

Research Subaward Agreement (Non-Government Prime)


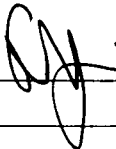
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Institution/Organization ("Prime Recipient") The Regents of the University of California; University of California, San Diego Prime Award No.: E111-SD-005 Awarding Agency: California HIV/AIDS Research Program	Institution/Organization ("Subrecipient") Name: City of Long Beach EIN # [REDACTED] CFDA# none Amount Funded This Action: \$206,700.00 Estimated Subrecipient COST SHARE Subrecipient PI: Deborah Collins
UCSD PI: Richard Haubrich, MD	Subrecipient PI: Deborah Collins

Subaward Period of Performance: Budget Period: From: 04/01/2012 To: 03/31/2013	Subaward No.: 32900297	
Project Title: ALERT - Active Linkage, Engagement & Retention to Reduce HIV	Marketplace Invoice PO# (TBD after final execution)	12/18 12

Terms & Conditions

- 1) Prime Recipient hereby awards a cost reimbursable subaward, as described above, to Subrecipient. The statement of work and budget for this subaward are as shown in Attachment A and A1, respectively. In its performance of subaward work, Subrecipient shall be an independent entity and not an employee or agent of UCSD.
- 2) Prime Recipient shall reimburse Subrecipient not more often than monthly for allowable costs. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), subaward number, and certification as to truth and accuracy of invoice. *Invoices that do not reference Prime Recipient's Subaward Number shall be returned to Subrecipient.* Allowable Costs shall be determined by Subrecipient in accordance with cost principles generally accepted by, or required to be used by, like organizations: 2 CFR 220 - Cost Principles for Educational Institutions (formerly OMB Circular A-21), 2 CFR 225 - Cost Principles for State & Local Governments and Indian Tribal Governments (formerly OMB Circular A-87), 2 CFR 230 - Cost Principles for Non-Profit Institutions (formerly OMB Circular A-122), 45 CFR 74, Appendix E - Cost Principles for Hospitals or 48 CFR 31.2 - Cost Principles for Commercial Organizations (FAR).
- 3) A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to Prime Recipient's Financial Contact, as shown in Attachments D, NOT LATER THAN sixty (60) days after subaward end date. The final statement of costs shall constitute Subrecipient's final financial report.
- 4) All payments shall be considered provisional and subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Subrecipient.
- 5) Matters concerning the technical performance of this subaward should be directed to the appropriate party's Principal Investigator, as shown in Attachments D. Technical reports are required as shown above, "Reporting Requirements".
- 6) Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this subaward agreement, and any changes requiring prior approval, should be directed to the appropriate party's Contract Officer Contact, as shown in Attachments D. Any such changes made to this subaward agreement require the written approval of each party's Authorized Official as shown in Attachments D.
- 7) Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or director's, to the extent allowed by law.
- 8) The Period of Performance ("POP") is deemed to be subject to or modified by any special terms (if present) of the Prime agreement that require the Subrecipient to have an IRB approval either before beginning any work or beginning work on such subjects, as specified. Costs incurred in violation of any such terms are both un-allocable as being outside the POP and unallowable by the terms of the prime.
- 9) Either party may terminate this subaward with thirty days written notice to the appropriate party's Contract Officer Contact as shown in Attachments D. Prime Recipient shall pay Subrecipient for termination costs as allowable under OMB Circular A-21 or A-122 or 45 CFR Part 74 Appendix E, "Principles for Determining Costs Applicable to Research and Development under Grants and Contracts with Hospitals" as applicable.
- 10) No-cost extensions require the approval of the Prime Recipient. Any requests for a no-cost extension should be addressed to and received by the Financial Contact, as shown in Attachments D, not less than thirty (30) days prior to the desired effective date of the requested change.
- 11) The Subaward is subject to the terms and conditions of the Prime Award, Attachment B, and other special terms and conditions, as identified in Attachment C1 and C2.
- 12) By signing below Subrecipient makes the certifications and assurances shown in Attachments C1 and C2.

