

**Research Subaward Agreement
Subaward Amendment-**

34445

Pass-through Entity (PTE)		Subrecipient	
PTE Name		Subrecipient Name	
The Regents of the University of California on behalf of the San Diego Campus		The City of Long Beach	
PTE Principal Investigator (PI): Richard Haubrich, MD		Subrecipient Principal Investigator (PI): Deborah Collins	
PTE Award No: EI11-SD-005	FAIN: Not Applicable	Awarding Agency: UC HIV/AIDS Research Program	
Project Title: ALERT - Active Linkage, Engagement & Retention to Reduce HIV			
Amount Funded This Action: - \$127,786.76	Amendment No: 004	Subaward No: 32900297	PO #: S9000157
Total Amount of Funds Obligated to date (including this action): \$428,005.24	Subject to FFATA: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Subaward Project Period: 4/1/2012 – 3/31/2016	

Amendment(s) to Original Terms and Conditions

This Amendment revises the above-referenced Research Subaward Agreement as follows:

DECREASED FUNDING. The Subrecipient's Year 4 funding is decreased Decrease Year 4 budget by \$127,786.76 for budget period 4/01/2015 - 3/31/2016.

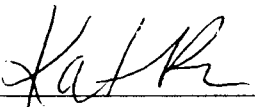

NOTE: The attached budget is less than the actual decreased amount of this amendment. This amendment reflects the actual funds remaining after the final invoice was submitted and paid.

INTERNAL ACCOUNTING
Req: 75304416
Fund: 19968A
Index: MED3215

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

If checked, no signature from Subrecipient is needed.

UCSD sometimes makes internal accounting changes that do not affect the Subrecipient but do affect the modification numbering and history. Also, UCSD sometimes issues unilateral increases of time and/or money where the statement of work and budget is unchanged. If Subrecipient does not wish to accept such changes, it is free to notify UCSD's PI and close out as previously agreed or request a bilateral modification. If checked but Subrecipient is aware the budget or statement of work needs to be modified, please contact UCSD's Authorized Official below.

By an Authorized Official of Pass-Through Entity:	By an Authorized Official of Subrecipient:	EXECUTED PURSUANT TO SECTION 301 OF THE CITY CHARTER.
	Assistant City Manager 	
<u>8/29/2016</u> Date	<u>7/26/16</u> Date	
Name: Katherine Philbin Title: Senior Contract Officer	Name: Patrick H. West Title: City Manager	

Attachments:

Statement of Work
Budget
Notice of Award

APPROVED AS TO FORM

7-25, 2016

CHARLES PARKIN, City Attorney


**AMY R. WEBBER
DEPUTY CITY ATTORNEY**

Attachment A Statement of Work PO

*required fields

City of Long Beach – ALERT 2015-2016

Total not to exceed*: \$	Revised Year 4 Total Budget: \$91,857 (4/1/2015-3/31/2016) Total project Period total \$428005.24 (4/1/2012-3/31/2016)
Equipment to be purchased by Subrecipient*:	Yes No <input checked="" type="checkbox"/>
Is Subrecipient for-profit?* (equipment purchased by for-profits are likely to be owned and tracked by UCSD)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If applicable, include each of the following:	
Deliverable deadlines:	Provide Quarterly Invoices 30 days after the end of each Quarter. Ensure all samples are shipped to UCSD by 8/1/16.
Report deadlines:	Submit Final Invoice by 5/30/16.
Milestones:	Complete all study activity by 3/31/2016.
Performance standards or required approvals:	N/A

Scope of Work*

(General description of the subject of research Subrecipient is performing and physically what they will be doing. Include specific descriptions of those things critical to the success of the Subrecipient's project or UCSD's deliverables to the sponsor. Also include specifically Subrecipient PI responsibilities)

SCIENTIFIC ABSTRACT

Background: Scientific evidence supports a new role of antiretroviral (ARV) medications in the prevention of HIV infection by suppressing viral load in potential sources of HIV infection and in reducing the risk of acquisition for exposed individuals. The use of ARVs to suppress HIV among a population of HIV-infected individuals can benefit both the health of the community and the individual. However, to achieve the greatest benefit, as many HIV-infected individuals as possible need to be engaged in medical care. Structural changes are needed in the current HIV care system to seamlessly transition individuals from the diagnosis of HIV to durable ARV treatment that sustains suppression of viral load.

