Community-Centered Demonstration Projects to Support Implementation of Long-Acting Injectable PrEP Adoption Across California

Request for Proposals 2023

Important Dates

Request for Proposals (RFP) Announced:	Monday, April 3, 2023
Applicant Webinar for All RFPs:	Thursday, April 27, 2023, 10:00-11:30 AM (will be recorded)
Questions Due:	Friday, May 5, 2023, 5:00 PM
Letters of Intent (LOI) Due:	**Thursday, May 25, 2023, 12:00 PM**
Invited Applications Due:	**Thursday, July 27, 2023, 12:00 PM**
Notification of Peer Review Outcome:	Friday, December 1, 2023, 12:00 PM
Performance Period:	February 1, 2024 – January 31, 2028

New or Notable

- New: All questions related to this RFP must be submitted in writing by May 5th 2023, with responses being posted to our website within two weeks. No questions will be answered after this date unless determined vital.
- New: Sex as a Biological Variable: Both sex and gender and their interactions can influence molecular and cellular processes, clinical characteristics, as well as health and disease outcomes. For this reason, applicants are expected to address how relevant biological variables, such as sex assigned at birth and sex hormone levels, are factored into research designs and analyses for all studies in primary cell lines, vertebrate animals, and humans. See Section 12 ("Peer Review and Scoring Criteria for Full Applications") for more information.
- Among all LOIs received, only the 25 most meritorious will be accepted and invited to submit a full application. See Section 10 ("Submitting a Letter of Intent") for more information.

1. CHRP Mission and Programmatic Priorities

Our mission is to support scientists in California to develop, evaluate, and disseminate innovative research for (a) eliminating new HIV infections, (b) optimizing treatment uptake and outcomes for all persons living with HIV, and (c) addressing the comorbidities and social determinants that threaten the health and well-being of persons at risk for or living with HIV.

CHRP Programmatic Priorities: *Across every aspect of our work, the California HIV/AIDS Research Program (CHRP) seeks to fund high-risk, high-reward, high-rigor research projects that aim to substantially and rapidly advance HIV epidemic control and/or treatment, and which address research priorities and gaps not supported by other funders. Further, CHRP is committed to diversity, equity, and inclusion as a means of increasing the effectiveness of its grantmaking and generating new knowledge that benefits all Californians.*

The California HIV/AIDS Research Program (CHRP) is a publicly funded grantmaking organization, administered through the Research Grants Program Office (RGPO) within the Division of Research and Innovation at the University of California, Office of the President. Since 1983, CHRP has invested over $383 million dollars through over 2,000 research and capacity building grants to support the development, implementation, evaluation, and dissemination of innovative HIV projects through its stated *mission and strategic directions*. These priorities align with other Ending the Epidemic(s) strategies developed by the *State of California*, through the federal government by both the *CDC* and *White House Office of AIDS Policy*, as well globally by the *WHO*.

2. Goals of this Funding Initiative

With this Request for Proposals (RFP), CHRP seeks to award between $6,000,000 and $10,000,000 by February 1, 2024, to fund three to five research projects for the development, implementation, and evaluation of traditional and non-traditional interventions to support integration of Long Acting Injectable (LAI) PrEP into HIV-prevention services. To do this, CHRP will fund multiple collaborative research teams across the state of California who will work to support efforts for widespread uptake of LAI PrEP within all impacted communities. Specifically, this research initiative aims to:

A. Establish new, or strengthen existing, partnerships to ensure **LAI PrEP is fully integrated into community prevention** strategies;
B. Support the development and implementation of demonstration projects focused on **integrating LAI PrEP into community-wide** HIV prevention efforts in both traditional and non-traditional settings;
C. Identify and address potential **social determinant(s) of health** that may impact equitable access to PrEP services;
D. Develop evaluation strategies for **measuring the impact and feasibility of LAI PrEP programs** to increase the likelihood of long-term success; and
E. Support diversity in the pipeline of future investigators with **additional funding for students** and trainees from diverse and underrepresented communities, from communities that are highly impacted by HIV in California, and/or who have demonstrated commitment to diversity efforts.