By an Authorized Official of Prime Recipient  Date: 03/21/2013	By an Authorized Official of Subrecipient  Assistant City Manager Date: 12-21-12
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EXECUTED PURSUANT
TO SECTION 301 OF
THE CITY CHARTER.

Attachment A Statement of Work PO

*required fields

City of Long Beach – ALERT 2012-2013

Total not to exceed*: \$	206,700
Equipment to be purchased by Subrecipient*:	Yes <input checked="" type="checkbox"/> No <input 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:	Click here to enter text.
Report deadlines:	Click here to enter text.
Milestones:	Click here to enter text.
Performance standards or required approvals:	Click here to enter text.

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

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 A1

Long Beach (CHRP)		Program Director/Principal Investigator (Last, First, Middle) Hausbrich, Richard					FROM		THROUGH	
DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY						04/01/12		03/31/13		
PERSONNEL (Applicant organization only)										
NAME	ROLE ON PROJECT	TYPE APPT <small>(month)</small>	% EFFORT ON PROJ	C/1 Mos	INST BASE SALARY	DOLLAR AMOUNT REQUESTED (same units)				
						SALARY REQUESTED	FRINGE BENEFITS	TOTALS		
Doborah Collins, P.A.	Co-Project Director	12	10%	1 20	99,787	9,979	4,387	14,346		
TBN RN	Study Nurse Coordinator	12	25%	3 00	76,636	19,160	9,499	28,659		
Veronica Morales	Counselor	12	100%	12 00	50,234	50,234	29,030	79,264		
Patricia Montes	Medical Assistant	12	20%	2 40	46,610	9,324	5,157	14,481		
SUBTOTALS						88,697	48,053	136,750		
CONSULTANT COSTS										
EVALUATION COSTS										
1 Laptop Computer @ \$1,500/year							1,500.			
Site Cell and Text Messaging							4,761.			
Miscellaneous supplies							1,800.			
Site Laboratory Costs							16,881.			
Site Patient Reimbursement							2,688.			
								27,610.		
EQUIPMENT (Depreciate) and RENTAL										
								0		
SUPPLIES & Other Expenses (Itemize by category)										
								0		
TRAVEL										
Project-related CHRP mtg for 1 Investig. X 2 mtgs/yr (1 mtg is for 2 days w/1 overnight & other is 1 day)							1,000.			
								1,000		
PATIENT CARE COSTS										
							0.	0		
							0.	0		
ALTERATIONS AND RENOVATIONS (Itemize by category)										
							0.	0		
OTHER EXPENSES (Itemize by category)										
								0.		
CONSORTIUM/CONTRACTUAL COSTS						DIRECT COSTS				
								0		
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (Item 7a, Face page)								165,360.		
CONSORTIUM/CONTRACTUAL COSTS						FACILITIES AND ADMINISTRATIVE COSTS 25%				
								41,340.		
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD								206,700.		

University of California
California HIV/AIDS Research Program

Award Notice

Principal Investigator: Richard Haubrich
Institution: University of California, San Diego
Project Title: ALERT- Active Linkage, Engagement & Retention to Reduce HIV

Award #: E111-SD-005

This award notice for period: April 1, 2012 - March 31, 2013

Approved Budget:

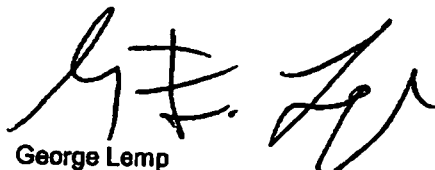
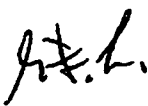
Personnel (Salaries, Wages, Benefits)	\$474,860
Consultant/Contract	\$825,033
Supplies and Expenses	\$121,371
Equipment	\$0
Travel - Annual Meeting	\$0
Travel - Project-Related	\$2,056
Travel - Scientific Meetings	\$0
Indirect Costs	\$0
TOTAL:	\$1,423,320

