalize unified protocols and definitions, which has been done as part of SSuN collaborative discussions.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Data definitions and protocols for reporting of required antibiotic susceptibility test results and awardee-required variables to CDPH and CDC	SFDPH GC Epidemiologist Coordinator	Oct 2016	Jul 2017

2	Protocols and data programming to submit required case and susceptibility data to CDPH and CDC electronically within 24 hours of testing	SFDPH GC Epidemiologist Coordinator	Dec 2016	Jul 2017
3			Select One	Select One
4			Select One	Select One
5			Select One	Select One

Evaluation and Performance Measurement Strategy

Required performance measures for the project period are listed within this project's guidance in the 'CDC Evaluation and Performance Management Strategy' section. These are measures that awardees will be expected to report on in next year's progress report. The table below provides an opportunity for you to provide any baseline data that you may have – you are not expected to have data for all of these measures.

Strategy 2) Enhance timely surveillance for detection of resistant GC threats	
Number of trained personnel who can perform E-Test.	
Number of viable, non-viable, and contaminated specimens received by the local laboratory.	Viable: Non-Viable: Contaminated:
Number of isolates tested for antimicrobial resistance within proficiency standards.	
Number of clinical settings submitting specimens for antimicrobial resistance testing.	
Days from specimen collection to receipt at laboratory, from receipt at laboratory to e-Test completion, and from e-Test completion to report to clinician and local health department within the awardee-required timeframe.	Collection to Receipt: Receipt to E-Test Completion: E-Test Completion to Report:
Number and percentage of isolates found to have reduced susceptibility or resistance to antibiotics tested.	(Number) (%)
Number and percentage of GC lab reports received at the local health department through ELR with awardee-required	(Number) (%)

variables	
Strategy 3) Enhance GC case investigations to identify transmission dynamics of emerging resistant GC threats	
Number of reported GC cases to local health department with complete awardee-required demographic, epidemiologic and clinical variables.	3726
Number and percentage of resistant GC cases, GC cases with reduced susceptibility or GC treatment failure cases investigated within the awardee-required timeframe.	12 (Number) 92% (%)
Number and percentage of sexual and social contacts investigated of cases unidentified in #2 within the awardee-required timeframe.	0 (Number) 0% (%)
Number and percentage of isolates demonstrating reduced cephalosporin susceptibility reported to the state health department and CDC within 24 hours of testing	0 (Number) 0% (%)

Please describe the applicant's plan and ability to collect the necessary data and report on each of the measures listed in the guidance.

The *CA-SF GC RDR* proposal is poised to address CDC's evaluation and performance measures. SFDPH already has extensive experience in integrating both qualitative and quantitative data from epidemiological analyses, clinical preventive and testing services, field services, and case interviews to evaluate and improve programs, data collection, and surveillance. Baseline data for some of the requested performance measures are provided to reflect SFDPH's current capacity to meet project objectives.

SFDPH and CDPH will prepare a list of qualified personnel hired or retained to support grant activities to meet Strategy 1.

SFDPH and CDPH will report on metrics to demonstrate how this work has enhanced timely surveillance for detection of resistant GC threats to meet Strategy 2. As part of GISP, SFDPH and CDPH have had to routinely report evaluation and performance metrics similar to the ones requested for this strategy. A table of recently reported SF GISP process measures is provided as an example:

Table 1. Example SF GISP Process Measures	Jan 1– Dec 31, 2014 No./%	Jan 1– June 30, 2015 No./%
Number of SF isolates submitted to the GISP regional laboratory	322 (74%)	160 (79%)
Percentage of submitted SF isolates that were found by the GISP regional laboratory to be non-viable or contaminated	1 (0.3%)	0 (0%)
Percentage of monthly SF isolate batches that were shipped to the GISP regional laboratory within one week after the end of monthly collection	2 (33%)	1 (17%)
Percentage of monthly SF demographic/clinical data transmissions that were submitted to CDC within one month of the completion of specimen collection	100%	100%
Percentage of collected SF isolates for which the following data elements were reported:		
Gender of sex partner/sexual orientation	98%	99%
HIV status	98%	93%
Treatment	89%	97%

Evaluation of performance metrics for Strategy 3, enhancing GC case investigations to identify transmission dynamics of emerging resistant GC threats, will be readily and routinely conducted using existing fields in ISCHTR, which can be seamlessly modified to account for any additional metrics required by CDC. Because ISCHTR integrates STD surveillance data with electronic medical record data from SFCC, field investigations, and all STD testing conducted by the PHL, data can be extracted from ISCHTR to evaluate data by STD test, person, or isolate. CDPH data systems (CalREDIE and the existing ARG database) will be modified to account for any requested evaluation metrics that are not accounted for by existing data fields.

SFDPH and CDPH will plan to monitor and report, as requested by ELC/CDC. SFDPH and CDPH will collaborate with ELC/CDC on the development of additional performance measurements, as appropriate.



**EXHIBIT B
TO SUBCONTRACT/SUBAWARD AGREEMENT**

Budget

Consortium/Contractual Cost (Contract 1: SFDPH)	
Personnel	
Epidemiologist I/II-TBD	\$65,372.50
T. Nguyen - EPI II	\$31,767.09
R. Kohn - EPI II	\$31,767.09
M. Mahersi - EPI I	\$40,963.43
Microbiologist-TBD	\$94,535.29
Health Worker III-TBD	\$135,059.13
Travel	
TC - Travel In State SFDPH Mileage	\$1,500.00
TC- Out of State	\$7,174.00
TC- Out of State	\$4,782
TC- Out of State	\$6,000.00
Other Costs	
Office Supplies	\$2,666.00
Office Furniture	\$2,000.00
IT Surveillance Systems Interoperability	\$25,000.00
Shipping	\$45,600.00
Staff Development Training	\$4,000.00
Indirect for Contractual	\$99,866.13
Total Consortium/Contractual Cost	\$598,052.66

**EXHIBIT C
TO SUBCONTRACT/SUBAWARD AGREEMENT**

FLOW DOWN PROVISIONS

Attached

1. DATE ISSUED MMDDYYYY 07/21/2016	2. CFDA NO. 93.323	3. ASSISTANCE TYPE Cooperative Agreement
1a. SUPERSEDES AWARD NOTICE dated except that any additions or restrictions previously imposed remain in effect unless specifically rescinded		
4. GRANT NO. 5 NU50CK000410-03-00 Formerly 31150CK000410-0251	5. ACTION TYPE Non-Competing Continuation	
6. PROJECT PERIOD From MMDDYYYY 08/01/2014	Through MMDDYYYY 07/31/2019	
7. BUDGET PERIOD From MMDDYYYY 08/01/2016	Through MMDDYYYY 07/31/2017	
8. TITLE OF PROJECT (OR PROGRAM) CALIFORNIA ELC 2014		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
CDC Office of Financial Resources
2920 Brandywine Road
Atlanta, GA 30341

NON
PDTIF

NOTICE OF AWARD
AUTHORIZATION (Legislation/Regulations)
42 USC 241 31 USC 6305 42 CFR 52

9a. GRANTEE NAME AND ADDRESS
PUBLIC HEALTH FOUNDATION ENTERPRISES, INC.
12801 CROSSROADS PKWY S STE 200
CITY OF INDUSTRY, CA 91746-3420

10a. GRANTEE AUTHORIZING OFFICIAL
Mr. Peter Dale
12801 Crossroads Pkwy. South, Suite 200
City of Industry, CA 91746
Phone: (562) 222-7823

9b. GRANTEE PROJECT DIRECTOR
Ms. Cheryl Starling
12801 Crossroads Parkway South, Suite 200
California Department of Public Health
City of Industry, CA 91746
Phone: 916-324-0336

10b. FEDERAL PROJECT OFFICER
Angelica O'Connor
1600 Clifton Rd
Atlanta, GA 30333
Phone: 404-639-7379

ALL AMOUNTS ARE SHOWN IN USD

11. APPROVED BUDGET (Excludes Direct Assistance)	
I Financial Assistance from the Federal Awarding Agency Only	<input checked="" type="checkbox"/>
II Total project costs including grant funds and all other financial participation	
a. Salaries and Wages	3,265,464.00
b. Fringe Benefits	1,183,110.00
c. Total Personnel Costs	4,448,574.00
d. Equipment	156,573.00
e. Supplies	381,982.00
f. Travel	221,109.00
g. Construction	0.00
h. Other	230,343.00
i. Contractual	1,999,323.00
j. TOTAL DIRECT COSTS	7,437,904.00
k. INDIRECT COSTS	637,488.00
l. TOTAL APPROVED BUDGET	8,075,392.00
m. Federal Share	8,075,392.00
n. Non-Federal Share	0.00

12. AWARD COMPUTATION

a. Amount of Federal Financial Assistance (from item 11m)	8,075,392.00
b. Less Unobligated Balance From Prior Budget Periods	0.00
c. Less Cumulative Prior Award(s) This Budget Period	0.00
d. AMOUNT OF FINANCIAL ASSISTANCE THIS ACTION	8,075,392.00
13. Total Federal Funds Awarded to Date for Project Period	23,005,233.00

14. RECOMMENDED FUTURE SUPPORT
(Subject to the availability of funds and satisfactory progress of the project)

YEAR	TOTAL DIRECT COSTS	YEAR	TOTAL DIRECT COSTS
d. 4		d. 7	
b. 5		e. 8	
c. 6		i. 9	

15. PROGRAM INCIPIUM SHALL BE USED IN ACCORD WITH ONE OF THE FOLLOWING ALTERNATIVES:

a. DEDUCTION	<input checked="" type="checkbox"/>
b. ADDITIONAL COSTS	
c. MATCHING	
d. OTHER RESEARCH (add / Deduct Other)	
e. OTHER (See REMARKS)	

16. THIS AWARD IS BASED ON AN APPLICATION SUBMITTED TO, AND AS APPROVED BY, THE FEDERAL AWARDOING AGENCY ON THE ABOVE TITLED PROJECT AND IS SUBJECT TO THE TERMS AND CONDITIONS INCORPORATED EITHER DIRECTLY OR BY REFERENCE IN THE FOLLOWING:

a. The grant award legislation
b. The grant program regulations
c. The award notice including terms and conditions, if any, noted herein under REMARKS
d. Federal administrative requirements, cost principles and such requirements applicable to this grant

In the event there are conflicting or otherwise inconsistent policies applicable to the grant, the above order of precedence shall prevail. Acceptance of the grant terms and conditions is acknowledged by the grantee when funds are drawn or otherwise obtained from the grant payment system.

REMARKS (Other Terms and Conditions Attached) Yes No

NOTE: Correct Project Period start date should read: Project Period 08/01/2014 to 7/31/2019 & Budget Period 08/01/2016 to 7/31/2017.

GRANTS MANAGEMENT OFFICIAL Louveta Keante

17. OBJ CLASS 41.51	18a. VENDOR CODE 1952557063A1	18b. EIN 952557063	19. DUNS 082199324	20. CONG. DIST. 32	
FY-ACCOUNT NO.	DOCUMENT NO.	CFDA	ADMINISTRATIVE CODE	AMT ACTION FIN ASST	APPROPRIATION
21 a. 6-92120YG	b. 000410CK14	c. 93.323	d. CK	e. \$582,221.00	f. 75-16-0959
22 a. 6-939014P	b. 000410CK14	c. 93.323	d. CK	e. \$75,720.00	f. 75-16-0949
23 a. 6-93903FE	b. 000410CK14	c. 93.323	d. CK	e. \$50,000.00	f. 75-16-0949

Funding Opportunity Announcement (FOA) Number: RFA-CK14-1401PPHF14
 Award Number: CK000410-03
 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 Part 75 supersedes regulations at 45 CFR Part 74 and Part 92

AWARD INFORMATION

Incorporation: The Centers for Disease Control and Prevention (CDC) hereby incorporates Funding Opportunity Announcement number RFA-CK14-1401PPHF14, entitled PPHF 2016 Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) – Building and Strengthening Epidemiology, Laboratory and Health Information Systems Capacity in State and Local Health Department, and application dated May 27, 2016, 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.

Note: In the event that any requirement in this Notice of Award, the Funding Opportunity Announcement, the HHS GPS, 45 CFR Part 75, or applicable statutes/appropriations acts conflict, then statutes and regulations take precedence.

Approved Funding: Funding in the amount of [REDACTED] is approved for the Year 03 budget period, which is August 1, 2016 through July 31, 2017. All future year funding will be based on satisfactory programmatic progress and the availability of funds.

ZIKA funding: Funding in the amount of [REDACTED] is approved to be used to support the current outbreak of ZIKA Virus; and, will also help more effectively detect and respond to future outbreaks.

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

Budget Revision Requirement: By September 15, 2016 the grantee must submit a revised budget with a narrative justification and work plan. Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to contact the GMS/GMO identified in the Staff Contacts section of this notice before the due date.

INDIRECT COSTS Indirect costs are approved based on the Indirect Cost Rate Agreement dated January 26, 2010, which calculates indirect costs as follows, a Provisional is approved at a rate of 30.1% of the base, which includes, total direct costs excluding capital expenditures (buildings, individual items of equipment; alterations and renovations), that portion of each subaward in excess of \$25,000 and flow-through funds. The effective dates of this indirect cost rate are from July 10, 2010 thru until amended.

COST LIMITATIONS AS STATED IN THE CONSOLIDATED APPROPRIATIONS ACT, 2014:

A. Cap on Salaries (Div. H, Title II, 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 and HHS contract or order; it merely limits the portion of that salary that may be paid with Federal funds.

B. Gun Control Prohibition (Div. H, Title II, 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. Proper Use of Appropriations – Publicity and Propaganda (LOBBYING) FY2012 (Div. H, Title V, Sec. 503):

- 503(a): No part of any appropriation contained in the 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 restrictions on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control.

For additional information, see Additional Requirement 12 at:

http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtml and Anti Lobbying Restrictions for CDC Grantees at http://www.cdc.gov/od/pgo/funding/grants/Anti-lobbying_Restrictions_for_CDC_Grantees_July_2012.pdf.

D. Needle Exchange (Div. H, Title V, Sec. 522): 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. Restricts dealing with corporations with recent felonies (Div. E, Title VI, Sec 623): None of the funds made available by this Act may be used to enter into a contract, memorandum of understanding, or cooperative agreement with, make a grant to, or provide a loan or loan guarantee to any corporation that was convicted (or had an officer or agent of such corporation acting on behalf of the corporation convicted) or a felony criminal violation under and Federal or State law within the preceding 24 months, where the awarding agency is aware of the conviction, unless the agency has considered suspension or debarment of the corporation, or such officer or agent, and made a determination that this further action is not necessary to protect the interests of the Government.

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 and 2 CFR Part 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards; 2 CFR Part 225, Cost Principles for State, Local,

and Indian Tribal Governments (OMB Circular A-87); and 2 CFR Part 230, Cost Principles for Non-Profits Organizations (OMB Circular A-122). The grantee also has a responsibility to ensure sub-recipients expend funds in compliance with 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. 1552(a) Procedure for Appropriation Accounts Available for Definite Periods states the following, On September 30th of the 5th fiscal year after the period of availability for obligation of a fixed year appropriation account ends, the account shall be closed and any remaining balances (whether obligated or unobligated) in the account shall be canceled and thereafter shall not be available for obligation or expenditure for any purpose. An example is provided below:

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

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 90 days after the end the calendar quarter in which the budget period ends period. The FFR for this budget period is due to the GMS/GMO by October 31, 2017. Reporting timeframe is August 1, 2016 through July 31, 2017.

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 Grants Officer listed in the contacts section of this notice before the due date.

FFR (SF-425) instructions for CDC Grantees are available at <http://grants.nih.gov/grants/forms.htm>. For further information, contact GrantsInfor@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: <http://www.cdc.gov/od/pgo/funding/grants/eramain.shtml>.

PERFORMANCE REPORTING: The Annual Performance Report is due no later than 120 days prior to the end of the budget period, April 1, 2017, and serves as the continuing application. This report should include the information specified in the FOA.

AUDIT REQUIREMENT: An organization that expends \$500,000 or more in a year in Federal awards shall have a single or program-specific audit conducted for that year in accordance with the provisions of OMB Circular A-133, Audit of States, Local Governments, and Non-Profit Organizations. The audit must be completed along with a data collection form, and the reporting package shall be submitted within the earlier of 30 days after receipt of the auditor's report(s), or nine (9) months after the end of the audit period. The audit report must be sent to:

Federal Audit Clearing House Internet Data Entry System
Electronic Submission:

[https://harvester.census.gov/facodes/\(S\(0vkw1zaelvzjibnahocqa5i0\)\)/account/login.aspx](https://harvester.census.gov/facodes/(S(0vkw1zaelvzjibnahocqa5i0))/account/login.aspx)

AND

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

After receipt of the audit report, the National External Audit Review Center will provide audit resolution instructions. CDC will resolve findings by issuing Final Determination Letters.

The grantee is to ensure that the sub-recipients receiving CDC funds also meet these requirements. The grantee must also ensure that appropriate corrective action is taken within six months after receipt of the sub-recipient audit report in instances of non-compliance with applicable Federal law and regulations (2 CFR 200 Subpart F and HHS Grants Policy Statement). The grantee may consider whether sub-recipient audits necessitate adjustment of the grantee's own accounting records. If a sub-recipient is not required to have a program-specific audit, the Grantee is still required to perform adequate monitoring of sub-recipient activities. The grantee is to require each sub-recipient to permit independent auditors to have access to the sub-recipient's records and financial statements. The grantee must include this requirement in all sub-recipient contracts.