3. Background

Evidence has shown that the use of long acting injectable Cabenuva (CAB-LA) every eight weeks is superior to daily tenofovir disoproxil fumarate–emtricitabine (TDF–FTC) for HIV pre-exposure prophylaxis (PrEP) prevention among multiple populations.[1,2] In Dec 2021 the US FDA approved CAB-LA for PrEP use, opening the door for wide-spread adoption across impacted communities through health care facilities.[3] Despite this, few projects piloting implementation of CAB-LA are underway, and investigations are needed to ensure that best practices are followed that ensure equitable availability.[4]

The purpose of this solicitation is to fund novel community centered demonstration projects that support wide-spread adoption of injectable forms of PrEP. These interventions can be stand alone or part of existing prevention efforts. Interventions involving collaborations between multiple agencies (e.g., health departments, universities, hospitals and hospital systems, community clinics, community-based organizations, pharmacies) will be prioritized.

4. Research Objectives to be Addressed by the Proposed Work

This funding opportunity will support community centered demonstration projects that promote the adoption of LAI PrEP in traditional and non-traditional settings throughout California. Full scoring criteria can be found in **Section 10** below. Successful applications will include how the project clearly addresses the following objectives relevant to this response:

Objective 1: Addresses a unique research question(s) related to the implementation of LAI PrEP services across California.

Objective 2: Supports equitable access to new or expanded PrEP services that takes into account historically underserved populations based on socio-demographics, age, geography, population-based vulnerabilities, and structural barriers.

Objective 3: Although not required, projects focused on collaborative approaches involving broad-based participation and partnerships (e.g., community-based organizations, advocacy groups, universities, and/or governments) are encouraged.

Objective 4: Projects must address sustainability and integration of scientifically validated best-practices into new or existing prevention strategies.

5. Eligibility

PIs at any stage in their careers are welcome to apply.

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[1] Landovitz RJ, Donnell D, Clement ME, HPTN 083 Study Team, et al. Cabotegravir for HIV Prevention in Cisgender Men and Transgender Women. N Engl J Med. 2021 Aug 12;385(7):595-608. doi: 10.1056/NEJMoa2101016. PMID: 34379922; PMCID: PMC8448593.

[2] Delany-Moretlwe S, Hughes JP, Bock P, HPTN 084 Study Team, et al., Cabotegravir for the prevention of HIV-1 in women: results from HPTN 084, a phase 3, randomised clinical trial. Lancet. 2022 May 7;399(10337):1779-1789. doi: 10.1016/S0140-6736(22)00538-4.

[3] https://www.fda.gov/news-events/press-announcements/fda-approves-first-injectable-treatment-hiv-pre-exposure-prevention

[4] Spinelli MA, Grinsztejn B, Landovitz RJ. Promises and challenges: cabotegravir for preexposure prophylaxis. Curr Opin HIV AIDS. 2022 Jul 1;17(4):186-191. doi: 10.1097/COH.0000000000000733. Epub 2022 Mar 4. PMID: 35762372; PMCID: PMC9240402.

Applicant PI may submit more than one Letter of Intent (LOI) to this RFP. If multiple LOIs are advanced, then the PI is allowed to submit multiple full applications (final funding decisions reflect the results of the peer review process and of programmatic review). PIs may also serve in different roles (e.g., PI, Co-PI, Co-Investigator) on additional applications. Individuals, community-based organizations, and health systems/jurisdictions may participate in more than one application under this mechanism as well.

Applicants who are key personnel on any current CHRP research awards are eligible to apply for funding under this initiative if the required scientific and fiscal reports on their existing grants are up-to-date. This means that Progress/Final Scientific Reports or Fiscal Reports that are more than one month overdue may subject an application to disqualification unless the issue is either (i) addressed by the PI and Institution within one month of notification, or (ii) the PI and Institution have received written permission from CHRP to allow an extension of any report deadlines.

The applicant PI is required to have PI status at a non-profit institution in California, or assurance in writing from their institution that PI status will be granted "just in time" upon an offer to fund this award. In accordance with *UC policy*. PIs who are UC employees and who receive any part of their salary through UC must submit grant proposals through their UC campus Contracts and Grants office. Exceptions must be approved by the UC campus where the PI is employed. Neither US citizenship nor permanent residency are requirements for the PI, nor for any personnel, to apply for or receive CHRP funding.