Anticipated award for FY 2013-2014 \$1,418,320
Anticipated award for FY 2014-2015 \$1,425,161
Anticipated award for FY 2015-2016 \$1,421,820

Obligations:

1. Inform CHRP if you receive funds for related research from any other source.
2. Conduct research involving human and animal subjects according to the standards of the appropriate review board or committee (i.e. Institutional Review Board or Institutional Animal Care and Use Committee). No funds for work requiring IRB or IACUC approvals may be expended until such approvals have been obtained. Approvals or applications for approvals must be furnished to CHRP upon request.
3. Submission of Annual Progress and Fiscal Reports on or before the due date.
4. Management of the grant according to CHRP Policies and Procedures.

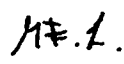
Refer to the U.C. Special Research Programs Grant Administration Manual online at http://www.californiaaidsresearch.org/grantees/gam_2011-12.pdf for specific policies governing the administration of this award. Reporting forms for Progress Reports and requests are available upon request. Pre-filled reporting forms for Fiscal Reports are sent by email 30 days prior to the due date. Direct any questions to the California HIV/AIDS Research Program Office, CHRP@ucop.edu or (510) 987-9855.



George Lemp
Director, California HIV/AIDS Research Program

FOR USE BY ACCOUNTING OFFICE ONLY (Please note the fund number)
HOLDING ACCOUNT NUMBER: ~~4-44000-18011~~ 6-440501-18011
INDIVIDUAL ACCOUNTS ASSIGNED BY CAMPUS ACCOUNTING OFFICE

cc: Principal Investigator
4/13/2012



Attachment D-Research Subaward Agreement
UCSD Contacts

Subaward/MP #

32900297

Institution/Organization ("Prime Recipient")

University of California, San Diego Address:
9500 Gilman Drive,
La Jolla CA 92093

Contract Officer and Authorized Official:

Name: Monique Cervantes

Address: 9500 Gilman Drive, Mailcode #0914
La Jolla CA 92093-0914

Phone: 858-822-7783

Fax: 858-534-5803

Email: mycervantes@ucsd.edu

Principal Investigator:

Name: Richard Haubrich, MD

Address: 200 West Arbor Drive, San Diego, CA 92103

Mail Code: 8208

Phone: 619-543-4747

Fax: 619-543-5066

Email: rhaubrich@ucsd.edu

Administrative Department Contact/Fund Manager:

Name: Colleen Burks

Address: 200 West Arbor Drive, San Diego, CA 92103

Mail Code: 8208

Phone: 619-543-8179

Fax: 619-543-5094

Email: cburks@ucsd.edu

Property Management Contact (if equipment is to be purchased):

Name: Jamie Wheat
Address: 9500 Gilman Dr. Mailcode #0953
La Jolla, CA 92093-0953
Phone: 858-534-6163
Email: jwheat@ucsd.edu

Invoices should be directed to:

UCSD Disbursements
Address: 9500 Gilman Dr. Mailcode #0955
La Jolla, CA 92093-0955
Fax: 858-534-7194

Attachment D-Research Subaward Agreement
Subrecipient Contacts

Subaward/MP #

32900297

Name:

Address:

City:

State:

Zip + 4:

EIN:

DUNS:

Administrative Contact

Name:

Address:

City:

State:

Zip+4:

Telephone:

Fax:

Email:

Principal Investigator

Name:

Address:

City:

State:

Zip+4:

Telephone:

Fax:

Email:

Financial Contact or Fund Manager

Name:

Address:

City:

State:

Zip+4:

Telephone:

Fax:

Email:

Authorized Contact

Name:

Address:

City:

State:

Zip+4:

Telephone:

Fax:

Email: