CALIFORNIA HIV/AIDS RESEARCH PROGRAM

CHRP Calls for Applications 2022

Questions and Answers -- Revised 01July2022

Throughout the application period, all questions posed to CHRP Program Staff, and our responses, will be added to this sheet. Thus, all applicants will have equal access to information shared by the program.

New Questions Received Between 18May and 24June

A. ***Are structural interventions (such as interventions conducted by members of the centered community, directed at health care providers, intended to increase the provider's capacity to provide culturally appropriate care to future members of the centered community) allowable for the Community Collaboratives RFP? (Applicable to Community Collaboratives RFP)*** The Community Collaboratives RFP is intended to support research agendas including interventions that will improve HIV-related health outcomes of the centered community. To the degree that the target of a structural intervention (health care providers, clinic managers, housing policy decision-makers) is not the individual members of the centered community, while it may technically meet the terms stated in the RFP, this may not be highly responsive to the RFP. A proposal that specifies more immediate HIV-related outcomes (such as viral suppression, ART/PrEP adherence) than structural distal outcomes (quality of care provided by individual clinicians) would be more responsive.

B. ***Do we need to specify the intervention to be used in the application, or can we still be in the planning stages? (Applicable to Community Collaboratives RFP)*** No; we would prefer to see full applications that have maximum creativity and input from the community partners, rather than definitive intervention selection before project start; if your centered community has been involved in intervention selection and you've decided on one, please do explain that and share details of the involvement of your community members. Important: if you have not yet determined which intervention you'll use, take time in your full application to explain what types of interventions you'll be choosing among, what aspects of those interventions make them appealing, which ones are evidence-based and is the evidence translatable to your centered community, and what will the decision-making process look like once the project starts.

C. ***Can we use a proxy measure for the HIV-related outcome, such as an index that is demonstrated to be predictive of viral suppression? (Applicable to both RFPs)*** You could, but why not also measure the outcome that is predictive of, e.g., viral suppression, itself? (See next question also.)

D. **Do we need to measure biologic outcomes, such as quantitative viral load (for viral suppression) or presence of drug product in dried blood spots (for ART/PrEP adherence)? *(Applicable to both RFPs)*** Not necessarily; biological outcomes are the gold standard, and yet they can be accessed via self-report instead of lab assays. Self-report may be more culturally appropriate than biomarker assessment for some communities.

New Questions Received Between 22April and 18May

A. ***When will LOI applicants be informed about whether they can submit a full application? (Applicable to both RFPs)*** We will announce LOI approvals no later than Friday 27th May at Noon. That will include a link to the final application materials.

B. ***In the LOI, does character count include citations? Can I attach a list of references? (Applicable to both RFPs)*** The character count does include references; however, for the LOI only, you can use abbreviated references (e.g. Author Surname, Journal Name or Standard Abbreviation, Year). Please do not add a list of references.

C. ***Is there additional guidance for the Youth Mental & Sexual Health RFP Abstract and Specific Aims sections? There were more detailed instructions for the Community Collaboratives RFP, but we were unsure if there was similar guidance for the other RFP.*** No, there is not further guidance for the Youth RFP. Beyond what is in the RFP itself, just use the space to make your case as best you can. The LOI is not competitive.

D. ***The Youth Mental and Sexual Health RFP states that the proposal budget should be $200K per year. Would it be possible to go over $200K in any one year as long as we did not exceed $600K over the 3 year project period?*** In the Youth RFP, it states "Budgets may not exceed $200,000 direct cost per year and $600,000 direct costs over the entire grant period", which disallows going over 200k in any one year. However, functionally, once a PI has an award, if their institution will allow them to overspend in one year then we defer to the institution. We likely will pay these awards as a lump sum at the start of the award, not three payments as we've done in the past.

E. ***Is it ok to use an HIV status-neutral approach? (Applicable to both RFPs)*** Yes, this would be welcome. (For Community Collaboratives only: If you do, consider being extra-specific on the other aspects of the community to be served; it is fine to be less specific at the LOI stage and have the final micro epidemic population that you specify be a result of asking folks in the community where they feel their needs are.)

F. ***When you want the proposals to implement existing evidence-based interventions, does that refer to the end product (e.g., PrEP uptake) or the way in which people are linked to PrEP (e.g., peer navigation)? We are trying to understand how much creativity the community partners will have in the implementation process. (Applicable to Community Collaboratives RFP)*** We would prefer to see a full application (not needed at LOI stage) that has maximum creativity and input from the community partners, so we'd lean in that direction. This is tricky, and I know we've set up a balancing act here: you need to be highly focused re: your science, but you also need to maximize community input, which takes time and resources and trust. We require evidence-based interventions primarily to exclude intervention development, as this mechanism isn't intended to fund development. If you're not proposing to test the efficacy of the intervention itself, then that aspect of your proposal will be responsive to the RFP. Specifically, using the outcome measure of PrEP uptake is great, of ART uptake is great, and peer navigation is an evidence-based intervention so that's great. Consider implementation science types of research questions that get at the needs of the community and utilize tools that we already must address those needs, and which will help inform the science about how we can do a better job of meeting those HIV-related needs of the community.

Community Collaborative Application Questions

1. ***The Call for Applications lists "pharmaceutical industry partner" as one type of partner that would fulfill the requirement of one partner from "Group C" (see Call, page 4, section 2c), but the slides in the webinar do not list this term. Which is correct?*** IMPORTANT: After publication of the Call for Applications, we reconsidered this language, and determined that a proposal that includes (a) an academic PI, (b) a group that serves the centered community, and (c) a company from the private sector would not serve the goals of this funding initiative well. Instead, we have revised "Group C" to read as shown in the box below (see lined-out clause under section iii). Any applicant PI who is unaware of this change and submits an LOI that proposes to include a pharmaceutical industry partner will be invited to revise and resubmit.

   c) One of the following:
      i. A representative from a Department of Public Health (DPH) that serves a portion of the identified community (which may span multiple DPH jurisdictions); funding for personnel in this category is not required; applicants should negotiate budgetary considerations directly with their DPH partner; or
      ii. A State or local government or governmental entity, such as a school district or a justice or carceral system; or
      iii. A ~~pharmaceutical industry partner or~~ community pharmacist; or
      iv. Others who stand to benefit from expanded HIV prevention, treatment, and other wraparound services.

2. ***Can there be multiple applicant PIs from the academic institution, say in the case of cross-departmental collaboration within a single academic institution?*** We require a single applicant PI, primarily to increase the chances of success of the funded projects via a named single point of responsibility. A single applicant PI with multiple Co-PIs is allowable. Please contact the Program Officer to discuss how your proposed collaboration could both be eligible for this mechanism and meet the needs of your institution and your partners.

3. ***Are the syndemics that should be highlighted for this announcement limited to HIV, HCV and STIs?*** No, the syndemic aspects addressed in your proposal can include things not listed here (such as substance use disorder; mental health disorder; etc.). Consider if you can make the case that there is an interaction or synergy between HIV and/or HCV and/or STIs and your other aspect? Further, ***Are the syndemics restricted to those that are already well-characterized, such as substance abuse, violence, and HIV/AIDS (SAVA)? Can local data be used to justify "micro syndemics"?*** Syndemic conditions or aspects beyond those specified in the Call are allowable; please do use local data to make the case for a micro syndemic that is important to your centered community.

4. ***Do I need to apply for the Diversity Supplement to be competitive?*** No, your main application will be scored in September, and you'll apply for the optional supplement after funding is announced in November.

5. ***If a PI holds dual appointments with a primary appointment at a DPH as well as an academic affiliation, are they eligible to apply as the applicant PI via their academic appointment?*** Yes.

6. ***If the intervention isn't a classic intervention, but we have a great ongoing partnership that is highly collaborative and meets all of the other requirements, would we still be eligible?*** If the intervention you have in mind doesn't currently have an established rate of efficacy or effectiveness in a population and setting that is somewhat similar to your centered community, then the intervention would not be allowable. This mechanism is intended to utilize existing, evidence-based, and effective interventions; if your intervention isn't yet established in that way, it's not a good fit for this opportunity and would be out of scope. Please contact a Program Officer if you would like guidance on what other next steps you might take beyond CHRP's capacity.

7. ***Does this mechanism allow hybrid studies – that is, both efficacy and implementation science?*** No, the funds provided by these awards are not intended to be used for intervention development, testing, or establishing efficacy.

Youth Mental & Sexual Health Application Questions

8. **Are applications required to include technology-based interventions?** No, interventions are not required to be technology-based.

9. **Tell me more about the restrictions against submitting applications that include use of new technology.** Interventions are allowed to be technology-based as long as the technology is already developed, with evidence of efficacy, and would simply be refined for the purposes of the proposed study. Development of a novel technology-based application that has not been tested previously and is of unestablished efficacy is not allowed.

10. **May community partners be listed in other roles, if co-PI designation is not allowed under this mechanism?** Yes, community partners can serve in any key personnel role under this mechanism, excluding Co-PI. Co-PI designation has a very specific meaning related to how budgets are created in SmartSimple that is not applicable to this mechanism.

11. **Is an implementation science approach or framework required for this mechanism?** No, an implementation science approach or framework is not required for the Youth Mental & Sexual Health mechanism.

12. **How young is allowable for the study population?** As long as good human subjects' protections are outlined, approved by the applicant's IRB, and followed, the inclusion criteria for the study population, understanding that the upper age limit is restricted to 26 years old, is up to the applicant.

13. **How integrated should the sexual health and mental health programing be?** The degree of integration of the sexual health and mental health programming is part of the application review criteria. The applicant can decide to focus more on sexual health or more on mental health but will need to justify why they have decided to do so.

14. **Should this be a more targeted intervention for youth at-risk for HIV and/or at-risk for adverse mental health, or is it meant to be more of a primary/universal prevention program?** The applicant

can decide how best to justify the inclusion criteria for the study population, understanding that at a minimum the study population is 26 years of age or younger and identifies at LGBTQ+. A narrower focus on populations with particular risks for HIV or adverse mental health is certainly encouraged and should be justified in the application.

General Application Questions that Apply to Both RFPs

15. ***Can I apply as PI on more than one application?*** At the LOI stage, multiple LOIs are allowed (either >1 LOI to a single Call or one or more LOIs to each of the two Calls). However, at the full application stage, each PI is limited to one full application per Call (one for Community Collaboratives, one for Youth Mental and Sexual Health). If you have more than one LOI approved, it is up to the PI to determine which to carry forward as a full application(s). The PI on one full application can be listed as any key personnel other than PI (this includes both applicant PI and co-PI) on another application, but not as PI or Co-PI. (Note, Co-PIs are not allowed under the Youth Mental and Sexual Health Call.)

16. ***Do the character limits include spaces?*** Yes.

17. ***We have a negotiated indirect cost rate agreement with DHHS that is higher than 30%, and we've used that rate with TRDRP in the past, can we use it here?*** No, CHRP limits indirect costs to no more than 30%, or your negotiated rate, whichever is *lower*. In this case, 30% applies.

18. ***Is the NIH salary cap enforced, or is the actual salary of the PI at his/her institution the figure we should use?*** CHRP does not have a salary cap but will honor whatever limits your institution imposes; enter the actual salary figure for all funded personnel.

19. ***Will you distribute the names of the reviewers? And can you send a list of study sections for this CHRP funding opportunity?*** We don't distribute reviewer names at this time.

20. ***Can the aims mentioned in the LOI be modified during main application submission?*** Yes, they can be changed. If you're considering this, please email the Program Officer to discuss briefly, to ensure continued appropriateness of your idea or your operationalization of it, and to help us to plan appropriate reviewers for the study section.

21. ***Are letters of support (LOS) required from each of my collaborators?*** No, LOS are not required, but they are encouraged as they help the reviewers to establish that you have the team and/or resources in place to get started without delay.

22. ***Under this mechanism, is the Principal Investigator allowed to claim salary/benefit support?*** Yes, we expect salary and fringe benefit support for both the applicant PI and the co-PI.

23. ***I have a dual appointment at the VA and UC, can I submit via either institution?*** It depends: "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."

24. ***Should collaborators who are key personnel without salary support be included in the budget justification, or just entered in the key personnel section of the proposal?*** All key personnel, both those provided with salary support and those without, should be (a) listed in the budget, (b) described in the justification, and (c) percent effort stated.

25. ***Can we state effort percentage to be "as needed", without a set percentage, or "minimal"? Must we define a percentage amount of effort?*** During the application stage, we would suggest indicating a specific percent effort for all key personnel (although there is no rule against stating effort as "as needed") because it would give reviewers a stronger sense of the level of commitment to the project. If the application is selected for funding, the percent effort may be revised during award negotiations and/or at a later stage, if appropriate.

26. ***I have approvals on hand from IRB for similar work that is ongoing, shall I include those in this application?*** Those protocols would not be considered true approval for the proposed project until the CHRP funding source is listed on the protocol. Thus at the application stage, we suggest listing the IRB approval as "pending." One might consider including a sentence on the Human Subjects page stating that you have similar approvals in place, as it demonstrates your capacity to do the type of work that is already approved, and an increased likelihood that you could go live with the proposed work without substantial IRB delay.

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