

Call for Applications

CHRP Basic Biomedical Sciences Discovery Initiative 2021

Call for Applications Release: Monday, March 29, 2021

Letter of Intent (LOI) Due: Thursday, May 13, 2021, 12:00 Noon Pacific Time

Invitations to Apply Distributed: Thursday, June 10, 2021

Webinar for Invited Applicants: Wednesday, June 16, 2021 12-1 PM (recording will be here)

Invited Applications Due: Thursday, August 12, 2021, 12:00 Noon Pacific Time

Decision Notification: Tuesday, November 16, 2021

Performance Period: February 1, 2022 – January 31, 2024

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www.californiaaidsresearch.org

New This Year:

- 1. We will employ external peer-review triage at the LOI stage to invite no more than the 25 most meritorious LOIs to submit full applications. See page 5 for more information.
- 2. New scoring criteria to emphasize innovation. Component scores for LOI merit review are **innovation** (50% of total score), significance (25%), and approach (25%). Component scores for the full application review have been changed to **innovation** (30% of total score), significance (20% of total score), and research plan (50% of total score). See pages 2, 5, and 7.
- 3. To encourage inclusion and career development for early stage investigators, multiple policies and procedures have been adopted. See page 3.
- 4. Diversity, Equity, and Inclusion supplements will be offered with onset in Year 02 of project activities, to partially support students or trainees (high school to post-doctoral level) who will contribute to the research project. See page 4.
- 5. Effort without support is no longer allowable for the Principal Investigator. Other key personnel may contribute effort without support, but the PI must commit to 10% effort with 10% support. See page 3.

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 have the potential 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.

Goals of this Funding Initiative

CHRP seeks to award up to \$2,090,000 on February 1, 2022, to support pilot studies in basic biomedical HIV research. Since 1983, CHRP has advanced HIV/AIDS science and supported the interests of California investigators and institutions by funding these small awards that support early-stage laboratory exploration aimed at understanding mechanisms of HIV prevention, treatment, or cure at the cellular or subcellular level. This year's initiative will fund projects to test exceptionally innovative ideas, yield the preliminary data needed to successfully compete for larger research grants (such as National Institutes of Health [NIH] R01s), and support diversity in the pipeline of future investigators with set-aside funding for students.

Research Objectives

This funding opportunity will support basic biomedical HIV research that is highly innovative, addresses an important question or barrier, and yields findings that can serve as a basis for compelling studies of larger magnitude or launch new areas of inquiry. Of these, the most important objective is innovation: for letters of intent, 50% of the total score will be their degree of innovation; in the full application, 30% of the total score will be innovation.

To be considered responsive, all applications must include the components listed below. Applications deemed non-responsive may be withdrawn without review.

- The proposed project must address an aspect of the host/pathogen interaction for HIV or SIV.
- The proposed project must be basic biomedical in nature, in the realms of biology (including molecular, cellular, structural, and microbiology), virology, immunology, chemistry (organic and biological), or other similar disciplines.
- The proposed project may focus on humans, non-human primates, animals with humanized immune systems and/or cells (including organoids), or any other animal model that can be justified in the full application. Novel animal models are welcome.
- Studies leveraging biospecimens from other studies are encouraged, with appropriate assurance(s) from the applicable institutional review board(s).
- This opportunity does not specify any topics/topic areas that are more highly desirable than others, beyond those that address basic biomedical aspects of HIV/SIV.

Topics that were funded in prior cycles are available on the CHRP website.

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 Basic Biomedical Discovery Initiative, CHRP intends to invest up to \$2,090,000 over two years. The number of awards to be offered is not predetermined, but will depend on the number and quality of 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).

Award Duration, Amount, and Requirements

Grants are one-time, non-renewable awards for a two-year project period (shorter periods are allowed). Initial budgets may not exceed \$200,000 in total direct costs over the proposed project period. University of California (UC) institutions are eligible for indirect costs up to 30% of modified total direct costs; non-UC institutions are eligible for the same, or their negotiated indirect cost rate agreement with the U.S. Department of Health and Human Services (or other similarly established rate), whichever is lower. 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 (scientific conference travel of no more than \$2,000 per year).

The Principal Investigator (PI) must commit a minimum of 10% effort to this project (1.2 person-months of effort for a 12-month appointment, or equivalent), with 10% support. Effort without support is allowable for all other key personnel, but not for the PI. This policy is part of our commitment to inclusion: CHRP hopes to encourage scientists whose salary support is sufficiently robust (preventing commitment of 10% effort with support to a new project) to share their project idea with an early stage investigator or trainee and mentor them through the application process, instead of applying themselves.

Proposals may utilize material of human origin from subjects with whom the PI interacts if appropriate institutional assurance is provided (an approved IRB protocol naming the present project by title and funder, on a "just in time" basis; informed consent documentation does not need to name this funded project). Appropriate animal models are also allowable.

Special Considerations for Early Stage Investigators

This funding mechanism can be an important resource for investigators who are in the early stages of their careers (those who have not yet received substantial independent NIH funding per <u>NIAID definition</u>; RGPO uses the term "new investigators" in application materials on SmartSimple). Specifically, because this mechanism invites applications from scientists who do not yet hold Principal Investigator status at their institution (but who can secure that status "just in time" if their proposal is selected for funding), a CHRP Basic Biomedical Discovery Initiative Award can propel scientists from the post-doctoral scholar or junior investigator level to the tenure track.

To support inclusion of and career development for early stage investigators, CHRP is committed to:

1. Coordinating with research institutions from across California to ensure that early stage

investigators are aware of this funding opportunity and have the information and encouragement they need to consider applying;

- 2. Ensuring that at least 50% of the LOIs that are invited to submit a full application come from early stage investigator applicants;
- 3. Newly requiring 10% effort *with* support of all Principal Investigators (which is intended to increase the relative competitiveness of applications from early stage investigators);
- 4. Providing expert technical assistance to ESI immediately after both the LOI and Full Application stages (including detailed critiques from peer reviewers, actionable feedback in their summary statements, and an optional consultation with the Program Officer either at the time of LOI declination or full application non-selection; no review decisions will be changed or impacted in any way by technical consultations after the fact).

Diversity, Equity, and Inclusion Supplements

All investigators selected for funding 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/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. Pls 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.

Administrative supplements must support work within the scope of the original (parent) award. The proposed research experience under this administrative supplement must be an integral part of the approved, ongoing research of the parent award, and it must have the potential to contribute to the research career development of the candidate. Individuals may not be transferred to a supplement to increase the availability of funds in the parent grant for other uses. Pls of parent awards are invited to submit only one application for an administrative student supplement under this mechanism, to support only one student. Allowable costs of up to \$10,000 include salary and fringe benefits; tuition; enrollment fees for trainees; supplies (up to \$2,200); and domestic project-related travel (up to \$500; must be justified). Indirect costs are not allowed.

All funded PIs in the 2021 CHRP BBDI will be invited by email to apply for these non-competing administrative supplements at the time of the first progress report. The application includes a modular budget with justification, a statement of student qualifications (limit one-half page), a plan for the research experience (limit one page), a mentoring plan for the student (limit one-half page, must be written by the PI), and curricula vitae (any format, no page limit) or biosketches (NIH format) for both the student and the PI. Applications must be received within 30 days of receipt of the invitation; they will be reviewed by CHRP Program Officers, and final funding decisions are at the discretion of the Program Director.

Submitting a Letter of Intent

Complete LOIs must be submitted via <u>SmartSimple</u> (https://ucop.smartsimple.com) no later than 12:00 PM Pacific Time on the date shown on page one. LOIs received after the deadline will not be accepted. Investigators may submit multiple LOIs as PI to this Call for Applications; no more than one LOI per PI will be invited to submit the full application.

A complete LOI for this mechanism consists of:			
	Applicant Profile including ORCID Identifier (PI only)		
	Project Title (100 characters)		
	Project Duration (one or two years)		
	Project Start Date (fixed as Feb 01, 2022) and Project End Date (suggest Jan 31, 2024)		
	New Investigator Checkbox (yes/no)		
	Referral Source (select all that apply)		
	LOI Abstract (limit 2,400 characters)		
	LOI Specific Aims (limit 2,400 characters)		
	LOI Innovation Narrative (limit 1,300 characters)		
	CHRP Research Priorities (all applicants should select "Basic biomedical sciences")		
	Subject Area (all applicants should select "Biological and Life Sciences")		
	Focus Area (all applicants should select "HIV/AIDS")		
	Amount Requested per project year		
	Applicant Electronic Signature and Date.		

Official signatures are not required by CHRP at the LOI stage; however, any differing applicant institutional policies supersede CHRP policy. Budget information is not included at the LOI stage for this funding mechanism. CHRP staff will review all LOIs to ensure that the proposed research is responsive to the scientific priorities listed in the Call for Applications (page 2) and that the applicant and institution meet eligibility criteria (page 3).

Peer Review of Letters of Intent

Because CHRP recognizes the multiple new responsibilities that are borne by infectious disease researchers during this time, we will employ **merit-based peer-review triage 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 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 members of a panel of peer scientists from outside California who are subject matter experts, have experience as NIH-funded Principal Investigators, and as have served as peer reviewers for NIH. 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 be asked to recuse themselves from all applicable LOIs/applications.

Reviewers will assign three component scores to each LOI, reflecting the relative scientific merit of the proposal: 50% of the LOI score will be innovation (1-9 points), 25% of the LOI score will be significance (1-9 points), and 25% of the LOI score will be approach (1-9 points).

- Innovation (50%): Does the project challenge and seek to shift current research paradigms by utilizing novel theoretical concepts, approaches, or models? Does the project address the proposed question in a new and creative way, test a hypothesis beyond the leading edge of the field, or explore an unusual biological phenomenon or unexpected previous result? Is the project taking risks rather than simply the next logical step? Do any proposed new tools or technologies offer clear and significant improvement over currently available methods?
- **Significance (25%)**: Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge or technical capability be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, or preventative interventions that drive this field?
- Approach (25%): Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?

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	A few strengths and a few major weaknesses
9	Poor	Very few strengths and a few major weaknesses

Final 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. LOI approval notifications will be emailed to all prospective applicants at the same time, on or before the date shown on page one. Investigators with approved LOIs will be invited to submit full proposals, and will receive the full application packet with the LOI approval notification.

Submitting a Full Application

Instructions for completing the full application will be distributed to invited PIs at the time of LOI approval. The format is similar to that of NIH R01 applications. Full applications must be **submitted via SmartSimple** no later than 12:00 Noon Pacific Time on the date shown on page one.

An optional webinar for applicants will be held after LOI dispositions are announced, to provide more details about the application content and process. Attendance is not required, and the webinar will be recorded and posted on our website for later viewing.

The full application includes a Research Plan; it is analogous to the Research Strategy in PHS 398, the template commonly used to apply for RO1-type funding from the National Institutes of Health. For this funding opportunity, applicants should use the NIAID format found under "Write Your Research Plan."
Definitions for all terms in this section are taken from the NIAID guidance found at that same link. For this funding opportunity, the Research Plan includes four sections (the abstract is entered into its own field in the online application):

- 1. Early Stage Investigator Statement, if applicable (limit one page)
- 2. Specific Aims (limit one page)
- 3. Research Strategy (limit twelve pages), including these suggested sections:
 - A. Significance (20% of total score)
 - B. Innovation (30% of total score)
 - C. Approach (50% of total score): include preliminary data, if applicable (not expected); study overview; capacity of Principal Investigator (describe potential instead of capacity if early stage investigator) and team; scientific environment in which the work will be conducted; and research design and methods.
- 4. Literature Cited (limit five pages).

Peer Review of Full Applications

All complete applications will be reviewed by at least two members of a panel of peer scientists from outside California who are subject matter experts, have experience as NIH-funded Principal Investigators, and as have served as peer reviewers for NIH. Reviewers will receive 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. The CHRP review process is modeled on the NIH process. Current RGPO policies and procedures concerning confidentiality and conflicts of interest will be observed.

Review criteria for scoring full applications include:

- 1. Innovation (30% score weighting)
 - Innovation in concept, approach, and/or methods;
- 2. Significance (20% score weighting)
 - Importance of the research question; potential for advancing science in HIV/AIDS;
- 3. Research Plan (50% score weighting)
 - Clarity of the research problem;
 - Rigor and feasibility of the conceptual framework, analytical plan, and methodology;
 - Potential to leverage results and compete for subsequent funding after the pilot stage;
 - Investigator's capacity or potential (if new investigator) to conduct the proposed research;
 - Suitability of the scientific environment in which the work will be conducted, including institutional support and any unique features of the setting.

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.

How to Get Help

For scientific questions regarding application preparation or guidance regarding the suitability of a proposed project, contact Lisa Loeb Stanga at lisa.loeb.stanga@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.

Contact: Lisa Loeb Stanga, Program Officer, lisa.loeb.stanga@ucop.edu or 510-587-6041 <u>www.californiaaidsresearch.org</u>



General Application Policies and Guidelines from RGPO and CHRP

CHRP Policies on 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.

CHRP Policies on Eligibility to Submit an Application

CHRP requires that applicant institutions must be non-profit research, academic, or community-based institutions 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 prefunding process to ensure all financial management and project management eligibility criteria can be met.

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.

US citizenship is not a requirement for the PI nor for any personnel to apply for CHRP funding.

RGPO Policy on Submitting Institution for PIs who are University of California Employees

In accordance with University of California <u>policy</u>, investigators who are University employees and who receive any part of their salary through the University must submit grant proposals through their campus contracts and grants office ("Policy on the Requirement to Submit Proposals and to Receive Awards for Grants and Contracts through the University," Office of the President, December 15, 1994). Exceptions must be approved by the UC campus where the investigator is employed.

RGPO Policy on Applications from PIs with Delinquent Grant Reports

Pls with current RGPO grant support will <u>not</u> be eligible to apply for additional funding unless 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.**

RGPO Human Subjects and Vertebrate Animal Use Assurance Policies

Documentation of human subject or human material research assurances (IRB approval, human subject "exemption" approval, etc.) and/or animal research assurance must be provided prior to funding, but is not needed for application review. Applicants are encouraged to apply to the appropriate board or committee as soon as possible in order to expedite the start of the project, and you must do so within 21 days of notification that an award has been offered. This deadline may be negotiable depending on the circumstances of the proposal. If all reasonable efforts are not made to obtain appropriate approvals in a timely fashion, funds may be reallocated to other potential grantees' proposed research projects. If a project proposes activities that pose unacceptable potential for human and animal subject risks, then a recommendation either not to fund or to delay funding until the issue is resolved may result.

RGPO Award Pre-Funding Requirements Policy

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

- Supply approved indirect (F&A) rate agreements as of the grant's start date and any derived budget calculations.
- Supply 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.

RGPO Grant Management Requirements and Policies

RGPO uses SmartSimple (http://ucop.smartsimple.com), an electronic submission portal, for all official correspondence (e.g., LOI and application submission). PIs are required to register and use their accounts.

All RGPO grant recipients must abide by other pre- and post-award requirements pertaining to Cost Share, Indirect Cost Rates, Monitoring & Payment of Subcontracts, Conflict of Interest, Disclosure of Violations, Return of Interest, Equipment and Residual Supplies, Records Retention, Open Access, and Reporting. Details concerning the requirements for grant recipients are available in the RGPO Grant Administration Manual, https://www.ucop.edu/research-grants-program/files/documents/srp_forms/srp_gam.pdf.

RGPO Publications Acknowledgement Policy

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.

RGPO Open Access Publications Policy

RGPO is committed to disseminating research as widely as possible to promote the public benefit, and all publications based on funding received from RGPO are subject to the University's Open Access Policy, https://www.ucop.edu/research-grants-program/grant-administration/rgpo-open-access-policy.html. To assist RGPO in disseminating and archiving research results, grantee institutions and/or the Principal Investigator must upload the final author version or provide a link to any open access publications in eScholarship, or the UC publication management system, promptly after publication. Notwithstanding the above, this policy does not in any way prescribe or limit the venue of publication.

RGPO Policy on Appeals of Funding Decisions

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 *RGPO Grant Administration Manual*, in Section 5 under Dispute Resolution: https://www.ucop.edu/research-grants-program/ files/documents/srp forms/srp gam.pdf.

www.californiaaidsresearch.org