Note: The standards set forth in 2 CFR Part 200 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(1)), 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 of 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. For instructions of reporting please visit FFATA: www.fsrs.gov.

TRAVEL COST: In accordance with Health and Human Services (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 Notice of Award. To prevent disallowance of cost, grantee is responsible for ensuring that only allowable travel reimbursements are applied in accordance with their organization's established travel policies and procedures. Grantee approved policies must meet the requirements of 2 CFR Parts 200, 225 and 230, as applicable and 45 CFR Parts 74 and 92 as applicable.

FOOD AND MEALS: Costs associated with food or meals are allowable when consistent OMB Circulars and guidance, 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 reasonableness has been performed by the grantee. Grantee approved policies must meet the requirements of 2 CFR Parts 200, 225, and 230, as applicable and 45 CFR Parts 74 and 92 as applicable.

PRIOR APPROVALS: All requests, which require prior approval, must bear the signature of the authorized organization representative. The grantee must submit these requests no later than 120 days prior to this budget period's end date. 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 approved budget

- Apply for supplemental funds
- Change in key personnel
- Extensions
- Conferences or meetings that were not specified in the approved budget

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:

<http://www.cdc.gov/grants/alreadyhavegrant/priorapprovalrequests.html>

KEY PERSONNEL: In accordance with 2 CFR Parts 200.308 and 215.25(c)(2) & (3), 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 recipients to comply with the standard patent rights clause in 37 CFR 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 FOA CK14-1401PPHF14 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 Human Services.

ACKNOWLEDGEMENT 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
- Percentage and dollar amount of the total costs of the project or program 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, Recipients agrees to submit into the National Institutes of Health (NIH) Manuscripts Submission (NIHMS) systems 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 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 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 housed 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 the PubMed Central identification number (PMCID) thereafter.

DISCLAIMER FOR CONFERENCE/MEETING/SEMINARS MATERIALS: Disclaimers for conferences/meetings, etc. and/or publications: If a conference/meeting/seminar is funded by a grant, cooperative agreement, subgrant 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 HHS nor the CDC logo may be displayed if such display would cause confusion as to the conference source or give false appearance of Government endorsement. Use of the HHS name or logo is governed by U.S.C. 1320b-10, which prohibits misuse of the HHS name and emblem in written communication. A non-federal entity is unauthorized to use the HHS name or logo governed by U.S.C. 1320b-10. The appropriate use of the HHS logo is subject to review and approval of the Office of the Assistant Secretary for Public Affairs (OASPA). Moreover, the Office of the Inspector General has authority to impose civil monetary penalties for violations (42 C.F.R. Part 1003). Neither the HHS nor the CDC logo can be used on conference materials, under a grant, cooperative agreement, and contract or co-sponsorship agreement without the expressed, written consent of either the Project Officer or the Grants Management Officer. It is the responsibility of the grantee (or recipient of funds under a cooperative agreement) to request consent for use of the logo in sufficient detail to ensure a complete depiction and disclosure of all uses of the Government logos. In all cases for utilization of Government logos, the grantee must ensure written consent is received from the Project Officer and/or the Grants Management Officer.

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

The grantee may use its own property management standards and procedures provided it observes provisions of the following sections in the Office of Management and Budget (OMB).

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

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

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_public_laws&docid=f:publ347.107.pdf

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 subcontractors are prohibited from discharging, demoting, 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 41 U.S.C. 4712 by section 828 of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112-239) and FAR 3.908.

(b) The Contractor shall inform its employees in writing, in the predominant language of the workforce, of employee whistleblower rights and protections under 41 U.S.C. 4712, as described in section 3.908 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, Division of Payment Management, OS/ASAM/PSC/FMS/DPM
P.O. Box 6021
Rockville, MD 20852
Phone Number: (877) 614-5533
Email: PMSSupport@psc.gov
Website: <http://www.dpm.psc.gov/help/help.aspx>

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

University and Non-Profit Payment Branch:

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

Governmental and Tribal Payment Branch:

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

Cross Servicing Payment Branch:

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

International Payment Branch:

Bhavin Patel (301) 443-9188

Email: Bhavin.patel@psc.hhs.gov

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

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

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

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

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 new grant awards. Funds awarded in support of approved activities have been obligated in a newly established subaccount in the PMS, herein identified as a P Account. A "P" Account is a subaccount created specifically for the purpose of tracking designated types of funding in the PMS. The grant document number and subaccount title below must be known in order to draw down funds from the P Account.

Grant Document Number: 000410CK14
Subaccount Title: CK141401ELCBUISTCA14

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

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

Grantees must closeout reports in a timely manner. Unless the Grants Management Specialist/Grants Management Officer (GMS/GMO) approves a deadline extension the grantee must submit within 90 days after the last day of the final budget period. Reporting timeframe is 08/01/2014 through 07/31/2019. 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 support 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 eRA Commons 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 Systems (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 2 CFR Parts 200.343 (Closeout), 225 and 230, the grantee must submit a letter requesting an extension that includes the justification for the delay and state the expected date 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 \$5000 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 2 CFR Parts 200, 215.37 or 2 CFR 215.71. These requirements do apply to equipment purchased with non-federal funds for this program. The awarding agency may exercise its right 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 \$5000 that is no longer to be used in projects or program 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 <http://www.hhs.gov/forms/hhs568.pdf>. 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: 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 close-out 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 the grant award including:

- Determining the appropriate award instrument, i.e.; grant or cooperative agreement
- Determining if an application meets the requirements of the FOA
- Ensuring objective review 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 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 office of the recipient organization.

GMO Contact: See Staff Contact below for the assigned GMO

Grants Management Specialist: The GMS is the federal staff member responsible for the day-to-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 Contact below for the assigned GMS

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

- The development of the programs and FOAs to meet the CDC 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 or prior approval requests, conducting site visits, and other activities complementary to those of the GMO/GMS

Programmatic and Technical Contact:

Janice Downing, Project Officer
Centers for Disease Control
National Center for Epidemiology and Laboratory
Capacity for Infectious Diseases (NCEZID)
1600 Clifton Road, NE Mailstop: C18
CLFT Bldg. 24, Cube 11111.5
Atlanta, Georgia 30333
Telephone: 404.639.7808
Fax: 404.235.1749
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**EXHIBIT D
TO SUBCONTRACT/SUBAWARD AGREEMENT**

FORM OF INVOICE

Invoice format submitted in previous year is acceptable.

Final invoice must be signed, marked "Final," and have the statement "This final invoice represents that all deliverables have been met."



ELC Project K8

Threat of Antibiotic-Resistant Gonorrhea: Rapid Detection and Response Capacity

Navigation

Click the name of a section below while holding the control key to jump to specific sections of this document.

Awardee Jurisdiction

Strategy 1

Strategy 2

Strategy 3

Evaluation and Performance Measurement Strategy

Guidance

The following work plan will outline the awardee’s plans, milestones, and expected outcomes related to the project described in attachment Antibiotic-Resistant Gonorrhea of the ELC 2016 Application. Please review this guidance prior to completing this application.

If there are any questions or concerns while completing this application, please contact the ELC or Program POC to address and resolve the issue.

When completing the form, it is important to note that this is a locked document and only specific form fields and sections are editable. Please do not attempt to edit or alter sections of the form that are not available for edit as it could delay and hinder the ability to review the application.

Spell Check: You can run a spelling check by clicking the button below.

Spell Check

Track Changes: You may use track changes with this document by clicking the buttons below.

Turn Track Changes On/Off

Accept All Changes

Awardee Jurisdiction

Please select your Awardee jurisdiction.

**States: Alabama through
Mississippi (Alphabetical)**

California

**States: Missouri through West
Virginia (Alphabetical)**

Select One

**Wisconsin, Wyoming and Non-
State Applicants (By Type)**

Select One

Project Approach

Problem Statement

In completing this section, reference the component projects 'Problem Statement' within the funding opportunity guidance and articulate its applicability and special considerations to the applicant jurisdiction. *Please limit the response to this section to half a page - This section is unrestricted to allow entry of additional materials beyond text (including graphics, pictures, etc.) as necessary.*

In 2013, CDC identified antibiotic-resistant *Neisseria gonorrhoeae* (ARG) as an urgent public health threat requiring significant resources to detect and prevent cases in the United States. California (CA) and San Francisco (SF) are areas of particular concern. In 2014, CA had the most gonorrhea (GC) cases of any state. In 2015, there were 54,307 GC cases, and from 2011 to 2015 male cases ages 15-44 increased 113% and female cases ages 15-44 increased 67%. Furthermore, SF has the highest GC case rate in CA; in 2015, 4266 reported cases represented a 30% increase from 2014. In 2013, the SF case rate was 313.2/100,000, which exceeded the case rate for the Los Angeles metropolitan statistical area (MSA), the New York MSA, the state of CA, and the United States (US) as a whole. Prevention and control of GC are key responsibilities of state and local sexually transmitted disease (STD) programs and rely on timely and effective antibiotic treatment. However, GC has repeatedly developed resistance to antimicrobials including sulfonamides, penicillin, tetracyclines, and fluoroquinolones. Data from the CDC Gonococcal Isolate Surveillance Project (GISP) have shown that decreased antibiotic susceptibility to cephalosporins, the current mainstay of GC treatment, is more likely to be detected in specimens from the Western US compared to other US regions, and from men who have sex with men (MSM) compared to men who have sex with women (MSW). With large populations of MSM and high rates of GC, CA and SF are critical jurisdictions to implement effective surveillance and control of ARG.



Epidemiology and Laboratory Capacity (ELC) –Building and Strengthening Epidemiology, Laboratory and Health Information Systems Capacity 2016

Purpose

Describe in 2-3 sentences specifically how the application will address the project’s problem as described in the component project’s ‘Problem Statement.’

Given California’s increased epidemiologic risk for ARG, both the San Francisco Department of Public Health (SFDPH) and California Department of Public Health (CDPH) have established efforts to prepare for and respond to this public health threat. Our proposed California-San Francisco Rapid Detection and Response Project (CA-SF GC RDR) will support, expand, and accelerate efforts to combat ARG in San Francisco, by 1) developing and implementing protocols for rapid identification and response to ARG cases, 2) expanding surveillance to additional clinic sites, populations including females and youth, and anatomic sites of infection, and 3) collaborating throughout the surrounding Bay Area region to provide comprehensive rapid response to ARG cases. Rigorous data collection and evaluation of novel methods for GC surveillance, laboratory testing, and case investigation will inform preparedness for rapid ARG detection and response throughout California.

Applicant Capacity

The below table provides some specific questions regarding gonorrhea morbidity and Public Health Lab capacity. Following the table is a free-response section for you to provide more information about your capacity.

Selection of a Local Health Jurisdiction	
If your organization is <u>not</u> a local health department, name the local health jurisdiction with whom you plan to partner to implement programmatic activities:	San Francisco Department of Public Health
Does the jurisdiction currently receive and electronically/automatically processes electronic lab reports (ELR)?	Yes, at state and local levels
Presence of a Categorical STD Clinic (a clinic whose primary mission is to provide diagnosis, treatment, counseling, and sex partner notification for STDs.)	
Provide the name(s) and location(s) of categorical STD clinics that serve the selected jurisdiction. If you will perform activities in only a select number of STD clinics, please denote the selected clinics:	San Francisco City Clinic 356 7 th Street San Francisco, CA 94103
Does/do the categorical STD clinic(s) that you proposed to work with utilize electronic medical records (EMR)?	Yes, All
If only some of the categorical STD clinics that you	

propose to work with utilize EMR, please indicate which clinics use EMR and which do not:	
Gonorrhea Morbidity	
How many cases of gonorrhea (GC) were reported in 2015 in the selected local jurisdiction?	Female: 372 Male (Overall): 3829 -- Male (Men who have sex with men): 3067 -- Male (Men who have sex with women only): 140 Non-Hispanic White: 1887 Non-Hispanic Black: 387 Hispanic: 631 Other races: 1352
How many cases of GC were reported in 2015 from the categorical STD clinic(s) where you plan to implement activities? Note: This program requires that at least one categorical STD clinic must diagnose at least 200 GC cases per year.	Number: 790 Proportion of total GC cases reported in the selected jurisdiction diagnosed by the categorical clinic(s): 18.50%
How many cases of GC from the selected local jurisdiction were cultured and tested for antibiotic susceptibility in 2015?	Number: 273 Proportion of total GC cases reported in the selected jurisdiction (i.e., not limited to the categorical clinics above): 6.40%
Laboratory Capacity	
Please provide the name and location of the state/local public health laboratory that will be performing antibiotic susceptibility testing for the project	Name: San Francisco Public Health Laboratory Location: 101 Grove Street, Room 419 San Francisco, CA 94102
Does the selected public health lab currently culture GC specimens for antibiotic susceptibility testing or diagnostic purposes?	Yes
If the selected public health lab currently cultures GC, please provide information on how many specimens the lab cultured and tested for antibiotic susceptibility in 2015 by test type.	Agar dilution: Disc diffusion: E-testing: 73

	Other:
If the selected public health lab currently cultures GC, please provide information on the mean time and range (in days) between specimen collection and the results being returned to the provider.	Mean time (days): 3 Range (high side, in days): 15 Range (low side, in days): 1

Address the jurisdiction's current capacity to successfully implement the proposed strategies and activities (including describing staff and other infrastructure already in place that you will build upon) to meet project period outcomes. *Please limit the response to this section to 1 page - This section is unrestricted to allow entry of additional materials beyond text (including graphics, pictures, etc.) as necessary.*

The SF Department of Public Health (SFDPH) Population Health Division (PHD) is a longtime leader in STD prevention, and contains the premier categorical STD clinic in CA, San Francisco City Clinic (SFCC). SFCC has been a CDC GISP site for 30 years; for the first half of 2015, 203 cases of gonococcal urethritis were diagnosed at SFCC, 126 of which were submitted to the regional GISP laboratory via SFDPH Public Health Laboratory (PHL), itself a state-of-the-art microbiology laboratory with demonstrated excellence in both standard and innovative GC testing, including being among the first to utilize GC NAAT. Sequence analysis of SFCC GC specimens at PHL in 2008 demonstrated the presence of two previously undescribed penA alleles associated with elevated cephalosporin MICs. PHL implemented Etest in 2011 to provide susceptibility data 2-3 weeks before GISP results were available on specimens from four public health clinics across CA (including SFCC). Susceptibility data from PHL and GISP are stored in the SFDPH STD data system (ISCHTR - Integrated Surveillance and Clinical Health Tracking Registry), a robust data management system that enables timely analyses for continuous quality improvement.

The California Department of Public Health (CDPH) STD Control Branch (STDCB) coordinates STD prevention and control across CA and is creating an advanced data management system to track California GISP isolates and any suspected GC treatment failures or ARG cases. STDCB has worked with LHJs to not only respond to GC outbreaks, treatment failures and ARG but also to conduct many successful enhanced GC projects, including Etest and an evaluation of an alternative GC culture medium (InTray GC) with SFDPH, a test of cure study with San Mateo, a collaboration with San Luis Obispo to evaluate a cluster of disseminated gonococcal infections, and partner services for patients with GISP alerts (through which, in 2015, SFDPH interviewed 12 of 14 patients with reduced susceptibility). Additionally, CA and SF collaborated to analyze partner services data from SF and neighboring Bay Area counties, which revealed that 41% of sexual partnerships in a large network of early syphilis cases in the SF-Bay Area region were between persons who resided in different counties, reinforcing the importance of collaborative disease control efforts. In late 2015, STDCB began working

closely with the CDPH Microbial Diseases Laboratory Branch (MDL) to build capacity for GC culture and antimicrobial susceptibility testing (AST). MDL is available to perform whole genome sequencing and provide subject matter expertise on molecular diagnostics. Both CDPH and SFDPH receive funding for the STD Surveillance Network (SSuN) to conduct enhanced population-based GC surveillance.

The *CA-SF GC RDR* leadership team has extensive STD experience. **Dr. Susan Philip, MD, MPH**, the SFDPH PHD Disease Prevention and Control (DPC) Branch Director, and STD Controller for SF, will serve as the SF Principal Investigator for this project. She has over 13 years of experience in STD and HIV clinical care, epidemiology, research and evaluation. Key units in DPC include SFCC, PHL, and all SFDPH DIS staff. **Dr. Trang Nguyen, PhD, MPH** is a senior epidemiologist with extensive knowledge of the STD surveillance and program activities. She will work closely with the *CA-SF GC RDR* staff to meet objectives, assisting them in engaging all key stakeholders and staff to develop and implement the evaluations. **Dr. Mark W. Pandori, PhD, HCLD(ABB)** is the interim Director for PHL. He is a national expert in public health laboratory methods for GC and other STDs, and led many of the PHL innovations in GC testing described above. **Dr. Heidi Bauer, MD, MS, MPH** is the Chief of the CDPH STDCB and will serve as the CDPH Principal Investigator for this project; she has over 15 years of experience in STD prevention program development, epidemiology, research, and evaluation. **Dr. Juliet Stoltey, MD, MPH** is Chief of the Office of Science and Policy and the Public Health Medical Officer of CDPH STDCB; she has expertise in infectious diseases and STDs, 6 years of experience in STD and HIV clinical care, serves as the lead for ARG efforts at STDCB, and will work closely with the *CA-SF GC RDR* staff to meet objectives. **Dr. Vishnu Chaturvedi, PhD** is a board-certified laboratory director for MDL and recognized academic scientist, educator, editor and subject matter expert with an eighteen-year track record in managing people and processes that ensure the highest quality public health laboratory operations.





