CREATE FAQ

1. What has been the community's involvement with CREATE?

Community council forums and advisory boards have been emphasizing the importance of community-based research for ending the HIV epidemic. In appreciation of this feedback from the community, Gilead decided to develop the CREATE RFP to specifically support community-based research so that those results may benefit others providing care for people with HIV.

The RFP was developed from the start with community involvement, and the community will continue to be involved through to proposal review and presentation. When developing CREATE, Gilead engaged with a panel of external community advisors. These community advisors discussed and selected the data gaps and open research questions that they felt would be most important for supporting community led research that should be highlighted in CREATE. These advisors also reviewed the process for how LOI applications would be evaluated. This resulted in an agreement between Gilead and the advisors that all full proposals will be reviewed by 2 of the external community advisors and 1 Gilead reviewer. Final decision on funding awards will be made through this collaborative process including the advisors and Gilead reviewers.

2. What do we mean by "community"?

In order to be as inclusive as possible, CREATE has defined community as everyone impacted by HIV, as well as people, entities and organizations working to provide health or social services, education or advocacy, for those impacted by HIV.

3. Who is eligible to apply for CREATE?

Any community organization, either for-profit or non-profit, that meets the definition of community as defined above is eligible to apply.

Since the intent of CREATE is to support the community, please note that the proposal should originate from a community entity and be led by a non-academic individual (e.g. one who has neither an academic appointment nor is employed at a higher learning institution).

Example 1: Can a community-based organization apply and list an advisor with an academic appointment as a member of the study team? Yes.

Example 2: Can a person working in a community-based organization with an academic appointment apply for CREATE?
No, it is recommended that the main investigator is an active member of the community-based organization without an academic appointment; however, the member with the academic appointment could still be on the project in support of the non-academic lead. Also, we recognize that many community-based organizations partner with academic institutions or specific individuals with academic appointments. Therefore, these individuals and institutions can be supporting partners in these research projects for CREATE.

Example 3: Can someone at a CBO who is a lecturer at an academic institution apply for CREATE?
Yes, since a lecturer is not a permanent academic appointment, this person can apply as the study lead for CREATE.

4. Why are there two tiers of grants?

CREATE was intended to build research capacity in community-based organizations that had less experience with research as well as support organizations with more extensive research experience. Therefore, a significant portion of CREATE funds and external *pro bono* vendor support are reserved for Tier B applicants who seek to build new research capacity in their organization to answer questions relevant to their community.

5. Who determines which tier an applicant will qualify for?

The organization chooses what tier they are most eligible for.

6. When do I apply for the *pro bono* research support? What is the cost?

All Tier B applicants will be eligible for research support from an external vendor. This research support is being provided free, complimentary by a company outside of Gilead Sciences and does not have to be included in the funds being requested by the applicant. CREATE will provide the contact information of the company when a Tier B LOI is invited to submit a full proposal.

To ensure impartial review of applications for CREATE and because these submissions are independent of Gilead Sciences, Gilead personnel including Medical Scientists cannot be involved with the LOI, discussions with the vendor, or proposal development. It will be up to the applicant to determine what kind of questions or support to ask of the company providing this free research support. This research support can be used to create or strengthen the full research proposal before it is submitted.

7. What type of support is the vendor providing?

The vendor is a company that is not affiliated with Gilead and is offering limited consultations on a pro bono basis. Topics could include research consultations for proposal development, including for study design, identification and measurement of endpoints, survey development, statistical analysis, consultation on IRB process, etc. Gilead has not contracted with the vendor for these services, and the community-based organization must independently reach out to the vendor for any consultation once they are provided the contact information.

8. What type of guidance can you give regarding IRB submissions?

The community organization will be responsible for determining whether to submit to an IRB or apply for an exemption depending on the type of research they will be doing. Tier B applicants invited to submit a full proposal can consult with a vendor for general guidance. Applicants can include IRB costs in their budget.

9. What level of detail is needed for a LOI?

If printed out, the content of the LOI should be about 1-2 pages long. Information should include a description of the organization, the research question you propose to study, how data will be collected and analyzed to answer the question, why the research is important and how the results will benefit the community.

An approximate total budget should be provided, but a detailed budget will not be needed until a full proposal is invited.

10. How do I start submitting a LOI?

We strongly recommend that the applicant create a G.Optics account and start a draft as soon as possible to familiarize yourself with the system and the questions asked. You will be able to save your work as a draft that you can review before submitting. There are also guidance documents

with screenshots on the RFP page to walk applicants through the process. If you have any questions or encounter technical difficulties, please contact CREATE@gilead.om

11. Can I submit more than one LOI?
Yes, provided that each LOI is about a different research project.

12. Is there a deadline for completion of the project?
Recognizing that research timelines can change, there isn't a specific deadline for completion of the project for an applicant who receives funding from CREATE. However, in general, we anticipate that most projects will be completed within one year after funding is received.

13. Is a detailed budget required? Is there guidance regarding patient reimbursements?
A detailed budget with line items is not required for a LOI. Only full proposals will be asked to provide a detailed budget.

With regard to patient reimbursements that are listed in a detailed budget for a full proposal, there are no specific limitations but the reimbursements must be within fair market value for the time the participant spends on study activities and they will have to eventually be reviewed and approved by an IRB (when the research is submitted for IRB approval, not at the time of LOI submission).

14. Who can I contact for more information?
Please email us at CREATE@gilead.com if you have any additional questions. Please keep in mind that the deadline for LOI submission is Oct. 3, 2023 (23:59 PDT), so it is best to contact us in advance of this date for assistance.