CHRP requires that applicant institutions are non-profit research, academic, or community-based institutions located in California. CHRP will accept applicants from any non-profit organization or institution, provided that the organization can manage the grant and demonstrate financial health. The organization must also meet our liability insurance requirements. Before funding, the University will collect additional information, such as tax ID numbers and financial reports, to review the organization during the pre-funding process to ensure all financial management and project management eligibility criteria can be met.

6. Available Funding, Anticipated Number of Awards

CHRP receives its funding as part of the University of California's unrestricted general fund revenue from the State of California. For this initiative, CHRP expects to fund three to five awards, with total anticipated investment ranging from $6,075,000 to $10,125,000. The number of awards to be offered is not predetermined but will depend on the number of meritorious applications received. Awards are contingent on the availability of funds, and funding allocations may be adjusted based on performance (criteria will be provided in the instructions for the Full Application).

7. Award Duration, Budget, and Requirements

Each award will support up to 4 year(s) of related activities. Initial budgets may not exceed $2,025,000 in total costs (including direct costs up to $1,500,000 and indirect costs up to 35%) over the entire project period. Monies can be unevenly distributed across the years in the 4-year project period to adjust for project lifecycle (e.g., lower annual costs in earlier time periods during start-up and planning, and higher annual costs during implementation).

Allowable direct costs include salaries, fringe benefits, supplies, sub-contracts (out-of-state sub-contracts and collaborations are generally not allowed), equipment (defined as any item costing $5,000 or more), and limited travel (project-related and/or scientific conference travel). The RGPO *Grants Administration Manual* outlines all policies and regulations with respect to allowable indirect costs (IDC), which is capped at 35%, and other restrictions on use of funds. Some institutions will not accept awards with IDC capped at 35%; PIs may wish to discuss this requirement with their institutions before submitting a full application. Continued funding beyond year one is contingent on progress toward milestones enumerated in the application.

The PI (and Co-Principal Investigators, if applicable) must commit a minimum of 10%, or 1.2 person-months, of effort in each project year, with support. Periods of effort without support are allowable for other key personnel, but not for the PI (or Co-PIs).

8. Prospective Applicant Webinar

CHRP will hold an informational webinar (**see date on page one of this RFP**) to provide an overview of the intent of the award mechanism(s), the application process(es), and allow prospective applicants and community members to ask questions relevant to their submission. Information on how to access the applicant webinar, and a recording of the webinar, will be posted on the *CHRP website*. During the webinar potential applicants will have the opportunity to submit questions, or ask for clarifications, through the chat window. We request that questions be submitted by chat so a written record can be retained.

9. Applicant Questions that Arise After the Webinar

After the webinar prospective applicants can submit additional questions via email by the date and time listed on page one of this RFP. CHRP will post written responses to all submitted questions on our website within two weeks. Questions or inquires submitted to CHRP after this date will not be answered unless determined vital by CHRP staff and leadership; in this instance all potential applicants who have initiated an LOI in *SmartSimple* will be notified of the question and the Program's response by email.

10. Submitting a Letter of Intent (LOI)

RGPO uses *SmartSimple*, an electronic submission portal, for all official correspondence (e.g., LOI and application submission). PIs are required to register and use their accounts. Complete LOIs must be submitted via *SmartSimple* **no later than on the date and time shown on page one**. LOIs received after the deadline will not be accepted. Any partnerships involved are allowed to be in formative stages at the time of LOI submission but must be established by the time of full application submission. Official signatures are not required by CHRP at the LOI stage; however, any differing applicant institutional policies supersede CHRP policy.

Investigators may submit multiple LOI as PI to this RFP. A complete LOI for this RFP consists of the following, in the order the appear in *SmartSimple*:

- ☐ Project Title (100 characters)

- ☐ Project Duration (up to 4 years), Performance Period (enter dates on page one of this RFP)
- ☐ Referral Source(s)
- ☐ PI Applicant Profile and Contact Details (including ORCID ID)
- ☐ **LOI Scientific Abstract (limit 2,400 characters)**
- ☐ **LOI Specific Aims (limit 2,400 characters)**
- ☐ CHRP Research Priority Area; Subject Area; Focus Area (see LOI instructions)
- ☐ Suggested Reviewers (optional)
- ☐ Total Amount of Funding Requested per Project Year (direct costs only)
- ☐ Applicant Electronic Signature and Date.

