

**FDP Amendment
Number**

Pass-Through Entity (PTE) **Subrecipient**

The Regents of the University of California, San Francisco	Entity Name	City and County of San Francisco
CGSubOutTeam@ucsf.edu	Email Address	osr_intake@stanford.edu
George W. Rutherford	Principal Investigator	William McFarland

Project Title:

PTE Federal Award No: <input type="text" value="5 NU2GGH002170-02-00"/>	Federal Awarding Agency: <input type="text" value="Other PHS Centers for Disease Control"/>
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Revised Period of Performance: Start Date: <input type="text" value="September 30, 2019"/> End Date: <input type="text" value="Sep 29, 2020"/>	Amount Funded This Action: <input type="text" value="\$ 70,196.00"/>	Subaward No: <input type="text" value="11580sc"/>
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Total Amount of Federal Funds Obligated to Date: <input type="text" value="\$ 81,731.00"/>	Cost Share: <input type="radio"/> Yes <input checked="" type="radio"/> No	Subject to FFATA: <input checked="" type="radio"/> Yes <input type="radio"/> No	Automatic Carryover: <input type="radio"/> Yes <input checked="" type="radio"/> No
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Amendment(s) to Original Terms and Conditions
This Amendment revises the above-referenced Subaward Agreement as follows:

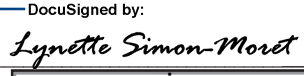
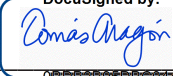
- This is a No Cost Extension. The Period of Performance is hereby extended through:
- to is hereby added to the Period of Performance, which is revised to be consistent with the Period of Performance Start and End Date above.
- Additional funds in the amount of are hereby authorized for the current period.
- Carryover in the amount of is hereby authorized as shown below.
- Other (see below)

NOTE: As of September 30, 2019 the previous subaward 11408sc has changed to a new subaward number 11580sc. All invoices for the project period September 30, 2019 through September 29, 2020 must reference this new subaward number.

The Scope of Work is modified to include those tasks in Attachment A to this Amendment.

For clarity: all amounts stated in this amendment are in United States Dollars.

All other terms and conditions of this Subaward Agreement remain in full force and effect.

By an Authorized Official of PTE: DocuSigned by:  <input type="text" value="Lynette Simon-Moret"/> <input type="text" value="10/21/2019"/> Name: <input type="text" value="Lynette Simon-Moret"/> Date Title: <input type="text" value="Subcontract Officer, RMS"/>	By an Authorized Official of Subrecipient: DocuSigned by:  <input type="text" value="Tomas Aragon"/> <input type="text" value="10/17/2019"/> 7:51 PM Name: <input type="text" value="Tomas Aragon"/> Date Title: <input type="text" value="Director of Population Health Division"/>
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ATTACHMENT A

SFDPH Subcontract

Scope of Work

- 1. Name of Contractor:** San Francisco Department of Public Health (SFDPH)
- 2. Award Budget Period:** 09/30/2019 – 9/29/2020
- 3. Subcontract Performance Period:** 09/30/2019 – 9/29/2020
- 4. Scope of Work:** In close collaboration with UCSF, SFDPH will provide technical assistance and capacity building for rollout of HIV recency in multiple countries, including Burundi, Cambodia, Kenya, Malawi, Namibia, Thailand/Laos, Uganda, Vietnam, and Zambia.

San Francisco Department of Public Health Subcontract
Budget Period: 9/30/2019-9/29/2020
Budget Name: Recency Revised Budget

A. Salaries and Wages

Personnel	Position Title	Current Salary	% effort	# mos.	(A) Salary	(B) Benefits	Total
McFarland, Willi	Director of Surveillance	\$192,300	25%	12	\$48,075	\$14,600	\$62,675
							\$0
Total Personnel				25%	\$48,075	\$14,600	\$62,675

Total Direct Costs

Overhead at 12%

Grand Total

\$62,675

\$7,521

\$70,196

SFDPH Subcontract

Award Budget Period: 09/30/2019 – 9/29/2020

Budget Justification:

Personnel:

Willi, McFarland, *Director of Surveillance*, has several years of experience working on surveillance in general and key populations, in both domestic and international settings. He will provide high-level technical assistance on surveillance strategy for HIV recency. We request 25% (\$48,075) salary support for this position for 12 months.

Subaward Fringe Benefit and Indirect Cost Rates:

The fringe benefit rate is calculated as 30.37% of Willi McFarland' salary (\$14,600).

The indirect cost rate is 12% of total direct expenses (\$7,521).

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
CDC Office of Financial Resources**

2939 Brandywine Road
Atlanta, GA 30341

NOTICE OF AWARD
AUTHORIZATION (Legislation/Regulations)
301(A)&307PHA42USC241&242&104 22USC151B

1. DATE ISSUED MM/DD/YYYY 08/13/2019		1a. SUPERSEDES AWARD NOTICE dated except that any additions or restrictions previously imposed remain in effect unless specifically rescinded	
2. CFDA NO. 93.067 - Global AIDS			
3. ASSISTANCE TYPE Cooperative Agreement			
4. GRANT NO. 5 NU2GGH002170-02-00 Formerly		5. TYPE OF AWARD Service	
4a. FAIN NU2GGH002170		5a. ACTION TYPE Non-Competing Continuation	
6. PROJECT PERIOD MM/DD/YYYY From 11/01/2018		Through MM/DD/YYYY 09/29/2023	
7. BUDGET PERIOD MM/DD/YYYY From 09/30/2019		Through MM/DD/YYYY 09/29/2020	
8. TITLE OF PROJECT (OR PROGRAM) Recent Infection Surveillance Consortium			

9a. GRANTEE NAME AND ADDRESS
Regents of the University of California, San Francisco, The
3333 California St
-DUP2
San Francisco, CA 94118-1981

9b. GRANTEE PROJECT DIRECTOR
Dr. George1147948 Rutherford
3333 California Street
San Francisco, CA 94118
Phone: +1 415 476-5781

10a. GRANTEE AUTHORIZING OFFICIAL
Lei-Lei Win
1855 Folsom St Ste 425
San Francisco, CA 94103-4249
Phone: 415-987-1540

10b. FEDERAL PROJECT OFFICER
Ms. Emily Stong
12 Corporate Blvd NE
Brookhaven, GA 30329-1909
Phone: 404.718.8292

ALL AMOUNTS ARE SHOWN IN USD

11. APPROVED BUDGET (Excludes Direct Assistance)	
I Financial Assistance from the Federal Awarding Agency Only	
II Total project costs including grant funds and all other financial participation I	
a. Salaries and WageS	1,989,607.00
b. Fringe Benefits	821,079.00
c. Total Personnel Costs	2,810,686.00
d. Equipment	0.00
e. Supplies	147,829.00
f. Travel	228,689.00
g. Construction	0.00
h. Other	941,396.00
i. Contractual	1,098,977.00
j. TOTAL DIRECT COSTS	5,227,577.00
k. INDIRECT COSTS	1,283,261.00
l. TOTAL APPROVED BUDGET	6,510,838.00
m. Federal Share	6,510,838.00
n. Non-Federal Share	0.00

12. AWARD COMPUTATION	
a. Amount of Federal Financial Assistance (from item 11m)	6,510,838.00
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	6,510,838.00
13. Total Federal Funds Awarded to Date for Project Period	10,364,838.00

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

YEAR	TOTAL DIRECT COSTS	YEAR	TOTAL DIRECT COSTS
a. 3		d. 6	
b. 4		e. 7	
c. 5		f. 8	

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

a. DEDUCTION b. ADDITIONAL COSTS c. MATCHING d. OTHER RESEARCH (Add / Deduct Option) e. OTHER (See REMARKS)	b
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16. THIS AWARD IS BASED ON AN APPLICATION SUBMITTED TO, AND AS APPROVED BY, THE FEDERAL AWARDING 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 program legislation
 b. The grant program regulations.
 c. This award notice including terms and conditions, if any, noted below under REMARKS.
 d. Federal administrative requirements, cost principles and audit 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)

GRANTS MANAGEMENT OFFICIAL:

Percy Jernigan
2936 Brandywine Rd
Mailstop K75
Atlanta, GA 30341-5504
Phone: 770.488.2811

17.OBJ CLASS 41.51	18a. VENDOR CODE 1946036493A6	18b. EIN 946036493	19. DUNS 094878337	20. CONG. DIST. 12
FY-ACCOUNT NO.	DOCUMENT NO.	ADMINISTRATIVE CODE	AMT ACTION FIN ASST	APPROPRIATION
21. a. 9-9390BJD	b. 19NU2GGH002170	c. GH	d. \$0.00	e. 75-19-1822-1031-001
22. a. 9-9390BKV	b. 19NU2GGH002170	c. GH	d. \$0.00	e. 75-19-1822-1031-001
23. a. 9-9390A1	b. 19NU2GGH00217019KECO	c. GH	d. \$200,000.00	e. 75-19-1721-1031-001

NOTICE OF AWARD (Continuation Sheet)

PAGE 2 of 2	DATE ISSUED 08/13/2019
GRANT NO. 5 NU2GGH002170-02-00	

FY-ACCOUNT NO.	DOCUMENT NO.	ADMINISTRATIVE CODE	AMT ACTION FIN ASST	APPROPRIATION
24.a. 9-9390BEF	b. 19NU2GGH00217019UGCO	c. GH	d. \$100,000.00	e. 75-1920-0955
25.a. 9-9390BHJ	b. 19NU2GGH00217019MWCO	c. GH	d. \$130,000.00	e. 75-19-1822-1031-001
26.a. 9-9390BHM	b. 19NU2GGH00217019NACO	c. GH	d. \$250,000.00	e. 75-19-1822-1031-001
27.a. 9-9390BHZ	b. 19NU2GGH00217019VNCO	c. GH	d. \$180,838.00	e. 75-19-1822-1031-001
28.a. 9-9390BJ0	b. 19NU2GGH00217019ZACO	c. GH	d. \$400,000.00	e. 75-19-1822-1031-001
29.a. 9-9390BL0	b. 19NU2GGH00217019ACCO	c. GH	d. \$50,000.00	e. 75-19-1822-1031-001
30.a. 9-9390BY2	b. 19NU2GGH002170	c. GH	d. \$5,200,000.00	e. 75-19-1519-1031-001

Direct Assistance

BUDGET CATEGORIES	PREVIOUS AMOUNT (A)	AMOUNT THIS ACTION (B)	TOTAL (A + B)
Personnel	\$0.00	\$0.00	\$0.00
Fringe Benefits	\$0.00	\$0.00	\$0.00
Travel	\$0.00	\$0.00	\$0.00
Equipment	\$0.00	\$0.00	\$0.00
Supplies	\$0.00	\$0.00	\$0.00
Contractual	\$0.00	\$0.00	\$0.00
Construction	\$0.00	\$0.00	\$0.00
Other	\$0.00	\$0.00	\$0.00
Total	\$0.00	\$0.00	\$0.00

AWARD ATTACHMENTS

Regents Of The University Of California, San Francisco, The

5 NU2GGH002170-02-00

1. UCSF terms 2019
2. Component breakdown
3. TR Part 1
4. TR Part 2

Incorporation: In addition to the federal laws, regulations, policies, and CDC General Terms and Conditions for Non-research awards at <https://www.cdc.gov/grants/federalregulationspolicies/index.html>, the Centers for Disease Control and Prevention (CDC) hereby incorporates Notice of Funding Opportunity (NOFO) number **GH19-1942**, entitled **Public Health Surveillance of Recent HIV Infection and Response under the President's Emergency Plan for AIDS Relief (PEPFAR)**, and application dated May 6, 2019, as may be amended, which are hereby made a part of this Non-research award, hereinafter referred to as the Notice of Award (NoA).

Approved Funding: Funding in the amount of **\$27,000,000.00** is approved for the **Year 02** budget period, which is September 30, 2019 through September 29, 2020. All future year funding will be based on satisfactory programmatic progress and the availability of funds.

The federal award amount is subject to adjustment based on total allowable costs incurred and/or the value of any third party in-kind contribution when applicable.

Available Funding: The CDC approves Component funding for components A. As a result, some components of the total approved funding amounts are approved but unfunded. Funding in the amount of **\$6,510,838.00** in Financial Assistance (FA) is awarded on this NoA.

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

Component/Project Funding: The NOFO provides for the funding of multiple components under this award. The approved component funding levels for this notice of award are:

NOFO Component	Amount
Component 1 September	\$ 6,510,838.00
Component 2 Q1 COP	\$ 949,950.00
Component 3 Q2 COP	\$ 423,250.00
Component 4 Q3 COP	\$ 363,250.00
Component 5 Q4 COP	\$ 320,000.00
Component 6 Burundi COP	\$ 700,000.00
Component 7 Asia Region Performance	\$ 200,000.00
Component 8 Performance Expansion Q1	\$ 5,000,000.00
Component 9 Performance Expansion Q2	\$ 5,000,000.00
Component 10 Performance Expansion Q3	\$ 7,532,712.00

NOTE: Please see attachment for detailed breakdown of components.

Financial Assistance Mechanism: Cooperative Agreement

Substantial Involvement by CDC: This is a cooperative agreement and CDC will have substantial programmatic involvement after the award is made. Substantial involvement is in addition to all post-award monitoring, technical assistance, and performance reviews undertaken in the normal course of stewardship of federal funds.

CDC program staff will assist, coordinate, or participate in carrying out effort under the award, and recipients agree to the responsibilities therein, as detailed in the NOFO.

Technical Review Statement Response Requirement: The review comments on the strengths and weaknesses of the proposal are provided as part of this award. A response to the weaknesses in these statements must be submitted to and approved, in writing, by the Grants Management Specialist/Grants Management Officer (GMS/GMO) noted in the CDC Staff Contacts section of this NoA, no later than 30 days from the budget period start date. Failure to submit the required information by the due date, October 31, 2019, will cause delay

Budget Revision Requirement: By October 31, 2019 the recipient must submit a revised budget with a narrative justification. 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 CDC Staff Contacts section of this notice before the due date.

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

Deduction alternative: Under this alternative, program income is deducted from total allowable project/program costs to determine the net allowable costs on which the federal share of costs is based. This is similar to an applicable credit being applied to reduce the amount of the federal award.

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

Cost sharing or matching alternative: Under this alternative, program income is used to finance some or the entire non-federal share of the project/program.

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

FUNDING RESTRICTIONS AND LIMITATIONS

Human Subjects Restriction(s): Human Subjects restrictions apply to this current budget period only and do not apply to carryover of unobligated funding from a prior budget year. All continuation activities and budget items will be reviewed by the Office of Associate Director for Science every budget period, and applicable restrictions will be enforced during that budget period.

This **Continuation** application proposes **\$27,000,000** of funding for activities in support of the above-mentioned project.

In addition to service provision, this application includes support for potential data collection from persons, personal records, or for laboratory specimen collection and testing that may result in public dissemination. Of the total approved budget **\$214,290**, shall be restricted until protocols describing the activities below have been submitted to CDC DGHT-Atlanta for scientific/technical review and review of institutional human subjects protection considerations.

A. Restriction ID Number: **HQ-19-002170-21**

Restricted Activity: Implementation of Recent Infection Surveillance - Vietnam

Page(s): 25 (narrative)

Restriction Amount: \$35,715

Cost Category: Indirect Cost

B. Restriction ID Number: **HQ-19-002170-22**

Restricted Activity: Implementation of Recent Infection Surveillance - Vietnam

Page(s): 25 (narrative)

Restriction Amount: \$35,715

Cost Category: Direct Cost

C. Restriction ID Number: **HQ-19-002170-23**

Restricted Activity: Implementation of Recent Infection Surveillance - Cambodia

Page(s): 26 (narrative)

Restriction Amount: \$35,715

Cost Category: Indirect Cost

Restricted Activity: Implementation of Recent Infection Surveillance - Cambodia

Page(s): 26 (narrative)

Restriction Amount: \$35,715

Cost Category: Direct Cost

E. Restriction ID Number: **HQ-19-002170-25**

Restricted Activity: Implementation of Recent Infection Surveillance - Burundi

Page(s): 27 (narrative)

Restriction Amount: \$35,715

Cost Category: Indirect Cost

F. Restriction ID Number: **HQ-19-002170-26**

Restricted Activity: Implementation of Recent Infection Surveillance - Burundi

Page(s): 27 (narrative)

Restriction Amount: \$35,715

Cost Category: Direct Cost

All funding restrictions placed on potential data collection activities involving human subjects must be resolved no later than the end of this budget year. Data collection protocols required to release funding restrictions placed on potential data collection activities involving human subjects must be submitted to the DGHT Science Integrity Branch for review within 6 months of receiving the Notice of Award. Exceptions to these deadlines will need to be submitted in writing to the Office of Financial Resources (OFR) Grants Management Officer. If any of the restricted activities have received local IRB approval, an IRB-exempt determination, or an institutional non-research determination please submit the approval documentation with the protocol to the **Headquarters** CDC DGHT Office.

When all necessary CDC approvals have been obtained for a restricted activity, please submit a copy of the approval(s) along with a release of Human Subjects Data Collection Restriction Release Request Form to your OFR Grants Management Specialist via email.

Note 1: If funds for preparatory activities (e.g., protocol development, training, equipment, reagents, and site preparation) were not included in the application, these funds may be provided prior to protocol approval. To request funds for preparatory activities please submit a narrative describing the activities along with a release of Human Subjects Data Collection Restriction Release Request Form to your OFR Grants Management Specialist via email.

Note 2: If the restricted activity is a part of routine clinic or program operations, or laboratory quality assurance that will not result in public dissemination, please submit a narrative justification along with a release of Human Subjects Data Collection Restriction Release Request Form and country approval to your OFR Grants Management Specialist via email. Protocol approval is not required for these activities.

Note 3: Restricted funds shall not be withdrawn until approval is received and the restrictions have been lifted by an amended notice of award. Conducting any restricted activities without receiving CDC approval will result in enforcement action, which may require repayment of expended funds.

Note 4: With regard to scientific conference attendance, as stated in the Notice of Funding Opportunity, "IPs with accepted oral posters or oral abstracts for presentations that give clear attribution to PEPFAR may be authorized to use PEPFAR funds for travel providing that funds are available for travel. Funds for travel must be drawn from an existing agreement with the IP and not from PEPFAR country program management and operations budget. IPs must obtain prior approval from their respective Project Officer for participation and on availability and use of funds." Please note that use of cooperative agreement funds to attend scientific conferences by non-presenters and non-oral poster presenters is not authorized, except by Partner Government Officials with approval of the PEPFAR Deputy Principals through the process outlined in the Notice of Funding Opportunity.

To obtain the Human Subjects Data Collection Restriction Release Request Form, or for more information on releasing human subjects data collection restrictions, contact the

Indirect costs: Indirect costs are based on the negotiated indirect cost rate agreement dated October 6, 2017. The rates in this agreement are to be used for the entire project period, including any approved extensions, in accordance with 45 CFR Part 75, Appendix III. Indirect cost/facilities and administration rates for subcontracts will be treated in the same manner as those for the recipient, if the subcontractor is covered by 45 CFR Part 75, Appendix III.

Foreign Taxes: Pursuant to applicable grant regulations, foreign taxes charged for the purchase of goods or services that a non-federal entity is legally required to pay in country are an allowable expense under federal awards. For purposes of this term, foreign taxes include value-added taxes (VAT), customs duties, and other similar charges levied on any transaction financed by HHS/CDC award funds in furtherance of program activities and objectives as set forth in the funding agreement, which may include the purchase, import, use or re-export of goods or services.

The determination of whether such foreign taxes are an allowable expense will depend on whether an exemption or effective reimbursement mechanism exists in country. Effective reimbursement is defined as a reimbursement mechanism that provides for no less than substantial reimbursement of USG funds. Generally such exemptions or rights to reimbursement are set forth in bilateral or other legal agreements between the United States Government (USG) and the host country.

1. **Countries where an exemption or right to reimbursement exists:**

In countries where a bilateral or other legal agreement sets forth an exemption, the recipient must take advantage of the exemption and may not pay taxes with award funds. If, however, the host country implements the exemption through a reimbursement mechanism, the recipient may pay the taxes with award funds but must request and receive the reimbursement, as those expenses are deemed an unallowable expense under the award. If the reimbursement mechanism is used, recipients should consult with the CDC project officer and the CDC grants management specialist to determine how the reimbursed funds should be handled. If reimbursement is requested but not received from the host country despite significant effort, so long as recipient provides sufficient documentation showing efforts to seek reimbursement to the CDC grants management specialist, the foreign tax payment will be an allowable expense.

2. **Countries where no exemption and/or no right to reimbursement exist:**

In countries where a) there is no bilateral or other legal agreement in force setting forth either an exemption or a right to reimbursement, b) a bilateral or other legal agreement is in force but does not provide for an exemption or a right to reimbursement, the recipient may pay foreign taxes with award funds. Such payments would be deemed allowable expenses.

3. **Countries where a specific bilateral agreement between the US and the host country (e.g., 1951 Bilateral Agreement between the US and the UK applicable to former UK territories; 1989 bilateral between the US and Swaziland) applies (Bahamas, India, Kenya, Suriname, Swaziland, Trinidad and Tobago, and Zambia):**

Consistent with the bilateral agreement, this Notice of Grant Award represents the implementing agreement required by the bilateral agreement for tax purposes. Pursuant to the specific bilateral agreement in force, the host country has agreed that USG funds (e.g., HHS/CDC funds, PEPFAR funds) provided to and utilized by recipient, as it carries out the program activities and objectives set forth in this implementing agreement, shall be free from taxes imposed under laws in effect in the host country. These tax exemptions on USG funds include, but are not limited to, the following:

a. Taxes, customs duties, and other similar charges levied on any transaction financed by HHS/CDC award funds in furtherance of program activities and objectives as set forth in this agreement, which may include the purchase, import, use or re-export of goods or services, including value-added taxes (VAT). Goods include, but are not limited to, commodities, equipment and supplies, including automobiles, which

have been imported for the purpose of the funded program activities and objectives.
 c. Recipient shall pay taxes on the income of the organization on income allowed by HHS/CDC to be derived from HHS/CDC funding of program activities and objectives set forth in this agreement.

- c. Taxation on personal income paid from HHS/CDC funds to employees of Recipient who pay taxes on their income to the United States Government; and
- d. Should any conflict or disagreement about the above exemptions arise, Recipient agrees to promptly notify CDC (project officer or grants management officer) to work to resolve such matters, guided by the principle that the funding furnished by HHS/CDC is free from taxation.

Prostitution and Sex Trafficking (Items 1 through 6):

1. Consistent with Section 7631(e) of the U.S. Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, 22 USC §§ 7601 et seq. (“the Leadership Act”), the U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons. None of the funds made available under this agreement may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.
2. Additionally, consistent with Section 7631(f) of the Leadership Act, a prime recipient that is a non-U.S. nongovernmental organization acknowledges that, by accepting this award, it agrees that it is opposed to the practices of prostitution and sex trafficking because of the psychological and physical risks they pose for women, men, and children.
3. Contractors and subcontractors are exempt from the above requirements if the contract or subcontract is for commercial items and services as defined in FAR 2.101, such as pharmaceuticals, medical supplies, logistics support, data management, and freight forwarding.
4. Notwithstanding the contract exemption above, not exempt from these provisions are recipients, subrecipients, contractors, and subcontractors that implement HIV/AIDS programs under this assistance award, any subaward, or procurement contract or subcontract by:
 - i. Providing supplies or services directly to the final populations receiving such supplies or services in host countries;
 - ii. Providing technical assistance and training directly to host country individuals or entities on the provision of supplies or services to the final populations receiving such supplies and services; or
 - iii. Providing the types of services listed in FAR 37.203(b)(1)-(6) that involve giving advice about substantive policies of a recipient, giving advice regarding the activities referenced in (i) and (ii), or making decisions or functioning in a recipient’s chain of command (e.g., providing managerial or supervisory services approving financial transactions, personnel actions).
5. Subrecipients
 - i. Prime recipient shall insert the following provision in subawards or subcontracts: “None of the funds made available under this agreement may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.”
 - ii. Prime recipients shall insert the following provision in subawards or subcontracts subject to Section 7631(f) (i.e., those to non-U.S. nongovernmental organizations): “By accepting this award, the subrecipient/ subcontractor agrees that it is opposed to the practices of prostitution and sex trafficking because of the psychological and physical risks they pose for women, men, and children.”

The following definitions apply for purposes of the above provisions:

- i. "Commercial sex act" means any sex act on account of which anything of value is given to or received by any person.
- ii. "Prostitution" means procuring or providing any commercial sex act and the "practice of prostitution" has the same meaning.
- iii. "Sex trafficking" means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act. 22 U.S.C. 7102(9).

This provision includes express terms and conditions of the award and any violation of it shall be grounds for unilateral termination of the award by (HHS OPDIV) prior to the end of its term.

Any enforcement of this provision is subject to courts' orders in *Alliance for Open Society International v. USAID* (See, e.g., S.D.N.Y. 05 Civ. 8209, Orders filed on January 30, 2015 and June 6, 2017, granting permanent injunction).

Special Provision for HHS Protecting Life in Global Health Assistance is applicable to this award. In accordance with the United States *Protecting Life in Global Health Assistance* policy, a non-governmental organization (NGO) recipient of this award acknowledges that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. The link to the full text is at:

<https://www.cdc.gov/grants/federal-regulations-policies/index.html>

REPORTING REQUIREMENTS

Performance Progress and Monitoring: Performance information collection initiated under this grant/cooperative agreement has been approved by the Office of Management and Budget under **OMB Number 0920-1132 "Performance Progress and Monitoring Report", Expiration Date 8/31/2019.** The components of the PPMR are available for download at: <https://www.cdc.gov/grants/alreadyhavegrant/Reporting.html> .

Reporting of Foreign Taxes: The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) of 2011 (United States foreign assistance funds). Outlined below are the specifics of this requirement:

- a. Annual Report. The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at \$500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 - September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]
- b. Quarterly Report. The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at \$500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.
- c. Terms: For purposes of this clause:
 - i. Commodity means any material, article, supplies, goods, or equipment;
 - ii. Foreign government includes any foreign government entity;

iii. Foreign taxes means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.

- d. Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.
- e. Contents of Reports. The reports must contain:
 - i. recipient name;
 - ii. contact name with phone, fax, and e-mail;
 - iii. agreement number(s) if reporting by agreement(s);
 - iv. reporting period;
 - v. amount of foreign taxes assessed by each foreign government;
 - vi. amount of any foreign taxes reimburse by each foreign government;
 - vii. amount of foreign taxes unreimbursed by each foreign government.
- f. Sub-agreements. The recipient must include this reporting requirement in all applicable subgrants and other sub-agreements.

Required Disclosures for Federal Awardee Performance and Integrity Information System (FAPIS):

Consistent with 45 CFR 75.113, applicants and recipients must disclose in a timely manner, in writing to the CDC, with a copy to the HHS Office of Inspector General (OIG), all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Subrecipients must disclose, in a timely manner in writing to the prime recipient (pass through entity) and the HHS OIG, all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Disclosures must be sent in writing to the CDC and to the HHS OIG at the following addresses:

CDC, Office of Grants Services
Percy Jernigan, Grants Management Officer/Specialist
Centers for Disease Control and Prevention
Global Health Services Branch

Page 9 of 12

2920 Brandywine Road
Atlanta, Georgia 30341
Fax: 770-488-2688
Email: ibj7@cdc.gov

AND

U.S. Department of Health and Human Services
Office of the Inspector General
ATTN: Mandatory Grant Disclosures, Intake Coordinator
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201

Fax: (202)-205-0604 (Include "Mandatory Grant Disclosures" in subject line) or
Email: MandatoryGranteeDisclosures@oig.hhs.gov

Recipients must include this mandatory disclosure requirement in all subawards and contracts under this award.

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371. Remedies for noncompliance, including suspension or debarment (See 2 CFR parts 180 and 376, and 31 U.S.C. 3321).

CDC is required to report any termination of a federal award prior to the end of the period of performance due to material failure to comply with the terms and conditions of this award in the OMB-designated integrity and performance system accessible through SAM (currently FAPIS). (45 CFR 75.372(b)) CDC must also notify the recipient if the federal award is

PROGRAM OR FUNDING GENERAL REQUIREMENTS

PEPFAR Branding: All PEPFAR-funded programs or activities must adhere to PEPFAR branding guidance, which includes guidance on the use of the PEPFAR logo and/or written attribution to PEPFAR. PEPFAR branding guidance can be found at <http://www.pepfar.gov/reports/guidance/branding/index.htm>

PAYMENT INFORMATION

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

Payment Management System Subaccount: Funds awarded in support of approved activities have been obligated in a subaccount in the PMS, herein identified as the "P Account". Funds must be used in support of approved activities in the NOFO and the approved application.

The grant document number identified on the bottom of Page 1 of the Notice of Award must be known in order to draw down funds.

Document Number: 19NU2GGH00217019ACCO – Cambodia

19NU2GGH00217019KECO – Kenya

19NU2GGH00217019MWCO – Malawi

19NU2GGH00217019VNCO – Vietnam

19NU2GGH00217019ZACO – Zambia

19NU2GGH00217019UGCO – Uganda

19NU2GGH00217019NACO – Namibia

19NU2GGH002170 - HQ

Exchange Rate: All requests for funds contained in the budget, shall be stated in U.S. dollars. Once an award is made, CDC may not compensate foreign recipients for currency exchange fluctuations through the issuance of supplemental awards.

CDC Staff Contacts

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.

GMS Contact:

Global Health Services Branch
2920 Brandywine Road
Atlanta, Georgia 30341
Telephone: 770-488-2811
Fax: 770-488-2688
Email: ibj7@cdc.gov

Program/Project Officer: The PO is the federal official responsible for monitoring the programmatic, scientific, and/or technical aspects of grants and cooperative agreements, as well as contributing to the effort of the award under cooperative agreements.

Programmatic Contact:

Emily Stong, Project Officer
Centers for Disease Control
Telephone: 404.718.8292
Email: wrs8@cdc.gov

Grants Management Officer: The GMO is the federal official responsible for the business and other non-programmatic aspects of grant awards. The GMO is the only official authorized to obligate federal funds and is responsible for signing the NoA, including revisions to the NoA that change the terms and conditions. The GMO serves as the counterpart to the business officer of the recipient organization.

GMO Contact:

Dionne Bounds, Grants Management Officer
Centers for Disease Control and Prevention
Global Health Services Branch
2920 Brandywine Road
Atlanta, GA 30341
Telephone: 770-488-2082
Fax: 770-488-2688
Email: Dbounds@cdc.gov

COMPONENT BREAKDOWN APPROVED BY PROJECT OFFICER

Budget Category	Component 1 September currently available	Component 2 Q1 COP approved but unfunded	Component 3 Q2 COP approved but unfunded	Component 4 Q3 COP approved but unfunded	Component 5 Q4 COP approved but unfunded	Component 6 Burundi COP approved but unfunded	Component 7 Asia Region Performance approved but unfunded	Component 8 Performance Expansion Q1 approved but unfunded	Component 9 Performance Expansion Q2 Approved but unfunded	Component 10 Performance Expansion Q3 Approved but unfunded	Total Approved Budget
Salaries & Wages	\$1,989,607	\$275,394	\$108,780	\$88,080	\$79,830	\$0	\$20,016	\$0	\$0	\$0	\$2,561,707
Fringe Benefits	\$821,079	\$65,063	\$24,153	\$19,958	\$19,958	\$0	\$0	\$0	\$0	\$0	\$950,211
Consultant Service	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Equipment	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Supplies	\$147,829	\$78,750	\$82,250	\$82,250	\$12,250	\$0	\$0	\$0	\$0	\$0	\$403,329
Travel Costs	\$228,689	\$28,630	\$24,345	\$21,265	\$21,265	\$0	\$5,910	\$0	\$0	\$0	\$330,104
Alterations and Renovations	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Other Costs	\$941,396	\$80,473	\$27,935	\$25,069	\$25,069	\$600,613	\$0	\$3,863,216	\$3,863,216	\$6,395,928	\$15,822,915
Consortium/Contractual Cost	\$1,098,977	\$280,000	\$50,560	\$50,560	\$101,120	\$0	\$155,231	\$0	\$0	\$0	\$1,736,448
Total Direct Costs	\$5,227,577	\$808,310	\$318,023	\$287,182	\$259,492	\$600,613	\$181,157	\$3,863,216	\$3,863,216	\$6,395,928	\$21,804,714
Indirect Costs	\$1,283,261	\$141,640	\$105,227	\$76,068	\$60,508	\$99,387	\$18,843	\$1,136,784	\$1,136,784	\$1,136,784	\$5,195,286
Total Approved Budget	\$6,510,838	\$949,950	\$423,250	\$363,250	\$320,000	\$700,000	\$200,000	\$5,000,000	\$5,000,000	\$7,532,712	\$27,000,000

COUNTRY BREAKDOWN OF AVAILABLE COMPONENT

Object Class Breakdown	HQ	Cambodia	Kenya	Malawi	Namibia	Uganda	Vietnam	Zambia
Salary and Wages	\$ 1,662,527	\$ 17,250	\$ 79,830	\$ -	\$ 123,000	\$ 45,750	\$ 61,250	
Fringe Benefits	\$ 755,438	\$ 3,496	\$ 19,958	\$ -	\$ 30,750	\$ 11,437	\$ -	
Travel	\$ 158,567	\$ 2,567	\$ 21,265	\$ 23,440	\$ 5,840	\$ 6,420	\$ 10,590	
Equipment		\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
Supplies	\$ 29,991	\$ 23,750	\$ 12,250	\$ -	\$ 2,000	\$ 2,250	\$ 77,588	
Contractual	\$ 601,090	\$ -	\$ -	\$ 97,887	\$ -	\$ -	\$ -	\$ 400,000
Construction		\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
Other	\$ 859,423	\$ 2,388	\$ 25,069		\$ 36,197	\$ 13,149	\$ 5,170	
Total Direct Charges	\$ 4,067,036	\$ 49,451	\$ 158,372	\$ 121,327	\$ 197,787	\$ 79,006	\$ 154,598	\$ 400,000
Indirect Costs	\$ 1,132,964	\$ 549	\$ 41,628	\$ 8,673	\$ 52,213	\$ 20,994	\$ 26,240	
Grand Total	\$ 5,200,000	\$ 50,000	\$ 200,000	\$ 130,000	\$ 250,000	\$ 100,000	\$ 180,838	\$ 400,000

Continuation Application Technical Review Form

CDC Country Offices:

To accommodate the changing extramural landscape and provide a better planning tool, PBEMB has made changes to the Technical Review form. Below please find definitions that explain the fields that have been revised and/ or changed. Please contact your PBEMB CoAg Specialist for any additional questions or assistance with this or other forms.

Definitions for the Technical Review Form

If the application requests funding from separate sources, please indicate the recommended funding level for each funding source. For example, if an application requests continuation and carryover funds, please list the funding levels separately.

	Recipient	Previously referred to as “grantee”, this is the new term that HHS is officially using for our partners and it is reflected throughout this form.
Page 2: General CoAg Information	Object Class Code	For non-research awards, use 41.51 For research awards, use 41.41
	CFDA Number	Catalog of Federal Domestic Assistance Number: 93.067 (HIV) 93.947 (TB)
	Amount Requested By Recipient:	Dollar amount the recipient requested in their application based on the solicitation
Page 2: Funding Information	(a.) Approved Budget Period Ceiling <i>Add (b.) + (c.) + (d.):</i>	Approved ceiling amount for entire current budget period (available + future funding + offset). This does not include carryover funding. This amount should include the currently available amount and is normally equal to or less than the amount requested by the recipient. If you intend to approve more than the recipient has requested, a revised budget will be required.
	(b.) Available Funding	Currently available funds that the Country or HQ Branch will award for this action. This amount CANNOT exceed the budget period ceiling.
	(c.) Offset	These funds have not been spent by the recipient and are deducted from the amount of new funding awarded to the recipient. Recipients must be aware of the plan to use offset before it is applied to their budget.
	(d.) Future Funding Amount <i>Subtract (a.) - (b.) - (c.):</i>	Amount of funding remaining in the budget period ceiling to be awarded, dependent on the availability of funds and/or performance.
	(e.) Total Approved Budget for this Action <i>Add (b.) + (c.):</i>	The total budget that the recipient will receive for this action, which includes the available funding and offset.
	Applicable Funding Components	The components approved under the current action based on the recipient’s SF424 Section B component funding request.
Page 2: CAN Information	Funding Source	For all non-COP funding being included on this action, please be sure to specify the funding source.

Continuation Application Technical Review Form

GENERAL COAG INFORMATION

Type of Action under Review: <i>Check all that apply</i> <input checked="" type="checkbox"/> Year <u>2</u> Continuation, including: <input type="checkbox"/> Carryover <input type="checkbox"/> Offset <input type="checkbox"/> Neither, new funding only	Country or HQ Branch:	Multiple
	Recipient:	UCSF
	NOFO #:	GH19-1942
	CoAg Award #:	GH002170
	Object Class Code:	<input checked="" type="checkbox"/> 41.51 <input type="checkbox"/> 41.41
	CFDA Number:	<input checked="" type="checkbox"/> 93.067 <input type="checkbox"/> 93.947
	Amount Requested by Recipient:	\$ 27,000,000.00

FUNDING INFORMATION

	Amount	
(a.) Approved Budget Period Ceiling <i>Add (b.) + (c.) + (d.):</i>	\$ 27,000,000	
(b.) Available New Funding	\$ 6,510,838	Applicable Funding Components:
(c.) Offset:	\$	Identify Budget Year 01-04 of which offset funds are from:
(d.) Future Funding Amount <i>Subtract (a.) - (b.) - (c.):</i>	\$ 20,600,000	Applicable Funding Components:

(e.) Total Approved Budget for this Action <i>Add (b.) + (c.):</i>	\$ 6,510,838
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CAN INFORMATION

Financial Account (CAN)	Amount	Funding Source (COP, Central Initiative, HOP/TLS, non-DGHT). Please specify for non-COP!
9390BL0	\$ 50,000	Cambodia
9390BY2	\$ 5,200,000	HQ
93909A1	\$ 200,000	Kenya
9390BHJ	\$ 130,000	Malawi
	\$	

Approval of Application

Approve Application (Please answer the questions below)

1. Are there any special conditions for the award, including budgetary restrictions? Yes No

If yes, please indicate conditions or restrictions in the budgetary and/or recommendations section.

2. Is a response to weaknesses by the recipient required to be in the Notice of Award? Yes No

3. Should a copy of the Technical Review be included in the Notice of Award? Yes No

(NOTE: This should be YES for all continuation applications.)

DGHT/PEPFAR FUNDING ONLY:

COP/ HOP MECHANISM ID #: 81074, 81712, 81751

Are these activities approved in the COP/HOP? Yes No

If no, PBEMB will hold the award pending the country's submission of an email approval from the OGAC Chair or PPM or receipt of final approved HOP.

Are these activities receiving funds outside the COP (i.e., Central Initiative, HOP/TLS)? Yes No

If yes, please identify the project here: HOP

Emily Stong

Print Name of Project Officer

Signature of Project Officer

Date

Valerie Naglich

Print Name of Country Director/HQ Branch Chief or Designee

Signature of Country Director/HQ Branch Chief or Designee

Date

COP 2019 BUDGET INFORMATION (should match COP19 FAST)

In the table below please include the budget details for COP19 for this mechanism. This information should match what is in the FAST, regardless of what is being awarded now or what will be funded in future components. Only include those central initiative funds that were included in the COP19 FAST submission.

(A) Current New Funding	
(B) Applied Pipeline Amount	
Total Planning Level COP 19 (A+B) and (a+b+c+d+e+f)	
(a) Care & Treatment (C&T)	
(b) Prevention (PREV)	
(c) Testing (HTS)	
(d) Social Economic (SE)	
(e) Above-Site Program (ASP)	
(f) Program Management (PM)	
Other Central Initiative Funding (included in COP19 FAST)	

IMPORTANT: As a reminder, during the COP Implementation Period (01 October to 30 September annually), it is expected that total country COP-related outlays over this period will not exceed the total funding level stated with the signed Approval Memo. Consequently, each individual implementing partner outlay over this period should not exceed the amounts programmed to the partner as approved and documented in the COP. Partner budgets may include funding sources that are additive to COP funds (central initiative funding noted above). These other funding sources are not subject to the same outlay restrictions.

COP19 Target Information (compare to FAST/Data Pack)

In the space below please include all relevant targets for COP19 for this mechanism. Performance on the targets listed below will be tracked in COP19 and if achievement is not on track, DGHT will work with OGS to initiate corrective actions, if necessary.

Review of Application

OGAC has provided an optional Key Activities Summary template that should be used if specific references to key activities are not clear in the work plan. This template is NOT required, but you are advised to reference page numbers and specifically note strengths, weaknesses, and recommendations for those key activities here.

Strengths of Application:

(Please use bullets and reference your comments with page numbers from the application)

Cambodia: Application demonstrates that partner has expertise and experience implementing the recency assay.

Kenya: The application lays out many of the key approaches required for implementation of recency surveillance in Kenya. In particular, on page 32, the application describes the various important steps required for the collection of high quality data and making that data available for public health decision-making. It is helpful to explicitly include the role for the development and implementation of continuous quality improvement.

The application also positively lays out the need to work with MOH officials to interpret and strategize on the use of recency surveillance data, and foresees the role of UCSF in ensuring complete and accurate reporting of these new indicators to the MER.

Malawi

- Planned monthly quality improvement visits to each site and QI dashboards
- Planned training for MOH officials on use of data - this will support MOH engagement and ownership of the recency surveillance activity
- Support for development of response strategy document for MOH - this is a priority for MOH and given that this is a new surveillance system, they will need a lot of support in terms of response
- Plans to develop dashboards which show real-time recency data

Weaknesses of Application:

(Please use bullets and reference your comments with page numbers from the application)

Overall

- **Cross-cutting TA (Activity 10 & 12):** Add activity: organizing workshops, in partnership with ICAP and CDC, for stakeholders in countries supported by UCSF, including data analysis and use workshop, report-writing/manuscript-writing workshops, and regional workshops for country sharing.
- **Country TA (Activities 1-9):** In addition to data reviews and building capacity of MOH officials on data use, we would like for UCSF to provide TA to MOHs to assist with production of semi-annual reports of recent infection surveillance. Please add as indicator/output “semi-annual reports from MOH” for countries that will have collected 6 months of recency data by year 2 of the award (e.g., Malawi, Namibia, Uganda, Zambia, Kenya, Vietnam). After the first semi-annual report in a country, annual reports will be expected.
- **Sub-contract to SFDPH:** Please provide more detail for activities and outputs associated with the SFDPH sub-contract referenced on pg. 72 (Willi McFarland for 35% salary for high level technical assistance on surveillance strategy for HIV recency).

Cambodia:

The description of the proposed activities with accompanying budget are limited. But based on the listed activities, **we request the following:**

1. The amount of HIV Rapid Tests for Recent Infection (RTRI) be increased to 5000 kits to cover approximately 4000 newly identified PLHIV cases annually with an additional 1000 kits to allow for training, quality control and wastage.
2. UCSF to develop the protocol to define use of the recency assay. UCSF will need to respond promptly to comments from all relevant ethics committees to get the protocol approved. CDC will provide detail on The Cambodian context for the protocol and will provide the translation into Khmer.
3. UCSF to develop study tools and materials, including questionnaires, consent forms, checklists, and Standard Operating Procedures (SOPs) for the implementation of the recency assay. CDC will provide detail on the Cambodian context for the protocol and will provide the translation into Khmer.
4. Along with CDC and the Cambodian Ministry of Health (MoH) UCSF should co-facilitate field team trainings on laboratory, data, and HTS procedures including:
 - a. Dissemination workshop for all MoH key players including national programs, provincial and district program directors, managers, coordinators and NGOs partners to orientate the use of recent infection surveillance.
 - b. Training of trainers (TOT) for national and provincial level staff members
 - c. Note, through a separate Cooperative Agreement with the National Center for HIV Dermatology and STD (NCHADS), the MoH conduct stepdown training for field staff at the site level in conjunction with trainers who were trained through TOT. NCHADS will also provide regular monitoring to track the quality of service provision and data, and will print the tools and other materials.
5. UCSF to conduct a monitoring and evaluation visit at the end of the first year to assess success of recency assay implementation and areas for improvement.
6. UCSF to plan to attend periodic partner meetings during the period of implementation by conference call although the frequency will need to be determined (and may not be bi-weekly as noted in the proposal).

Recommended Actions for Weaknesses of Application:

(Please use bullets and reference your comments with page numbers from the application)

Overall

- The SOW should include, "procurement, as needed, for all PEPFAR-supported countries working on Recency."
- **Cross-cutting TA (Activity 10 & 12):** Add activity: organizing workshops, in partnership with ICAP and CDC, for stakeholders in countries supported by UCSF, including data analysis and use workshop, report-writing/manuscript-writing workshops, and regional workshops for country sharing.
- **Country TA (Activities 1-9):** In addition to data reviews and building capacity of MOH officials on data use, we would like for UCSF to provide TA to MOHs to assist with production of semi-annual reports of recent infection surveillance. Please add as indicator/output "semi-annual reports from MOH" for countries that will have collected 6 months of recency data by year 2 of the award (e.g., Malawi, Namibia, Uganda, Zambia, Kenya, Vietnam). After the first semi-annual report in a country, annual reports will be expected.
- **Sub-contract to SFDPH:** Please provide more detail for activities and outputs associated with the SFDPH sub-contract referenced on pg. 72 (Willi McFarland for 35% salary for high level technical assistance on surveillance strategy for HIV recency).

Adjust YR2 EPMP template to reflect updated SOW, and submit quarterly.

Work with CDC to obtain CDC logo permission, and include on eLearning Hub and materials. Ensure proper attribution on site.

Cambodia: Please revise budget and narrative application in line with comments in the 'Weaknesses' section.

Additionally;

- Increase the number trips and decrease the duration of each trip. Suggest 3-4 trips of 6-7 days duration at the beginning of the trainings, after 6 months, and after 1 year for a monitoring and evaluation visit. The MOH will not have a "Kick-Off meeting" given the recency assay has been in limited use already, so please consider focusing these trips on working level objectives. Also, CDC Cambodia cannot support \$8,000 for one round trip plane ticket. Please decrease the amount or remove.
- Because Cambodia does not report MER targets and the MoH will manage the data collection and reporting, reduce the proportion of time for the Data Systems Analyst or replace with salary and benefits support for staff to help with training and development of tools (e.g. protocol, SOPs, and job aids).
- Increase the budget for test kit procurement to approximately \$25K given the need for 5,000 kits.

Kenya

- For Activity 3, p 32, please describe that UCSF will work with the county team to support the roll out of recent infection surveillance in all 47 counties in Kenya, per OGAC's expectation that recency surveillance will be a nation-wide tool. It is reasonable to assume that the saturation of counties in terms of number of facilities involved in recency surveillance will differ markedly.
- For Activity 3, p 32, under specific activities, please omit the procurement and shipping of rapid tests for recent infection from the description of activities and describe alternate activities required for roll-out of recency surveillance, such as training of facility-level staff who will recruit, counsel, consent and collect information from recency surveillance participants, and facility-level laboratory staff who will collect the specimen and package it to the hub lab for further analysis, as well as development of Standards of Practice for these activities.
- For Activity 3, p 32, under specific activities please include hub laboratories in the description of CQI activities, as this is where the RTRI activities will be conducted.

Review of Annual Progress Report (APR)

Strengths of Annual Progress Report:

(Please use bullets and reference your comments with page numbers from the application)

Weaknesses of Annual Progress Report:

(Please use bullets and reference your comments with page numbers from the application)

Recommended Actions for Weaknesses of Annual Progress Report:

(Please use bullets and reference your comments with page numbers from the application)

Programmatic Budgetary Comments

Note: Programmatic budget restrictions, concerns, and comments should be addressed prior to the award being made. This will take place during the OGS Budget negotiations.

Marked-Up Budget Certification (select one)

This box signifies the Project Officer's official review of the applicant's proposed budget. This check box applies to all awards with new funding. PBEMB will consider a Technical Review to be incomplete if this box is left unchecked.

The recommended budget should be outlined in the GMM Budget Markup Spreadsheet for funding actions.

I certify that I support the recipient's proposed categorical budget submitted in this application as it relates to the technical aspects of the project. No changes are required and no restrictions are recommended.

I wish to make changes to the recipient's proposed categorical budget.

- If additional space is needed to justify the recommended funding amount, please use this space below to provide detailed comments for the recipient:

(Please use bullets and reference your comments with page numbers from the recipient budget)

Programmatic Restrictions:

Indicate programmatic restrictions in table below (if applicable): Do not put potential human subjects or IRB restrictions or conditions in this section:

PLEASE NOTE BEFORE COMPLETING RESTRICTIONS:

- Recipients are not always funded at the level of the approved budget period ceiling, generally due to delays in CDC's receipt of funds. As such, **do not penalize recipients for not completing unfunded activities.**
- When possible, the response to TR should be used as a management tool, as opposed to restricting funds. **Funds should only be restricted when absolutely necessary.**
- **REMEMBER:** Only include programmatic restrictions that should be put in place for the funding components that will be awarded at this time. If future restrictions are needed, they can be added once future funding components are awarded.

Object Classification	Programmatic Restriction Amount
Personnel	\$
Fringe Benefits	\$
Travel	\$
Equipment	\$
Supplies	\$
Contractual	\$
Facilities/Construction	\$
Other	\$
Total	\$0

If additional space is needed to justify the programmatic restrictions, please use this space below to provide detailed comments for the recipient:

(Please use bullets and reference your comments with page numbers from the recipient budget)

Potential Human Subject Data Collection Activities (DGHT ONLY)

This section highlights the Country Office’s technical review and recommendations for potential human subject/data collection activities. CDC DGHT Science Integrity Branch (SIB) will consider these comments/recommendations when reviewing this application. The only human subjects data collection restrictions that will be included in the NGA are those listed in the official memo from the DGHT Science Integrity Branch (SIB).

Use the checkboxes below to indicate whether the application includes any potential data collection activities involving human subjects. These activities can include, but are not limited to, program evaluation, interviews, focus groups, surveys, assessments, surveillance, review/extraction of data from patient records, and lab testing of specimens beyond routine clinical management.

- Application **includes** plans for potential data collection activities involving human subjects
 - Do any of these activities have the necessary CDC protocol approval(s)?
 - No** Note: Funds for implementing potential data collection activities that may result in a public report should be restricted until all necessary institutional protocol approvals have been obtained.¹ Please specify the restrictions in **Table I below**.
 - Yes** Note: Activities with CDC protocol approval should not be restricted. Provide details in **Table II below** and include an electronic copy of the CDC protocol approval related to the data collection activity listed in the application when returning this form to PBEMB.
- Application **does not include** plans for potential data collection activities involving human subjects. Note: No further information is required.

Table I. Proposed Data Collection Activities Potentially Involving Human Subjects

Activity Description (Type of Activity/Study Population)	Page(s)	Proposed Restriction Amount ² <i>(If activity is for programmatic purposes and will not result in a public report, please list \$0)</i>	Budget Category <i>(i.e., Salary, Travel, Contracts, Supplies, etc.)</i>	Comments
1.		\$		
2.		\$		
3.		\$		
4.		\$		
5.		\$		
6.		\$		
7.		\$		
8.		\$		
9.		\$		
10.		\$		

Table II. Human Subjects Data Collection Activities Already Approved by CDC

A copy of the CDC protocol approval (e.g., CGH Project Determination form signed by the CGH Human Research Protection Coordinator, a copy of CDC IRB approval memo) must be included when this technical review is returned to PBEMB. If no CDC approval document is provided, funds for implementing the activity will be restricted.

Activity Description (Type of Activity/Study Population)	Page(s)	Attached CDC Protocol Approval	Comments
1.			
2.			
3.			
4.			
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10.			

Recipients engaged in human subjects research should be notified that they may need to apply to the U.S. Office for Human Research Protections for a Federal-Wide Assurance (FWA). An FWA is a pledge by an institution that they will adhere to ethical principles when engaged in research activities involving human subjects.

¹ If the activity is strictly for programmatic purposes and will not result in a public report, funds should not be restricted. Provide an activity description and page number, but list \$0 in the Proposed Restriction Amount column.

² Funds for preparatory activities (e.g., protocol development, training, equipment, reagents, and site preparation) may be provided prior to protocol approval. To facilitate the availability of preparatory funding, specify a restriction only on funds associated with implementation, and make a note of the preparatory budget in the comments column.

Signature of Country ADS or ADS POC

Continuation Application Technical Review Form

CDC Country Offices:

To accommodate the changing extramural landscape and provide a better planning tool, PBEMB has made changes to the Technical Review form. Below please find definitions that explain the fields that have been revised and/ or changed. Please contact your PBEMB CoAg Specialist for any additional questions or assistance with this or other forms.

Definitions for the Technical Review Form

If the application requests funding from separate sources, please indicate the recommended funding level for each funding source. For example, if an application requests continuation and carryover funds, please list the funding levels separately.

	Recipient	Previously referred to as “grantee”, this is the new term that HHS is officially using for our partners and it is reflected throughout this form.
Page 2: General CoAg Information	Object Class Code	For non-research awards, use 41.51 For research awards, use 41.41
	CFDA Number	Catalog of Federal Domestic Assistance Number: 93.067 (HIV) 93.947 (TB)
	Amount Requested By Recipient:	Dollar amount the recipient requested in their application based on the solicitation
	(a.) Approved Budget Period Ceiling <i>Add (b.) + (c.) + (d.):</i>	Approved ceiling amount for entire current budget period (available + future funding + offset). This does not include carryover funding. This amount should include the currently available amount and is normally equal to or less than the amount requested by the recipient. If you intend to approve more than the recipient has requested, a revised budget will be required.
Page 2: Funding Information	(b.) Available Funding	Currently available funds that the Country or HQ Branch will award for this action. This amount CANNOT exceed the budget period ceiling.
	(c.) Offset	These funds have not been spent by the recipient and are deducted from the amount of new funding awarded to the recipient. Recipients must be aware of the plan to use offset before it is applied to their budget.
	(d.) Future Funding Amount <i>Subtract (a.) - (b.) - (c.):</i>	Amount of funding remaining in the budget period ceiling to be awarded, dependent on the availability of funds and/or performance.
	(e.) Total Approved Budget for this Action <i>Add (b.) + (c.):</i>	The total budget that the recipient will receive for this action, which includes the available funding and offset.
	Applicable Funding Components	The components approved under the current action based on the recipient’s SF424 Section B component funding request.
Page 2: CAN Information	Funding Source	For all non-COP funding being included on this action, please be sure to specify the funding source.

Continuation Application Technical Review Form

GENERAL COAG INFORMATION

Type of Action under Review: <i>Check all that apply</i> <input checked="" type="checkbox"/> Year <u>2</u> Continuation, including: <input type="checkbox"/> Carryover <input type="checkbox"/> Offset <input type="checkbox"/> Neither, new funding only	Country or HQ Branch:	Multiple
	Recipient:	UCSF
	NOFO #:	GH19-1942
	CoAg Award #:	GH002170
	Object Class Code:	<input checked="" type="checkbox"/> 41.51 <input type="checkbox"/> 41.41
	CFDA Number:	<input checked="" type="checkbox"/> 93.067 <input type="checkbox"/> 93.947
	Amount Requested by Recipient:	\$ 27,000,000.00

FUNDING INFORMATION

	Amount	
(a.) Approved Budget Period Ceiling <i>Add (b.) + (c.) + (d.):</i>	\$ 27,000,000	
(b.) Available New Funding	\$ 6,510,838	Applicable Funding Components:
(c.) Offset:	\$	Identify Budget Year 01-04 of which offset funds are from:
(d.) Future Funding Amount <i>Subtract (a.) - (b.) - (c.):</i>	\$ 20,600,000	Applicable Funding Components:

(e.) Total Approved Budget for this Action <i>Add (b.) + (c.):</i>	\$ 6,510,838
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CAN INFORMATION

Financial Account (CAN)	Amount	Funding Source (COP, Central Initiative, HOP/TLS, non-DGHT). Please specify for non-COP!
9390BHM	\$ 250,000	Namibia
9390BEF	\$ 100,000	Uganda
9390BHZ	\$ 180,838	Vietnam
9390BJ0	\$ 400,000	Zambia
	\$	

Approval of Application

Approve Application (Please answer the questions below)

1. Are there any special conditions for the award, including budgetary restrictions? Yes No

If yes, please indicate conditions or restrictions in the budgetary and/or recommendations section.

2. Is a response to weaknesses by the recipient required to be in the Notice of Award? Yes No

3. Should a copy of the Technical Review be included in the Notice of Award? Yes No

(NOTE: This should be YES for all continuation applications.)

DGHT/PEPFAR FUNDING ONLY:

COP/ HOP MECHANISM ID #: 82035, 82066, 81976, 81824 _____

Are these activities approved in the COP/HOP? Yes No

If no, PBEMB will hold the award pending the country's submission of an email approval from the OGAC Chair or PPM or receipt of final approved HOP.

Are these activities receiving funds outside the COP (i.e., Central Initiative, HOP/TLS)? Yes No

If yes, please identify the project here: HOP _____

Emily Stong

Print Name of Project Officer

Signature of Project Officer

Date

Valerie Naglich

Print Name of Country Director/HQ
Branch Chief or Designee

Signature of Country Director/HQ
Branch Chief or Designee

Date

COP 2019 BUDGET INFORMATION (should match COP19 FAST)

In the table below please include the budget details for COP19 for this mechanism. This information should match what is in the FAST, regardless of what is being awarded now or what will be funded in future components. Only include those central initiative funds that were included in the COP19 FAST submission.

(A) Current New Funding	
(B) Applied Pipeline Amount	
Total Planning Level COP 19 (A+B) and (a+b+c+d+e+f)	
(a) Care & Treatment (C&T)	
(b) Prevention (PREV)	
(c) Testing (HTS)	
(d) Social Economic (SE)	
(e) Above-Site Program (ASP)	
(f) Program Management (PM)	
Other Central Initiative Funding (included in COP19 FAST)	

IMPORTANT: As a reminder, during the COP Implementation Period (01 October to 30 September annually), it is expected that total country COP-related outlays over this period will not exceed the total funding level stated with the signed Approval Memo. Consequently, each individual implementing partner outlay over this period should not exceed the amounts programmed to the partner as approved and documented in the COP. Partner budgets may include funding sources that are additive to COP funds (central initiative funding noted above). These other funding sources are not subject to the same outlay restrictions.

COP19 Target Information (compare to FAST/Data Pack)

In the space below please include all relevant targets for COP19 for this mechanism. Performance on the targets listed below will be tracked in COP19 and if achievement is not on track, DGHT will work with OGS to initiate corrective actions, if necessary.

Review of Application

OGAC has provided an optional Key Activities Summary template that should be used if specific references to key activities are not clear in the work plan. This template is NOT required, but you are advised to reference page numbers and specifically note strengths, weaknesses, and recommendations for those key activities here.

Strengths of Application:

(Please use bullets and reference your comments with page numbers from the application)

Namibia

- Objectives reflect good understanding of role and importance of recency testing "to characterize areas of high transmission and allow for focused prevention efforts in those areas", and the importance of real-time data availability. (page 35/173)
- The Partner understands that activities will work with various partners (MoHSS, NIP, CDC) to ensure successful rollout of the surveillance system. (page 35/173)
- The Partner plans to support the ministry in areas of continuous quality improvement (CQI), data capture, data dashboards, training of MoHSS to use and interpret data, quarterly reporting of MER indicators. (page 35/173)
- Partner has a strong plan for data quality, data review, dashboards and real-time data use for public health action. (page 24/173)

Thailand

- This application is part of an existing UCSF Co-Ag with CDC HQ to provide technical assistance to in-country implementation of the recency assay. The proposal is a supplemental activity to support the expansion of recency assay use to Thailand and Lao PDR.

Uganda

- The application clearly articulates the scope of technical assistance that the partner will provide to other implementing partners and MOH, including supporting critical personnel positions that would ensure the efficient implementation of the project.

Vietnam

- Clear focus with supporting Recency implementation in Vietnam.

Weaknesses of Application:*(Please use bullets and reference your comments with page numbers from the application)***Namibia**

- Partner states that rollout will be in 5 districts in some places and nationwide in other places. Starting in October 2019 Recency rollout will be nationwide with the goal of offering recency testing for all newly identified positive clients. (page 35/173)
- There is no mention of technical assistance for new protocol development or revision of protocol if needed for nationwide rollout. (page 24/173)
- There is no mention about how this Recency activity will contribute to development of case-based surveillance in Namibia.
- There is a lack of clarity in how this award will work together with the HQ funding so as to synergize and not duplicate.

Thailand

- The proposed contractor, TRCARC, is a one of PEPFAR supported partners who will receive training, introduce and implement recency testing at their supported sites in Thailand. It would not be possible for them to serve as a TA provider to themselves. Would expect that some of these services be incorporated into existing quality improvement activities instead of a parallel process.
- Propose to hire recency advisor and two quality improvement officer as subcontract. Would be preferable if could determine how to use existing CDC technical staff, local university or government institutional staff since this would be more sustainable and assist with integration into routine programmatic services.
- There is no budget for capacity building of local staff at sites. Please provide more detailed information on TA plans to build capacity of local staff in the country to implement and accomplished this new intervention.
- There is no mention of translation to Thai of training materials, SOP's, documents and job aids
- UCSF will be assisting local partners with the quarterly reporting of the MER indicators.

Uganda

- No mention of TA support to Uganda MOH for development /adaptation of tools, SOPs and training materials
- Recent HIV infection data will be captured directly in the Uganda EMR instance which is already developed.
- Activity 4.4 needs to be rephrased to include as suggested below.

Vietnam

- The CDC Vietnam team, Vietnam Authority for AIDS Control (VAAC) have not worked with the Hanoi University of Public Health (HUPH) on recency implementation, so it will take a lot of time for HUPH for administration paper work with the Government of Vietnam before the project can be fully implemented.
- YR2 Budget, page 3: The total budget for local salary is 168,492\$ (67.4% total budget), and 30,000 for travel. The proposal support for the whole team (9 members) and it is not necessary since Vietnam already implemented recency at HIV Testing and Counseling sites and sentinel surveillance with different partners: VAAC is taking the lead, Pasteur Institute (PI) and National Hygiene and Epidemiology (NIHE) provide technical assistance.
- YR2 Application, page 25, some activities are not applicable such as:

Recommended Actions for Weaknesses of Application:*(Please use bullets and reference your comments with page numbers from the application)***Namibia**

- Partner should plan to provide assistance in the training and rollout of Recency nationwide in collaboration with MoHSS and NIP.
- Partner should plan on providing technical assistance for new protocol writing or protocol revision if needed for nationwide rollout.
- Partner should plan on contributing substantially to the development of case-based surveillance in Namibia through these Recency activities.
- There should be a clear plan how this plan and budget fits in with the HQ mechanism funding.
- Ensure that positions are not duplicated within in-country and HQ mechanisms.
- There are not positions to cover the public health response to recency testing.
- There is not enough money for in-country training for national rollout.
- 2 full-time data clerks should be budgeted to be able to enter in national data in real time

Thailand

- Identify new local subcontractor who won't also won't be an implementing site and can assist with sustainability. Suggest university, government institute, or one of many foundations of the ministry of Public Health
- Determine how to best incorporate QI activities for recency assay into already existing QI activities at the site
- Translate all English language ILB and other existing recency training materials, documents into Thai/Lao
- Change language to outcomes from "supervision visits completed" to "QI visits completed"
- Dashboard system will need to be able to work with existing facility HMIS/LIS; there should not be a separate data collection system develop.

Uganda

- Uganda is just starting to implement HIV recency testing as a new tool for HIV surveillance. The application should articulate support to the Uganda MOH for the development/ adaptation of tools, SOPs and training materials for recency roll out.
- Activity 4.4: Recent HIV infection data will be captured directly in the Uganda EMR instance which is already developed. UCSF TA should be directed towards roll out of Uganda EMR to other facilities and training of data capture officers. TA should further support the development of systems focusing on platforms that support service delivery areas with infrastructural challenges i.e facilities or communities. Prioritized solutions should be premised on android technology and compatible with existing open MRS based systems.
- Related to the above, not all facilities may have a functional EMR system. Some of the TA support should be directed towards supporting facilities to institute a paper-based case reporting tool that would eventually be entered into the EMR system at a higher level.
- Some TA support will be needed at the national level to build capacity of national level staff for surveillance of recent HIV infections in the context of case based surveillance

Vietnam

Review of Annual Progress Report (APR)

Strengths of Annual Progress Report:

(Please use bullets and reference your comments with page numbers from the application)

Weaknesses of Annual Progress Report:

(Please use bullets and reference your comments with page numbers from the application)

Recommended Actions for Weaknesses of Annual Progress Report:

(Please use bullets and reference your comments with page numbers from the application)

Programmatic Budgetary Comments

Note: Programmatic budget restrictions, concerns, and comments should be addressed prior to the award being made. This will take place during the OGS Budget negotiations.

Marked-Up Budget Certification (select one)

This box signifies the Project Officer’s official review of the applicant’s proposed budget. This check box applies to all awards with new funding. PBEMB will consider a Technical Review to be incomplete if this box is left unchecked.

The recommended budget should be outlined in the GMM Budget Markup Spreadsheet for funding actions.

I certify that I support the recipient’s proposed categorical budget submitted in this application as it relates to the technical aspects of the project. No changes are required and no restrictions are recommended.

I wish to make changes to the recipient’s proposed categorical budget.

- If additional space is needed to justify the recommended funding amount, please use this space below to provide detailed comments for the recipient:

(Please use bullets and reference your comments with page numbers from the recipient budget)

Revise Vietnam budget to complete \$337,000 worth of activities

Programmatic Restrictions:

Indicate programmatic restrictions in table below (if applicable): Do not put potential human subjects or IRB restrictions or conditions in this section:

PLEASE NOTE BEFORE COMPLETING RESTRICTIONS:

- Recipients are not always funded at the level of the approved budget period ceiling, generally due to delays in CDC’s receipt of funds. As such, **do not penalize recipients for not completing unfunded activities.**
- When possible, the response to TR should be used as a management tool, as opposed to restricting funds. **Funds should only be restricted when absolutely necessary.**
- **REMEMBER:** Only include programmatic restrictions that should be put in place for the funding components that will be awarded at this time. If future restrictions are needed, they can be added once future funding components are awarded.

Object Classification	Programmatic Restriction Amount
Personnel	\$
Fringe Benefits	\$
Travel	\$
Equipment	\$
Supplies	\$
Contractual	\$
Facilities/Construction	\$
Other	\$
Total	\$0

If additional space is needed to justify the programmatic restrictions, please use this space below to provide detailed comments for the recipient:

(Please use bullets and reference your comments with page numbers from the recipient budget)

Potential Human Subject Data Collection Activities (DGHT ONLY)

This section highlights the Country Office’s technical review and recommendations for potential human subject/data collection activities. CDC DGHT Science Integrity Branch (SIB) will consider these comments/recommendations when reviewing this application. The only human subjects data collection restrictions that will be included in the NGA are those listed in the official memo from the DGHT Science Integrity Branch (SIB).

Use the checkboxes below to indicate whether the application includes any potential data collection activities involving human subjects. These activities can include, but are not limited to, program evaluation, interviews, focus groups, surveys, assessments, surveillance, review/extraction of data from patient records, and lab testing of specimens beyond routine clinical management.

- Application **includes** plans for potential data collection activities involving human subjects
 - Do any of these activities have the necessary CDC protocol approval(s)?
 - No** Note: Funds for implementing potential data collection activities that may result in a public report should be restricted until all necessary institutional protocol approvals have been obtained.¹ Please specify the restrictions in **Table I below**.
 - Yes** Note: Activities with CDC protocol approval should not be restricted. Provide details in **Table II below** and include an electronic copy of the CDC protocol approval related to the data collection activity listed in the application when returning this form to PBEMB.
- Application **does not include** plans for potential data collection activities involving human subjects. Note: No further information is required.

Table I. Proposed Data Collection Activities Potentially Involving Human Subjects

Activity Description (Type of Activity/Study Population)	Page(s)	Proposed Restriction Amount ² <i>(If activity is for programmatic purposes and will not result in a public report, please list \$0)</i>	Budget Category <i>(i.e., Salary, Travel, Contracts, Supplies, etc.)</i>	Comments
1.		\$		
2.		\$		
3.		\$		
4.		\$		
5.		\$		
6.		\$		
7.		\$		
8.		\$		
9.		\$		
10.		\$		

Table II. Human Subjects Data Collection Activities Already Approved by CDC

A copy of the CDC protocol approval (e.g., CGH Project Determination form signed by the CGH Human Research Protection Coordinator, a copy of CDC IRB approval memo) must be included when this technical review is returned to PBEMB. If no CDC approval document is provided, funds for implementing the activity will be restricted.

Activity Description (Type of Activity/Study Population)	Page(s)	Attached CDC Protocol Approval	Comments
1.			
2.			
3			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

Recipients engaged in human subjects research should be notified that they may need to apply to the U.S. Office for Human Research Protections for a Federal-Wide Assurance (FWA). An FWA is a pledge by an institution that they will adhere to ethical principles when engaged in research activities involving human subjects.

¹ If the activity is strictly for programmatic purposes and will not result in a public report, funds should not be restricted. Provide an activity description and page number, but list \$0 in the Proposed Restriction Amount column.

² Funds for preparatory activities (e.g., protocol development, training, equipment, reagents, and site preparation) may be provided prior to protocol approval. To facilitate the availability of preparatory funding, specify a restriction only on funds associated with implementation, and make a note of the preparatory budget in the comments column.

Signature of Country ADS or ADS POC