Strategy 1

Strategy: Strengthen local resistant GC threat coordination and epidemiological capacity

Add New Activity

Strategy 1: New Activity #1

Name (500 Character Maximum):

Designate an epidemiologist coordinator responsible for local resistant GC activities

Implementation Plan (1000 Character Maximum):

The San Francisco Department of Public Health (SFDPH) will define a scope of work and hire a GC Epidemiologist Coordinator (EC). This coordinator will be the primary person responsible for the activities of the CA-SF GC RDR in San Francisco. Additionally, CDPH will hire a Regional GC RDR Coordinator (RDRC). Named partners of SF cases come from both inside and outside SF and historically STD outbreaks in CA have involved multiple independent jurisdictions. Thus, a regional effort is necessary for both capacity building and surveillance to facilitate inter-jurisdictional coordination, data-sharing, and partner follow-up to provide a comprehensive public health infrastructure and capacity for detection and response, and to better characterize sexual transmission networks. This position will provide overall epidemiologic support and coordination with SFDPH and other regional and statewide partners.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Hire SFDPH GC Epidemiology Coordinator	Susan Philip and Trang Nguyen	Aug 2016	Nov 2016
2	Hire CDPH Regional GC RDR Coordinator	Heidi Bauer and Julie Stoltey	Aug 2016	Nov 2016
3			Select One	Select One

Strategy 1: New Activity #2

Name (500 Character Maximum):

Develop flow charts and definitions detailing case reporting, laboratory testing, and epidemiologic investigation and analysis

Implementation Plan (1000 Character Maximum):

The SFDPH GC EC will identify protocols, data systems, and staff associated with GC case reporting, laboratory testing, and epidemiologic investigation and analysis to develop a plan to meet project deliverables. The GC EC will work with key staff to develop the timeline for expanded GC culture and AST to include female and extragenital specimens of SFCC patients, and from the 3rd Street Youth Center and Clinic (a high volume youth clinic primarily serving African Americans in the highest adolescent STD prevalence area). The CDPH Regional GC RDRC will work closely with the SFDPH GC EC

to develop updated workflows that: link to regional GC efforts; facilitate data sharing on partners and for regional and state epidemiologic analyses; and ensure collaboration with other CA GC partners (e.g., Los Angeles). CDPH and SFPDPH will conduct a SF-Bay Area meeting with key local health jurisdiction partners to develop an ARG Regional Strategic Plan that includes best practices for ARG response.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Catalog of existing and newly developed case surveillance, epidemiology, and laboratory protocols with flow charts and definitions	Trang Nguyen until SFPDPH GC Epidemiologist Coordinator hired	Sep 2016	Jul 2017
2	CA-SF GC RDR strategic plan for expansion of GC specimen collection and AST beyond SFCC GISP specimens	SFPDPH GC Epidemiologist Coordinator	Oct 2016	Jul 2017
3	SF-Bay Area ARG Regional Strategic Plan	CDPH Regional GC RDR Coordinator	Oct 2016	May 2017

Strategy 1: New Activity #3

Name (500 Character Maximum):

Hire needed staff (such as surveillance and field epidemiologists, laboratorians, case investigators, and data entry personnel) to support local coordination and capacity

Implementation Plan (1000 Character Maximum):

SFPDPH will additionally hire CA-SF GC RDR: microbiologist responsible for GC culture and AST, developing protocols including expanded culture and testing of new specimen sources and from new media (e.g., InTray from 3rd Street Youth Center and Clinic (YCC)); and 2 health workers to conduct partner services (PS) (one at SFCC, one embedded at 3rd St YCC to develop, implement, and evaluate PS protocols for youth). CDPH will additionally hire CA-SF GC RDR: regional health worker responsible for case investigation and partner follow-up of GC cases with reduced susceptibility outside SF, training and technical assistance to LHJs for investigations on ARG GC cases; and microbiologist to perform AST of GC isolates, communicate results to staff and LHJs, and initiate and coordinate the collection and storage of a repository of ARG isolates. CDPH/SFPDPH will develop training protocols and evaluation methods.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Post and hire SFPDPH positions	Susan Philip and Trang Nguyen	Aug 2016	Feb 2017
2	Post and hire CDPH positions	Heidi Bauer and Julie	Aug 2016	Feb 2017

	Stoltey		
3 CA-SF GC RDR staff training protocols and evaluation plans	SFDPH GC Epidemiologist Coordinator and CDPH Regional GC RDR Coordinator	Nov 2016	Feb 2017

Strategy 1: New Activity #4

Name (500 Character Maximum):

Advance workforce development and training related to rapid response for resistant GC (optional)

Implementation Plan (1000 Character Maximum):

SFDPH and CDPH staff with a role in ARG detection and response must be proficient in continuous quality improvement methods and standardized, applied problem solving. These skills are fundamental to every proposed ARG response activity and will increase SFDPH and CDPH workforce capacity for innovation by teaching standardized problem solving and evaluation to improve efficiency. CA-SF RDR hired and in-kind staff, as well as select SFDPH and CDPH clinicians, laboratorians, and health workers with roles in ARG detection and response, will undergo training on A3 Thinking to learn a common 'language' of problem solving. This method has already been taught at the SFDPH clinics and hospitals that will be partners in expanded GC culture efforts – proving further usefulness of ensuring this standard. Also, the CA STD/HIV Prevention Training Center (CAPTC), DIS Training Center (DISTC) will develop training materials for DIS on rapid response case investigation and partner services of ARG cases.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Final A3 Thinking training schedule, contract, and staff attendee list	Susan Philip with Heidi Bauer	Aug 2016	Jul 2017
2	Identify CDPH or SFDPH staff to attend national STD and microbiology conferences for workforce development	Heidi Bauer and Susan Phillip	Aug 2016	Mar 2017
3	Training materials on rapid response case investigations and field services of ARG cases	CDPH Regional GC RDR Coordinator and CAPTC-DISTC	Oct 2016	Jul 2017

Strategy 2

Strategy: Enhance timely surveillance for detection of resistant GC threats

Strategy 2: New Activity #1

Name (500 Character Maximum):

Establish local lab capacity and protocols for implementing e-test for timely antibiotic susceptibility testing

Implementation Plan (1000 Character Maximum):

In collaboration with the SFDPH GC EC, the SFDPH interim PHL Director Dr. Mark Pandori will work with the newly hired CA-SF GC RDR Microbiologist to update existing protocols for Etest for timely antibiotic susceptibility testing and protocols for providing results to clinicians in short time frames. PHL implemented Etest in 2011 and recently tested approximately 70 isolates per month for all CA GISP sites, but results have not yet been used to inform patient care. Again, the models of change and evaluation the lab staff, epidemiologists and DIS will be trained in will guide how this effort will be designed and evaluated. The CDPH MDL will continue to build capacity to conduct GC culture and AST with Etest. MDL will provide subject matter expertise and serve as a back-up and reference laboratory for additional testing of isolates from SFDPH. MDL will also maintain stock and surveillance cultures of notable ARG isolates for any future testing.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Catalog of existing and necessary protocols for Etest at PHL of SFCC GISP samples	Mark Pandori until SFDPH Microbiologist hired	Aug 2016	Oct 2016
2	Validated GC culture and Etest at CDPH MDL laboratory	Vishnu Chaturvedi until CDPH Microbiologist is hired	Aug 2016	Dec 2016
3	Number of antibiotic-resistant gonorrhea isolates archived at MDL	Vishnu Chaturvedi until CDPH Microbiologist is hired	Aug 2016	Jul 2017

Strategy 2: New Activity #2

Name (500 Character Maximum):

Develop processes for rapid communication of e-test results to surveillance and field epidemiology staff

Implementation Plan (1000 Character Maximum):

Importation of PHL results, including susceptibility data, into ISCHTR occurs routinely. Using the proposed training in standardized, applied problem solving, these processes will be automated and alerts developed to ensure timely use of critical Etest results for action (e.g., case investigation, verification of treatment to evaluate potential treatment failures). In collaboration with the CDPH Regional GC RDRC, the SFDPH GC EC will work with related SFDPH PHL, SFCC, epidemiology staff, and

CDPH staff to develop protocols and templates for rapid reporting of Etest results to appropriate SF and CA health workers and providers. The CDPH Regional GC RDRC will coordinate discussions to facilitate interoperability across SFDPH and CDPH IT systems to ensure seamless state and local data exchange and will work to operationalize real-time data transfer between CDPH MDL information systems and the existing CDPH ARG database.

2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1 Catalog of protocols and templates for rapid reporting of Etest results to SFDPH health workers and local providers	SFDPH GC Epidemiologist Coordinator	Oct 2016	Jul 2017
2 Catalog of protocols and templates for communication of Etest results to CDPH regional health worker and regional providers	CDPH Regional GC RDR Coordinator	Oct 2016	Jul 2017
3 Average turn-around-time for the collection and rapid reporting of ARG data fields from CDPH MDL laboratory information system to CDPH ARG database	CDPH Regional GC RDR Coordinator	Dec 2016	Jul 2017

Strategy 2: New Activity #3

Name (500 Character Maximum):

Increase and improve timeliness of reporting and complete capture of data relevant to antibiotic-resistant GC surveillance and epidemiology in electronic surveillance systems. These may include: treatment date and regimen, anatomic site of infection, gender of sexual partners

Implementation Plan (1000 Character Maximum):

The SFDPH GC EC, in collaboration with the CDPH Regional GC RDRC, will finalize a list of key variables (e.g., treatment date and regimen, anatomic site of infection) to assess and prioritize projects to improve reporting timeliness and completeness, including the evaluation of sending electronic patient and laboratory data messages from providers such as the SFDPH outpatient clinics for importation to ISCHTR. The CDPH Regional GC RDRC will work within CDPH to facilitate SF providers' use of the California integrated communicable disease surveillance system, CalREDIE provider portal for rapid reporting and retrieval of GC treatment, and other relevant clinical data; evaluate a mechanism for rapid data exchange between CalREDIE and ISCHTR, including susceptibility data from PHL and MDL, and case/partner data for PS outside SF; and work to improve completeness of electronic laboratory reporting. This activity is linked to meeting requirements for Strategy 2: Activity #8.

2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
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1	List of key variables for ARG surveillance and epidemiology; timeline for evaluating and finalizing mechanisms to improve data completeness and timeliness	SFDPH GC Epidemiologist Coordinator with IT consultant	Sep 2016	Jul 2017
2	Determine the interoperability between SFDPH and CDPH electronic data systems to facilitate real-time sharing of relevant clinical data fields (i.e., treatment date and regimen, anatomic site of infection, gender of sexual partners)	CDPH Regional GC RDR Coordinator	Oct 2016	Jul 2017
3			Select One	Select One

Strategy 2: New Activity #4

Name (500 Character Maximum):

Establish a plan for expanded collection of GC culture and performance of GC antibiotic susceptibility testing (e.g., collection of specimens from clinical sites outside of the STD clinic, collection of culture from female GC cases, collection of culture from extragenital sites of GC cases)

Implementation Plan (1000 Character Maximum):

The SFDPH GC EC will collaborate with the CDPH Regional GC RDRC to create a timeline and protocols for collecting additional specimens at SFCC from females and extragenital sites (males and females) and at the 3rd Street YCC (with InTray) to attempt to isolate cultures and conduct Etests. During Year 1, SFDPH will increase the number of non-GISP specimens to culture from SFCC and 3rd St YCC, eventually trying to successfully culture isolates from an additional estimated 200 urethral, 50 cervical, 100 pharyngeal, and 100 rectal specimens, based on likely eligible patients using 2015 clinic data. Also, SFDPH will develop mechanisms to identify potential treatment failures and providers to target for expanded GC culture. Analyzing case report data might identify providers who should routinely collect cultures at the original and follow-up GC tests. CDPH MDL will provide GC culture and AST for Bay Area partners named by SF cases.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Number of GC culture and Etest of non-GISP specimens from SFCC and 3rd St YCC	SFDPH GC Epidemiologist Coordinator	Nov 2016	Mar 2017
2	Catalog of protocols for Etest at PHL of SFCC and 3rd St YCC non-GISP specimens	Mark Pandori until SFDPH Microbiologist hired	Jan 2017	Jul 2017
3	Number of GC culture and Etest specimens tested from populations outside SF boundaries	Vishnu Chaturvedi until CDPH Microbiologist is hired	Jan 2017	Jul 2017

Strategy 2: New Activity #5

Name (500 Character Maximum):

Pilot novel approaches to detect resistance in non-STD clinic settings, including but not limited to public health detailing to distribute culture media plates (InTray GC™) to high-volume providers that do not routinely perform culture-based testing due to lab capacity issues.

Implementation Plan (1000 Character Maximum):

CDPH led an evaluation of InTray GC to culture male urethral specimens at SFCC and found that the InTray GC system was 87.5% sensitive for GC culture. SFDPH will collect specimens using InTray GC at the 3rd St YCC, benefitting from lessons learned to create protocols and an evaluation plan. Symptomatic female youth will be initially prioritized for culture; in 2015, 71 GC tests were conducted among symptomatic females ages ≤ 25 (24 GC tests among symptomatic male youth). CA-SF GC RDR staff will analyze the yield of culture by InTray and the proportion of cultures that underwent AST with Etest, using results to plan expansion to other clinics. Additionally, the CDPH Regional GC RDRC will meet with large regional medical groups to discuss InTray GC/AST, and academic partners to explore piloting novel molecular assays to detect GC resistance.

2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1. Eligibility criteria and evaluation plan for GC culture collection using InTray and conducting Etest of 3rd St YCC specimens	SFDPH GC Epidemiologist Coordinator	Nov 2016	Mar 2017
2. Catalog of protocols for InTray specimen collection at 3rd St YCC	Mark Pandori until SFDPH Microbiologist hired	Jan 2017	Jul 2017
3. Number of meetings conducted with regional medical providers to discuss InTray GC and AST	CDPH Regional RDR Coordinator	Oct 2016	Jul 2017

Strategy 2: New Activity #6

Name (500 Character Maximum):

Package and ship specimens per protocols to the appropriate Antibiotic-Resistant Lab Network (ARLN) laboratory for confirmatory agar dilution and molecular characterization, such as whole genome sequencing.

Implementation Plan (1000 Character Maximum):

SFDPH is committed to packaging and shipping of specimens per protocol to the appropriate Antibiotic-Resistant Lab Network (ARLN) laboratory for confirmatory testing and molecular characterization. Having participated in GISP since its inception, SFDPH has extensive experience in preparing inoculated culture plates from SFCC to the PHL for processing and shipment of frozen isolates to regional laboratories. SFDPH will be readily able to update existing protocols for shipment to

an ARLN laboratory for additional testing. While SFDPH will collaborate with CDC and other funded GC RDR sites on finalizing protocols and the proportion or types of specimens to send to an ARLN laboratory, SFDPH has estimated the proportion of GISP and non-GISP cultures from SFCC and 3rd St YCC that will be isolated and available for shipment to the ARLN, and its related costs. SFDPH will also package and ship a small number of isolates to CDPH MDL for additional reference testing.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Shipment protocols to ARLN	SFDPH GC Epidemiologist Coordinator	Oct 2016	Jul 2017
2	Number of PHL staff trained on ARLN shipment protocols	SFDPH Microbiologist	Dec 2016	Jul 2017
3			Select One	Select One

Strategy 2: New Activity #7

Name (500 Character Maximum):

Electronically submit associated data to ARLN for addition of whole genome sequencing data, and for ultimate submission to CDC.

Implementation Plan (1000 Character Maximum):

Having a longstanding history of sending associated GC case and laboratory data to CDC as part of the GISP protocol, SFDPH will be readily able to update existing protocols and programming for electronic submission of required data to ARLN. SFDPH anticipates collaborating with CDC and other funded GC RDR sites on protocols and definitions. SFDPH will also continue to submit data to CDPH, per current protocols.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Data definitions and protocols for required GC RDR data to send to ARLN and CDC	SFDPH GC Epidemiologist Coordinator	Oct 2016	Jul 2017
2	Data programming to send associated data to ARLN and CDC	SFDPH GC Epidemiologist Coordinator	Dec 2016	Jul 2017
3			Select One	Select One

Strategy 2: New Activity #8

Name (500 Character Maximum):

Enhance local health department capacity to appropriately record antibiotic susceptibility testing data

(e.g., date of test, test type, and MIC results by drug tested) in the state/local information system.

Implementation Plan (1000 Character Maximum):

Given its experience with Etest, the SFDPH PHL has a database for capturing all relevant AST data. These data were routinely uploaded and stored in ISCHTR. GISP results from the regional GISP laboratory are sent to SFDPH and stored in ISCHTR. The PHL database and ISCHTR will be evaluated and enhanced for interoperability and facile data exchange with CDPH as discussions with CDC and CDPH about testing and results variables lead to definitions and protocols for data-entry and quality assurance to implement. CDPH and SFDPH will evaluate mechanisms for sharing these data readily with surveillance and DIS. AST results will be added to existing state electronic laboratory reported data streams. Relevant ARG data fields (e.g., MIC) will be added to CalREDIE, and the existing CDPH ARG data system. CDPH will lead data system interoperability efforts across ISCHTR, CalREDIE, MDL laboratory information system and existing CDPH ARG database (in alignment with meeting Strategy 2: Activity #3).

2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1 Updated database used by PHL for Etest and other AST results	SFDPH GC Epidemiologist Coordinator	Oct 2016	Mar 2017
2 AST results added to ELR data streams; relevant project data fields added to CalREDIE	CDPH Regional GC RDR Coordinator	Oct 2016	Jul 2017
3 Determine the interoperability between SFDPH and CDPH data systems to facilitate real-time data sharing of relevant laboratory data fields (i.e., date of test, test type, and MIC results by drug tested)	CDPH Regional GC RDR Coordinator	Oct 2016	Jul 2017

Strategy 2: New Activity #9

Name (500 Character Maximum):

Evaluate time-to-clearance among persons tested and treated for GC who return for a test-of-cure (optional)

Implementation Plan (1000 Character Maximum):

San Francisco City Clinic has experience implementing an evaluation of GC molecular test of cure in men who have sex with men. Existing experience, protocols, and remaining questions will be built upon in future years of this grant to expand the evaluation of GC time to clearance in youth, females, and heterosexual males. Additional clinical sites would be considered within San Francisco and in other CA public health STD clinics (e.g., Orange County, San Diego). In addition, AST with Etest would also be considered to address correlation between time to clearance and antibiotic susceptibility profile. The

CDPH Regional GC RDR Coordinator would be responsible for planning the evaluation and coordinating with SF and other clinical sites in Year 1, to pursue the evaluation in subsequent project years.

2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1 List of potential additional clinical sites within San Francisco to participate in time-to-clearance evaluation	SFDPH GC Epidemiologist Coordinator	Feb 2017	Jul 2017
2 GC time-to-clearance project plan	CDPH Regional GC RDR Coordinator	Nov 2016	Jul 2017
3		Select One	Select One

Strategy 3

Strategy: Enhance GC case investigations to identify transmission dynamics of emerging resistant GC threats

Strategy 3: New Activity #1

Add New Activity

Name (500 Character Maximum):

With CDC guidance, funded sites will draft and implement an unified case investigation guide for resistant GC cases or GC cases with reduced susceptibility that encompasses areas of interest (e.g., travel history, anatomic sites of exposure)

Implementation Plan (1000 Character Maximum):

Based on the combination of the long history of SFDPH and CDPH participation in SSuN, SFDPH experience in interviewing GISP/Etest alert cases, and a CDPH draft protocol and instrument for ARG case investigation, CA-SF GC RDR will contribute extensive lessons learned and best practices to discussions with CDC and other RDR funded sites to finalize a unified case investigation guide for resistant GC cases or GC cases with reduced susceptibility. Our historic data collection from patients with GC, particularly with those who were contacted because of a GISP/Etest alert, will inform discussions on the quality and completeness of variables of interest, as well as how best to discuss public health concerns about antibiotic resistance in order to maximize the potential for new ARG cases to provide high quality information. The unified case investigation guide will be shared and built upon at a planned regional Bay Area meeting of ~20 key state and LHJ partners working on GISP and ARG efforts.

2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
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1	Data tables of relevant SFDPH SSuN and GISP data variables to inform discussion on a unified case investigation guide for resistant GC cases or GC cases with reduced susceptibility	SFDPH GC Epidemiologist Coordinator	Nov 2016	Jan 2017
2	Data tables of relevant CDPH SSuN and GISP data variables to inform discussion on a unified case investigation guide for resistant GC cases or GC cases with reduced susceptibility	CDPH Regional GC RDR Coordinator	Nov 2016	Jan 2017
3	Unified GC ARG case investigation guide	SFDPH GC Epidemiologist Coordinator and CDPH Regional GC RDR Coordinator	Nov 2016	Jul 2017
4			Select One	Select One
5			Select One	Select One

Strategy 3: New Activity #2

Name (500 Character Maximum):

Rapidly (within 2 days) interview all GC cases found through laboratory diagnostics or clinical presentation (e.g. unsuccessful treatment) to be infected with a strain of reduced-susceptibility GC.

Implementation Plan (1000 Character Maximum):

In San Francisco through 2015, all patients found to have an MIC above a GISP or Etest alert value were assigned for further interview, assessment of travel and antibiotic use, re-testing and partner notification. In 2015, all 14 cases with GISP alert values were assigned for interview within 24 hours; 10 of 14 cases were interviewed within 7 days, 4 of which were interviewed within 2 days. Local protocols will be evaluated and compared to CA GISP interview protocols to identify mechanisms that could be evaluated to increase timeliness and completeness of interviews. The CDPH regional health worker will rapidly interview all ARG cases that reside outside SF. Case assignment will initially begin with GC cases with reduced susceptibility or antibiotic resistance, but productivity and completeness of interviews will be continually monitored to determine how best to prioritize assigning other GC cases for interview (e.g., by gender of sex partner, HIV status, history of STD).

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Protocol for alerting staff of any cases requiring CA-SF GC RDR case investigation and partner services	Trang Nguyen until SFDPH GC Epidemiologist Coordinator hired	Aug 2016	Jul 2017

2	Evaluation plan to assess different modalities for CA-SF GC RDR case investigation and partner services	SFDPH GC Epidemiologist Coordinator and CDPH GC RDR Coordinator	Oct 2016	Jan 2017
3	Proportion of ARG cases residing in SF that were interviewed within 2 days among total number of ARG cases in SF	SFDPH Health Workers	Oct 2016	Jul 2017
4	Proportion of ARG cases residing outside of SF referred to CDPH regional health worker for interview within 2 days among total number of cases that reside outside of SF that are referred to the CDPH health worker for interview	CDPH Regional GC RDR Coordinator	Oct 2016	Jul 2017
5	Proportion of ARG cases residing outside SF that were interviewed within 2 days of assignment among total number of ARG cases residing outside SF that were assigned	CDPH Regional Health Worker	Oct 2016	Jul 2017

Strategy 3: New Activity #3

Name (500 Character Maximum):

Conduct investigations of sexual and social contacts and develop methods for describing social and sexual networks of interviewed cases.

Implementation Plan (1000 Character Maximum):

SFDPH has extensively enhanced its DIS program to integrate STD and HIV priorities and outcomes. Existing PS protocols for the CA-SF GC RDR will be enriched with CDPH expertise from other successful LHJ PS protocols. SFDPH will also develop a PS protocol for partners of youth at 3rd St YCC. Case and partner data are stored in ISCHTR in a way that has enabled actionable analysis of sexual networks. SFDPH will evaluate and enhance the way susceptibility and partnership data are collected, stored, and analyzed to assess different methods for describing social and sexual networks of GC cases. The CDPH regional health worker will provide PS for ARG cases outside SF, and CA and SF will build on existing expertise and analyses to characterize the regional sexual networks in order to enhance collaborative disease control efforts.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Partner services protocol for GC cases with reduced susceptibility or antibiotic-resistant strains within SF	Trang Nguyen until SFDPH GC Epidemiologist Coordinator	Aug 2016	Feb 2017

2	Evaluation of ISCHTR data needs for enhancing social and sexual network analysis of GC cases with reduced susceptibility or antibiotic-resistant strains; updated data collection and routine analysis (ensuring continuous quality improvement) of social and sexual networks of GC cases with reduced susceptibility or antibiotic-resistant strains	Trang Nguyen until SFDPH GC Epidemiologist Coordinator	Aug 2016	Jul 2017
3	Proportion of interviews of partners of ARG cases that reside in SF among total number of partners of ARG cases identified in SF	SFDPH Health Workers	Nov 2016	Jul 2017
4	Partner services protocol for GC cases with reduced susceptibility or antibiotic-resistant strains outside SF, and across the SF-Bay Area Region	CDPH Regional GC RDR Coordinator	Oct 2016	Feb 2017
5	Proportion of interviews of partners of ARG cases that reside outside of SF among total number of partners of ARG cases identified outside of SF	CDPH Regional Health Worker	Nov 2016	Jul 2017

Strategy 3: New Activity #4

Name (500 Character Maximum):

Analyze phenotypic susceptibility testing, sociodemographic, risk behavior, and whole genome sequencing data (where available) concurrently to improve understanding of local GC epidemiology and transmission dynamics of emerging resistant GC threats.

Implementation Plan (1000 Character Maximum):

Existing SFDPH and CDPH systems will be updated to store Etest and ARLN data, including whole genome sequencing. SFDPH and CDPH will develop analytic plans in collaboration with CDC to determine the data elements and methods that will be useful to improving the local and regional epidemiology and transmission dynamics of emerging ARG threats. Because most GC patients for whom ARG data are available will have been identified through SFCC, we will have a rich dataset of sociodemographic and risk behavior data collected through medical care visits. Those patients able to be interviewed will have provided additional detail about risk behaviors, sexual partnerships, travel history, recent antibiotic use and meeting locations that will enrich the analyses. We anticipate having laboratory STD testing and AST results and sociodemographic data from a proportion of named contacts that we are able to reach, interview, and test, through SFDPH or CDPH PS and any MDL reference testing.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	List of data that will be reported from ARLN and added to local data systems	SFDPH GC Epidemiologist Coordinator	Jan 2017	Jul 2017
2	Analysis plan and draft table shells for SF epidemiology of emerging GC resistance	SFDPH GC Epidemiologist Coordinator and CDPH	Mar 2017	Jul 2017
3	Analysis plan and draft table shells for SF-Bay Area regional epidemiology of emerging GC resistance	Regional GC RDR Coordinator in collaboration with regional bay area counties	Mar 2017	Jul 2017
4			Select One	Select One
5			Select One	Select One

Strategy 3: New Activity #5

Name (500 Character Maximum):

Report all antibiotic susceptibility results and awardee-required variables to state health department and CDC and all susceptibility results demonstrating reduced susceptibility to state health department and CDC within 24 hours of testing.

Implementation Plan (1000 Character Maximum):

SFDPH has an extensive history with reporting data to CDPH and CDC in different formats, with reports using different visualizations and layouts (e.g., line lists, table summaries, pivot tables), and utilizing various mechanisms (e.g., CDC Secure Access Management Services, NETSS, CDPH secure file transfer), often in automated or routine modalities. ISCHTR already stores antibiotic susceptibility results provided by the regional GISP laboratory and Etest results from PHL. SFDPH routinely sends associated GC case and laboratory data to CDC as part of the GISP protocol. SFDPH will be readily able to update ISCHTR fields and update/prepare protocols and programming for electronic submission of required data to CDPH and CDC. SFDPH and CDPH will collaborate with CDC and other funded GC RDR sites to finalize unified protocols and definitions, which has been done as part of SSuN collaborative discussions.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Data definitions and protocols for reporting of required antibiotic susceptibility test results and awardee-required variables to CDPH and CDC	SFDPH GC Epidemiologist Coordinator	Oct 2016	Jul 2017

2	Protocols and data programming to submit required case and susceptibility data to CDPH and CDC electronically within 24 hours of testing	SFDPH GC Epidemiologist Coordinator	Dec 2016	Jul 2017
3			Select One	Select One
4			Select One	Select One
5			Select One	Select One

Evaluation and Performance Measurement Strategy

Required performance measures for the project period are listed within this project's guidance in the 'CDC Evaluation and Performance Management Strategy' section. These are measures that awardees will be expected to report on in next year's progress report. The table below provides an opportunity for you to provide any baseline data that you may have – you are not expected to have data for all of these measures.

Strategy 2) Enhance timely surveillance for detection of resistant GC threats	
Number of trained personnel who can perform E-Test.	
Number of viable, non-viable, and contaminated specimens received by the local laboratory.	Viable: Non-Viable: Contaminated:
Number of isolates tested for antimicrobial resistance within proficiency standards.	
Number of clinical settings submitting specimens for antimicrobial resistance testing.	
Days from specimen collection to receipt at laboratory, from receipt at laboratory to e-Test completion, and from e-Test completion to report to clinician and local health department within the awardee-required timeframe.	Collection to Receipt: Receipt to E-Test Completion: E-Test Completion to Report:
Number and percentage of isolates found to have reduced susceptibility or resistance to antibiotics tested.	(Number) (%)
Number and percentage of GC lab reports received at the local health department through ELR with awardee-required	(Number) (%)

variables	
Strategy 3) Enhance GC case investigations to identify transmission dynamics of emerging resistant GC threats	
Number of reported GC cases to local health department with complete awardee-required demographic, epidemiologic and clinical variables.	3726
Number and percentage of resistant GC cases, GC cases with reduced susceptibility or GC treatment failure cases investigated within the awardee-required timeframe.	12 (Number) 92% (%)
Number and percentage of sexual and social contacts investigated of cases unidentified in #2 within the awardee-required timeframe.	0 (Number) 0% (%)
Number and percentage of isolates demonstrating reduced cephalosporin susceptibility reported to the state health department and CDC within 24 hours of testing	0 (Number) 0% (%)

Please describe the applicant's plan and ability to collect the necessary data and report on each of the measures listed in the guidance.

The *CA-SF GC RDR* proposal is poised to address CDC's evaluation and performance measures. SFDPH already has extensive experience in integrating both qualitative and quantitative data from epidemiological analyses, clinical preventive and testing services, field services, and case interviews to evaluate and improve programs, data collection, and surveillance. Baseline data for some of the requested performance measures are provided to reflect SFDPH's current capacity to meet project objectives.

SFDPH and CDPH will prepare a list of qualified personnel hired or retained to support grant activities to meet Strategy 1.

SFDPH and CDPH will report on metrics to demonstrate how this work has enhanced timely surveillance for detection of resistant GC threats to meet Strategy 2. As part of GISP, SFDPH and CDPH have had to routinely report evaluation and performance metrics similar to the ones requested for this strategy. A table of recently reported SF GISP process measures is provided as an example:

Table 1. Example SF GISP Process Measures	Jan 1– Dec 31, 2014 No./%	Jan 1– June 30, 2015 No./%
Number of SF isolates submitted to the GISP regional laboratory	322 (74%)	160 (79%)
Percentage of submitted SF isolates that were found by the GISP regional laboratory to be non-viable or contaminated	1 (0.3%)	0 (0%)
Percentage of monthly SF isolate batches that were shipped to the GISP regional laboratory within one week after the end of monthly collection	2 (33%)	1 (17%)
Percentage of monthly SF demographic/clinical data transmissions that were submitted to CDC within one month of the completion of specimen collection	100%	100%
Percentage of collected SF isolates for which the following data elements were reported:		
Gender of sex partner/sexual orientation	98%	99%
HIV status	98%	93%
Treatment	89%	97%

Evaluation of performance metrics for Strategy 3, enhancing GC case investigations to identify transmission dynamics of emerging resistant GC threats, will be readily and routinely conducted using existing fields in ISCHTR, which can be seamlessly modified to account for any additional metrics required by CDC. Because ISCHTR integrates STD surveillance data with electronic medical record data from SFCC, field investigations, and all STD testing conducted by the PHL, data can be extracted from ISCHTR to evaluate data by STD test, person, or isolate. CDPH data systems (CalREDIE and the existing ARG database) will be modified to account for any requested evaluation metrics that are not accounted for by existing data fields.

SFDPH and CDPH will plan to monitor and report, as requested by ELC/CDC. SFDPH and CDPH will collaborate with ELC/CDC on the development of additional performance measurements, as appropriate.



Edwin M. Lee
Mayor

Barbara A. Garcia, MPA
Director of Health

TO: Angela Calvillo, Clerk of the Board of Supervisors

FROM: Barbara A. Garcia, MPA
Director of Health *[Signature]*

DATE: November 10, 2016

SUBJECT: Grant Accept and Expend

GRANT TITLE: Epidemiology and Laboratory Capacity Gonorrhea Rapid Detection and Response Project- \$598,052.66

Attached please find the original and 2 copies of each of the following:

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

Special Timeline Requirements:

Departmental representative to receive a copy of the adopted resolution:

Name: Richelle-Lynn Mojica Phone: 255-3555

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

Certified copy required Yes

No

Introduction Form

By a Member of the Board of Supervisors or the Mayor

Time stamp
or meeting date

I hereby submit the following item for introduction (select only one):

- 1. For reference to Committee. (An Ordinance, Resolution, Motion, or Charter Amendment)
- 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 [redacted] inquires"
- 5. City Attorney request.
- 6. Call File No. [redacted] from Committee.
- 7. Budget Analyst request (attach written motion).
- 8. Substitute Legislation File No. [redacted]
- 9. Reactivate File No. [redacted]
- 10. Question(s) submitted for Mayoral Appearance before the BOS on [redacted]

2017 JAN 20 PM 2:03
 inquires"
 [Handwritten initials]

Please check the appropriate boxes. The proposed legislation should be forwarded to the following:

- Small Business Commission Youth Commission Ethics Commission
- Planning Commission Building Inspection Commission

Note: For the Imperative Agenda (a resolution not on the printed agenda), use a Imperative Form.

Sponsor(s):

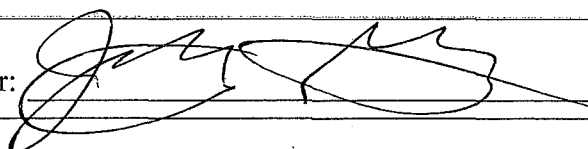
Supervisor Sheehy

Subject:

Accept and Expend Grant- Epidemiology and Laboratory Capacity Gonorrhoea Rapid Detection and Response Project- \$598,052.66

The text is listed below or attached:

Resolution authorizing the San Francisco Department of Public Health to retroactively accept and expend a grant in the amount of \$598,052.66 from Public Health Foundation Enterprises, Inc. to participate in a program entitled Epidemiology and Laboratory Capacity Gonorrhoea Rapid Detection and Response Project for the period of August 1, 2016, through July 31, 2017.

Signature of Sponsoring Supervisor: 

For Clerk's Use Only:

