

# CHRP LAI PrEP RFP Questions and Answers Updated July 11, 2023

	Date Added
<b>Questions About LAI PrEP Funding Decisions</b>	
Are there any criteria that would judge one application over another because they are using study drug?	20-Jun
No, it is not part of the scoring criteria	
<b>Questions About LAI PrEP Budgeting Details</b>	
If the application has 2 Co-I, can the 10% requirement be split between to 2 so each could have 5%?	20-Jun
Any designated PI/CO-PIs needs to have 10% LOE. If you have multiple PIs, each is required to give a minimum of 10%. This is not required for your Co-investigators.	
Could the project include issuing TBD fiscal support to pilot sites for start-up / research activities?	20-Jun
Please provide more information by emailing the appropriate program officer about the specifics of why the funding is TBD.	
Can we include a new position to help patients navigate insurance benefits when starting injectable PrEP?	20-Jun
Yes	
Can we use funds to provide incentives or stipends to clinics for capacity building efforts?	11-Jul
Yes, with clear justification.	
How should we categorize incentives or stipends for capacity building in the budget?	11-Jul
These costs should be documented in the budget under "Other Project Expenses".	
<b>Questions About LAI PrEP Sub Awardees</b>	
If we have a Co-PI from a community organization, will CHRP issue a separate NOA or would this organization be treated as a subawardee?	20-Jun
This is a single-investigator award, but you may bring on sub-contractors to complete various aspects of this work. You may include Co-Is from agencies you plan on partnering with.	
Regarding sub recipients, would you be interested in giving notice awards directly to the organization (as opposed to a sub award)? If so, would we lay that out in our plan?	20-Jun
This is a single-investigator award. So only one NOA will be generated to the lead agency. You may sub-contract with additional agencies if you wish.	
<b>Questions About LAI PrEP Award Requirements</b>	
Assurances Required (if applicable: Human Subjects; Vertebrate Animals; Biohazards; DEA Controlled Substance Use), what does this mean?	20-Jun
If you are planning to work with human subjects, you must have IRB approval (or a timeline to obtain IRB approval). IRB approval can be obtained on a "just in time" basis. The DEA assurance only pertains to any project with plans to provide illegal substances to clients. In this case, contact your Program Officer for more information.	

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"Protection of Human Subjects and/or Care of Vertebrate Animals (if applicable)", what does this mean?	20-Jun
Please see previous response.	
Can we edit the initial proposal to incorporate a larger population for injectable PrEP?	20-Jun
Yes, you may edit your proposal based on what you wrote in the LOI to expand your project or specify a broader population.	
Do you need any SOPs from us to know more about the extent of PrEP uptake currently at our clinics?	20-Jun
No you do not need to provide SOPs about current clinical activities.	
What are the milestones that you look for to consider the implementation impactful?	20-Jun
You should define milestone relevant to your project within your application.	
Do you need any documentation of how we overcame certain barriers or addressed social determinants?	20-Jun
We do not need this information, but you can include it to demonstrate that you have the capacity to complete the goals of the project as they relate to addressing barriers and social determinants of health.	
Is there a word count/character limit for all sections in the full application?	20-Jun
No, just a 15 page limit	
Do I need to name all community partners in the proposal?	20-Jun
You may leave partners unnamed during the application process and can focus on the steps to select appropriate partners. Selecting partners may be a formative part of a research study, which is appropriate and applicable.	
Do we need to submit AIMS on both the project Information Tab and the Research Plan Template?	20-Jun
Yes, the AIMS need to be in both parts of the application. Note, the project information tab has a word limit, meaning the description of AIMS in this section may be shorter than what you describe in your research plan.	
How extensive do we need to be in the sustainability section?	11-Jul
Proposals should have a sustainability plan for integration of best practices into prevention practices and discuss how the proposed work could be scalable. As to the question of scope, we are not looking for robust or detailed plans, just outlines or roadmaps explaining how your project supports ongoing use of LAI PrEP after study completion for both institutional settings and interested participants.	

### Questions About LAI PrEP Post Award Requirements

Are there any regular reports that you would need to check the performance/progress?	20-Jun
Performance progress will be monitored through annual progress reports.	
Is the annual funding renewal contingent on certain goals/milestones?	20-Jun
All CHRP contracts state that further funding is contingent on successful progress towards stated goals based as stated in your annual progress report.	

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### Questions About LAI PrEP Community Engagement

The application requirements list in the FOA calls for a Community Engagement Plan, if required, but I cannot locate any additional guidance on the items to include. Can you provide more guidance on this item? 20-Jun

The community engagement plan is optional. If you are going to have community engagement, you do want to address it as part of your larger research plan and discussion of collaborations.

For the community engagement plan, is there guidance on where we would place it? Can it be an appendix? 20-Jun

The community engagement plan can be incorporated as a paragraph in your research plan.

### Questions About LAI PrEP Study Drug

Will ViiV provide study drug? 20-Jun

ViiV will potentially provide drug to investigators who apply and are approved through their internal review.

If we are awarded funding, are we guaranteed approval for study drug? 20-Jun

The decision to award study drug will be made independent of the decision to award CHRP funding. Investigators who wish to apply for study drug, must submit an application to ViiV directly. There is an understanding that the RFP and ViiV's priorities align, but we can not guarantee any investigator will be approved for study drug.

If study drug is to be provided, would ViiV consider a reimbursement method versus providing study drug for distribution, which will be challenging to implement in the community environment? 20-Jun

This is a discussion point between the investigator and ViiV. However ViiV has indicated that they typically provide drug and do not have a mechanism in place for providing reimbursement.