Competitive Review of Letters of Intent: After review by CHRP staff to ensure that the applicant and institution(s) meet eligibility criteria (Sections 4 and 5 of this RFP), merit-based peer-review triage will be conducted at the LOI stage to invite no more than the 25 most meritorious LOIs to submit full applications; our intention is to engage fewer scientists with the labor-intensive requirements of writing the full proposal, which in turn will increase the proportion of applications we are able to fund. All letters of intent will be reviewed by at least two persons who are subject matter experts. Reviewers will receive a manual of policies and procedures for LOI scoring and review before distribution of any LOI content; the manual is available to applicants by request. Current *RGPO policies and procedures* concerning confidentiality and conflicts of interest will be observed. Letters of Intent will be extracted from SmartSimple without investigator or institutional identifiers and these "blinded" files will be sent to the review panel. Reviewers who recognize the identity of and have a potential conflict of interest with an applicant or institution will recuse themselves from all applicable LOIs/applications.

Reviewers will assign three component scores to each LOI, reflecting their relative scientific merit:

- **LOI ONLY: Innovation and Collaboration (50% of LOI score)**
- **LOI ONLY: Significance of the Research Question and Potential Impact (30% of LOI score)**
- **LOI ONLY: Approach and Feasibility (20% of LOI score)**

Score values correspond to the following descriptors.

Score	Descriptor	Strengths/Weaknesses
1	Exceptional	Extremely strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses
7	Fair	Some strengths but with at least one major weakness
8	Marginal	Some strengths but with at least one major weakness
9	Poor	Some strengths but with at least one major weakness

Final LOI scores will be ranked, and the 25 most meritorious LOIs by score will be advanced to the invited full proposal stage. All final invitation decisions will take into account programmatic priorities

such as portfolio equity, distribution of resources, and representativeness of the HIV epidemic in California. CHRP staff will review LOI to ensure that the proposed research is responsive to the research objectives and that the applicant and institution(s) meet eligibility criteria (see section 5 above).

All applicants will be notified of LOI approval/rejection via *SmartSimple* at the same time, on or before the date shown on page one of this RFP. PIs with approved LOIs will gain access to the full application materials at time of LOI notification. No application may move forward without an approved LOI.

11. Submitting a Full Application

Full applications must be submitted by the **date stated on page one** of this RFP. Documents providing a comprehensive description of all application sections are found on *SmartSimple,* as are required templates for certain sections. Proposal narratives should be succinct, self-explanatory, and organized in alignment with the sections outlined below and in supplemental attachments. The Full Application will include the following sections:

- ☐ Scientific Abstract, Lay Abstract, Specific Aims
- ☐ Demographics of Anticipated Study Volunteers
- ☐ Milestones and Timetable
- ☐ Institution Contacts
- ☐ Personnel Table
- ☐ Biosketches for all Key Personnel
- ☐ Budget and Justification
- ☐ Assurances Required (if applicable: Human Subjects; Vertebrate Animals; Biohazards; DEA Controlled Substance use)
- ☐ Research Plan
- ☐ Community Engagement Plan (if applicable)
- ☐ Facilities
- ☐ Protection of Human Subjects and/or Care of Vertebrate Animals (if applicable)
- ☐ Appendix List and Attachments

12. Peer Review and Scoring Criteria for Full Applications

All complete applications will be reviewed by a panel which includes (a) persons with lived experience in communities that are highly impacted by HIV in California, and (b) scientists from outside California who are subject matter experts and experienced peer reviewers. Reviewers will receive training and a manual of policies and procedures for application scoring and review before access to the applications is allowed; the manual is available to applicants by request. Current *RGPO policies and procedures* concerning confidentiality and conflicts of interest will be observed.

The following scoring criteria will be used to review your proposal:

1. **Innovation and Collaboration** (20% of total score): Scoring will reflect the extent to which the application presents innovative strategies and methods for implementing LAI PrEP into

proposed settings (e.g., clinical, non-clinical, hybrid). Applications that involve collaborations across multiple partner agencies (e.g., health departments, hospital/hospital systems, community clinics, community-based organizations, pharmacies) will be prioritized.

2. **Impact** (15% of total score): Scoring will reflect the proposals potential impact for increasing adoption of LAI PrEP as part of community-wide HIV prevention efforts, and how it supports adoption among marginalized risk populations historically underserved when new biomedical prevention options become available on commercial markets.
3. **Sustainability** (15% of total score): Scoring will reflect the sustainability and scalability of the intervention long-term, and the suitability of the evaluation framework for ensuring program maturity over time, and the strategies for ensuring that best practices are adopted and expanded to ensure that LAI PrEP is available, especially to historically underserved populations, after the study is completed.
4. **Approach** (50% of total score)**:**
    a. **Overall Research Plan and Design:** Scoring will reflect the appropriateness and scientific rigor of the overall approach(es) used to address stated aims.
    b. **Conceptual Framework(s):** Scoring will reflect how frameworks and/or models will be used to support stated study design and outcomes.
    c. **Implementation Strategy:** Scoring will reflect the feasibility and rigor proposed to execute all aspects of the investigation(s). This section should provide a full and succinct descriptions and justifications related to topics such sampling and recruitment strategies, statistical approaches, and project timelines.
    d. **Dissemination Plan**: Scoring will be based on the breadth of the dissemination plan and the degree to which it is inclusive of all relevant stakeholders.
    e. **Management Plan**: Scoring will reflect the capacity or the potential of the team/institution to carry out the work, the value of the partnerships brought forward from other disciplines, how the project will be managed, the feasibility and completeness of the milestones and timeline, and strategies for addressing roadblocks that may impact study completion. Clearly defined roles of all partners/partner agencies should be discussed.

Reviewers will comment on but not score the following:

- **Budget**: Appropriateness of the budget request for the project.
- **Estimation of Pharmaceutical Need(s)**: Please detail the amounts of medication(s) (e.g., Cabenuva, doxyPrEP) your project will need, both annually and overall, to successfully complete your study.
- **Inclusion of Women, Minorities and Individuals Across the Lifespan in Research**: If human subjects are involved, the adequacy of plans to include subjects of all genders, all racial and ethnic groups (and subgroups) as well as individuals across the lifespan (including children and elderly individuals) as appropriate for the scientific goals of the research will be assessed.
- **(Where Applicable) Protection of Human Subjects from Research Risk**: Appropriateness of protections from research risk relating to human subjects participation in the proposed research.

- **Sex as a biological variable (SABV):** Both sex and gender and their interactions can influence clinical characteristics, as well as health and disease outcomes. CHRP requires all proposals in all areas of study to account for sex as a biological variable in the Research Plan. CHRP policy is based on current NIH Policy but goes further, to include exogenous and endogenous sex hormones, and research using cell lines. Applicants are expected to explain how relevant biological variables, such as sex at birth and exogenous sex hormone levels, are factored into research designs and analyses for studies in cell lines, vertebrate animals, and humans. Applicants should demonstrate inclusion of SABV in the literature review, study sample (cells, animals, humans), data collection strategy, data analysis, and reporting plan.

Reviewers will assign component scores for each criteria listed reflecting the relative scientific merit of the proposal sections. RGPO generally adheres to NIH scoring methods. Each criterion will receive a score of between 1 and 9 corresponding to the table in the LOI section above. Final scores will be ranked, and the most meritorious by score will be advanced for review and approval by CHRP's Advisory Council for funding consideration. CHRP is committed to diversity, equity, and inclusion as a means of increasing the effectiveness of its grantmaking and generating new knowledge that benefits all Californians. Final funding decisions may take into account these and other programmatic priorities.

13. Diversity, Equity, and Inclusion Supplements

All projects selected for funding under this RFP will be encouraged to apply for an additional $10,000 in supplemental funds to promote diversity, equity, and inclusion in the pipeline of future investigators in HIV research. These supplemental funds are intended to partially support the scientific contributions of students or trainees (high school, undergraduate, graduate/clinical, post-doctoral) from sociodemographic groups that are underrepresented among health researchers, or with lived experience in a community with elevated HIV incidence in California, to the funded project. PI should consider all trainees who will promote diversity in HIV research, including trainees from diverse socioeconomic, cultural, ethnic, racial, gender, sexual orientation, ability/disability, linguistic, and geographic backgrounds who would otherwise not be adequately represented in their field, trainees who are from underserved communities, and trainees who have demonstrated commitment to diversity efforts. More details will be provided to PIs with applications that are selected for funding.

14. How to Get Help

For scientific questions regarding application preparation or guidance regarding the suitability of a proposed project, contact Rhodri Dierst-Davies at Rhodri.Dierst-Davies@ucop.edu.

For general questions regarding the electronic submission of an LOI or application, including using SmartSimple, please contact the Research Grants Program Office, Contracts and Grants Unit at *RGPOGrants@ucop.edu*, or 510-987-9386.

APPENDIX: Standard Policies and Procedures for all CHRP RFPs

A. RGPO Award Pre-Funding Requirements Policy

Following notification by RGPO of an offer of funding, the PI and applicant organization must accept and satisfy standard RGPO pre-funding requirements in a timely manner. Common pre-funding requirements include:

- Supplying approved indirect (F&A) rate agreements as of the grant's start date and any derived budget calculations.
- Supplying current "other support" documents for review by the Program Officer to rule out scientific, budgetary, and commitment overlap; and resolving any issues raised.
- Supplying any missing application forms or materials, including detailed budgets and justifications for any subcontract(s).
- IRB or IACU applications or approvals pertaining to the award.
- Resolution of any scientific overlap issues with other grants or pending applications.
- Resolution of any Review Committee and Program recommendations, including specific aims, award budget, or duration.
- Modify the title and lay abstract, if requested.

B. Stipulations

Funding: Awards are contingent upon availability of funding, as well as compliance with all research and reporting requirements. Grantees will be subject to funding renewal on an annual basis. The number of awards made will depend on the number and quality of applications received.

Human or animal subjects: Approvals or exemptions for the use of human or animal subjects are not required before the time of LOI or full application submission or review but will be required before any funded work with such subjects commences. Principal Investigators are encouraged to apply to the appropriate board or committee as soon as possible after submitting a proposal to expedite the start of the project.

Grants management procedures and policies: Details concerning the requirements for grant recipients are available in the latest version of the *Grants Administration Manual*.

Application and award confidentiality: CHRP maintains confidentiality for all submitted applications with respect to the identity of applicants and applicant organizations, all contents of every application, and the outcome of reviews. For those applications that are funded, CHRP makes public: (i) the project title, Principal Investigator(s), the name of the organization, and award amount; (ii) direct and indirect costs in CHRP's annual report, (iii) the project abstract on the CHRP website. If the Program receives a request for additional information on a funded grant, the Principal Investigator and institution will be notified prior to the Program's response to the request. Any sensitive or proprietary intellectual property in a grant will be redacted and approved by the PI(s) and institution prior to release of the

requested information. No information will be released without prior approval from the PI for any application that is not funded.

Publications acknowledgement: All scientific publications and other products from any RGPO-funded research project must acknowledge the funding support from UC Office of the President, with reference to the program (CHRP) and the assigned grant ID number.

Open access: The University Office of the President is committed to disseminating research as widely as possible to promote the public benefit. All publications based on funding received from RGPO are subject to the *University's Open Access Policy*. To assist RGPO in dissemination and archiving, the grantee institution will deposit an electronic copy of all publications in the *UC Publication Management System*, UC's open access repository, promptly after publication. Notwithstanding the above, this policy does not in any way prescribe or limit the venue of publication. This policy does not transfer copyright ownership, which remains with the author(s) or copyright owners.

Appeals of review decisions: Final funding decisions are at the discretion of the CHRP Director and are subject to oversight from the CHRP Advisory Council and the Research Grants Program Office. Declined proposals may be submitted to future competitions without prejudice. An appeal regarding the funding decision of a grant application may be made only on the basis of an alleged error in, or deviation from, a stated procedure (e.g., undeclared reviewer conflict of interest or mishandling of an application). The period open for the appeal process is within 30 days of receipt of the application evaluation from the Program. Before submitting appeals, applicants are encouraged to talk about their concerns informally with the appropriate Program Officer or the Program Director. Final decisions on application funding appeals will be made by the Vice President of Research and Graduate Studies, University of California, Office of the President. The full appeals policy can be found in the *Grants Administration Manual*.