Results from recent prevention studies give credence to the clinical practice of using ARVs not only as a treatment for the HIV positive, but also as a viable pre-exposure prophylaxis (PrEP) option for high-risk, HIV negative individuals. Methods to implement PrEP in populations at high-risk for HIV
UCSD Procurement & Contracts (rev 5/16)

Attachment A

Statement of Work PO

acquisition have not been fully developed. Similar to treating those with HIV infection, the individuals targeted for PrEP will need to be identified and engaged in medical care with provision of comprehensive prevention services, provision of ARVs, monitoring for safety and reinforcement of medication adherence.

Aims: There are three parts for our proposed demonstration project:

- 1) The first part (Test and Link) will focus on linking new HIV diagnoses and those at highest risk of acquiring HIV into care for assessment. The project will hire an Active Linkage, Engagement, and Retention (ALERT) specialist and measure how many and how well the specialist connects new patients from the testing site to a healthcare provider.
- 2) The second part (Engagement in Care for HIV-Infected) will study how effective the ALERT specialist is to retain HIV-infected patients in care compared to current Standard of Care (SoC).
- 3) The third part (PrEP) will focus on developing a system to engage HIV negative individuals at high risk for HIV in comprehensive PrEP preventive care. The project will study how the ALERT specialist using a texting adherence application helps the patient keep on their PrEP schedule compared to comprehensive preventive care alone.

Study Design: Our demonstration project will be a collaboration of three HIV testing sites (San Diego HIV, STD, and Hepatitis Branch, Long Beach Health and Human Services and LAC-USC Emergency) with a main local HIV provider affiliated with the CCTG (UCSD Owen Clinic, Harbor-UCLA Medical Center and LAC-USC Rand Schrader Clinic) to enroll 300 newly diagnosed or lost or care HIV infected patients and 300 individuals at high-risk for HIV acquisition. Participants will be on study for at least 12 months at one of the three existing CCTG HIV primary care clinics to receive HIV care or PrEP.

Newly diagnosed HIV+ patients willing to be linked to primary care will be placed into the Engagement in Care Project, randomized 1:1 into either SoC or the ALERT intervention arm. The Intervention arm will include enhanced retention efforts by an ALERT specialist. Participants determined as having sustained high risk for HIV and who are willing to take PrEP will all receive comprehensive preventive care and be randomized 1:1 into either comprehensive preventive care alone or combined with the ALERT intervention. The intervention arm will receive the ALERT specialist using a developed text-messaging system for ARV adherence.

Attach additional pages as needed.

Deborah Collins P.A., Co-Project Director - She will serve as the principal investigator, at the Long Beach Health Department site in collaboration with Dr. Eric Daar. She will supervise all staff and the provision of PrEP in study subjects. She will work closely in coordinating efforts between Harbor-UCLA site and Long Beach Health Department testing sites for follow-up of those found to be HIV-infected as well as those uninfected who are eligible for PrEP. There will be a Study Nurse, ALERT Specialist and a Testing and Counseling Staff member. Their duties will include: NURSE - to coordinate and integrate all study-related activities. The nurse will be responsible for completing all regulatory documents at the LBDHHS. She or he will work with other staff in the collection of data on those tested and found to be positive or negative, present to care at the Health Department or other local sites and are referred for PrEP. The latter activity will include monitoring the clinical activities and completion of case report forms for those initiated on PrEP at the Harbor-UCLA site. ALERT Specialist - This person will work with staff at Harbor-UCLA and Long Beach to perform specific tasks and monitor patient follow-up. Those eligible for PrEP will have the option of attending a clinic at LBDHHS or Harbor-UCLA. Those who choose to have follow-up at LBDHHS will be followed and monitored by this individual. The ALERT specialist will also perform phone- and email/web-based follow-up retention activities on those patients assigned to them. Thus, this person will maintain engagement and re-engage subjects that miss appointments or fall out of PrEP. TESTER - will be responsible for performing testing and counseling services, blood collection and working closely with the ALERT worker to ensure all high risk negative individuals are referred to PrEP and positive individuals are referred to care services.

Attachment A
Statement of Work PO #

Refer all patient follow-up activity to Harbor-UCLA after 03/31/16. All compensated study activity to be completed by 3/31/2016. Ensure all samples are shipped to UCSD by 8/1/16.

City of Long Beach Sub-contract Budget Period Year 4 Revised Budget

Period 4/1/2015- 3/31/2016
PO Number: S9000157
Name of Vendor: City of Long Beach Sub-contract

Category	4/1/2015- 3/31/2016		4/1/2015- 3/31/2016	Unobligated
	Y3 Carryforward	Original Y4 Award Budget	Revised Y4 Budget	Award Reduction
PERSONNEL	\$ 62,673	\$ 95,135	\$ 64,936	\$ 92,872
CONSULTANT/CONTRACTUAL				
SUPPLIES & EXPENSES	\$ (2,745)	\$ 33,387	\$ 13,215	\$ 17,427
EQUIPMENT				
TRAVEL: PROGRAM MEETING			\$ 374	
TRAVEL: PROJECT RELATED	\$ 1,873			
TRAVEL: SCIENTIFIC MEETINGS				
DIRECT COSTS	\$ 61,801	\$ 128,522	\$ 78,526	\$ 111,797
INDIRECT (F&A) COSTS	\$ 15,451	\$ 13,870	\$ 13,332	\$ 15,989
TOTAL COSTS	\$ 77,252	\$ 142,392	\$ 91,857	\$ 127,787

University of California
California HIV/AIDS Research Program

Award Notice

Principal Investigator: Sheldon Morris

Award #: EI11-SD-005

Institution: University of California, San Diego

Project Title: ALERT- Active Linkage, Engagement & Retention to Reduce HIV

This award notice for period: April 1, 2015 - March 31, 2016

Approved Budget:

Personnel (Salaries, Wages, Benefits)	\$713,908
Consultant/Contract	\$832,838
Supplies and Expenses	\$118,845
Equipment	\$0
Travel - Annual Meeting	\$0
Travel - Project-Related	\$6,300
Travel - Scientific Meetings	\$1,000
Indirect Costs	\$0
TOTAL:	\$1,672,891

This award will be paid in two installments: \$1,421,820 in April 2015 and \$251,071 in November 2015.

CONDITIONS:

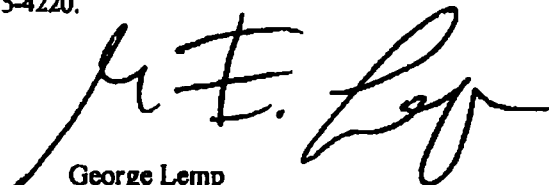
1. AUDIT

This grant shall be subject to examination and audit by The Regents of the University of California and the California State Auditor for a period of three years after receipt of final fiscal and/or scientific reports. The examination and audit shall be confined to those matters connected with the performance of this grant, including, but not limited to, the cost of administering this grant.

2. GENERAL CONDITIONS

Refer to the California HIV/AIDS Research Program's most current Grant Administration Manual for policies and rule governing the administration of this award. Each year, this grant shall be subject to the policies and rules in the annual revision of the Manual which will be sent to the recipient with the annual fund distribution notice at the start of each year.

Direct any questions to the California HIV/AIDS Research Program, University of California, 300 Lakeside Drive, 6th Floor, Oakland, CA 94612-3550. Phone: (510) 987-9855; Fax: (510) 835-4220.



George Lemp
Director, California HIV/AIDS Research Program

FOR USE BY ACCOUNTING OFFICE ONLY (Please note the fund number)
HOLDING ACCOUNT NUMBER: 6-440501-19968
INDIVIDUAL ACCOUNTS ASSIGNED BY CAMPUS ACCOUNTING OFFICE
cc: Principal Investigator
4/7/2015

