

**Gilead Sciences, Inc.**

**Medical Affairs**

**Request for Proposals: CREATE Community Based Participatory Research Program**

**Community REseArch To End the HIV Epidemic-U.S.  
Request for Proposals (RFP)**

Community-based organizations, community-based health centers and other organizations providing support or care to people with HIV (PWH) are committed to improving health outcomes for conditions commonly seen in their communities. Research plays an important role in improving services and quality of care for populations most impacted by HIV. It is critical that community organizations, the people who work in these organization, and the individuals who receive HIV treatment and care from these groups have opportunities to identify critical research topics and are drivers in carrying-out the research. Results from a national survey of community health centers indicate more than half currently participate in research, primarily through partnerships, and more than two thirds want to expand their research activities.<sup>1</sup>

Gilead supports the research efforts of community organizations, academic institutions, clinical investigators, and research networks to help improve long-term care and engagement for people with HIV. Through this request for proposals, Gilead is making a specific request for community-based participatory research study proposals in the therapeutic area of HIV treatment. The CREATE CBPR RFP Program is in addition to Gilead's existing [Investigator Sponsored Research Program](#), which supports investigator-sponsored research conducted by clinicians and researchers on Gilead's marketed products and/or within therapeutic areas of interest to the company.

**Through the CREATE U.S. Program, Gilead will evaluate and potentially support proposals which address one of the following topic areas:**

With a particular focus of key affected communities and sub-populations\* of PWH facing barriers to access, adherence and/or quality of care:

- Identifying innovative approaches to re-engage and continually engage people with HIV in HIV care, in particular ensuring rapidly re-starting HIV treatment following a treatment interruption
- Adapting, pilot testing or evaluating practical evidenced-based initiatives, programs or support systems to support PWH
  - sustain long term virologic suppression
  - access stigma free care
  - obtain person centered care
  - enhance quality of life including mental health

\*Key affected communities/sub-populations include (but may not be limited to): Black, Indigenous, and/or people of color; transgender women; cisgender women; individuals  $\geq$  50 years of age; youth; immigrants/migrants; homeless/marginally housed; commercial sex workers; persons who use drugs or other substances; those with mental illness and/or clinical co-morbidities; individuals with viremia, low CD4, and/or pre-existing resistance; and low socioeconomic status/uninsured populations

**Research**

The intent of the CREATE U.S. RFP is to proactively request research proposals from the community or

community based organizations. The community is defined as entities and organizations including but not limited to those providing health or social services, education or advocacy for populations most impacted by HIV. To qualify as “research”, a hypothesis, objective, endpoints should be specified in the proposal. Qualitative research should be well defined, and how data will be used to improve/modify programs should be clear. The community organization must be the driver behind the research proposal and the orchestrator of the research project – not a secondary partner to a research entity - whether the study is qualitative or quantitative in nature. Community sites and investigators with limited research capacity or experience may partner with an institution or individuals as needed (e.g. academic institutions, etc), but the research funds need to go directly to the community site performing the research. This is not a grant for program development, but a research program with expectations that the study results will be presented and/or published in an appropriate forum. The CREATE U.S. RFP is intended to provide the community with the results of the funded research so that those results may benefit others providing care for PWH.

For this CREATE U.S. RFP, there will be two award tiers as described below:

Tier A (award up to \$200,000)

-Applicant is a community-based organization with an established track record in conducting and presenting/publishing CBPR

-Proposed study involves a larger scale or more involved/intensive intervention or the impact of the research program that will affect a wider population

Tier B (award up to \$50,000)

-Applicants from all other community-based organizations

-For community-based organizations who are applying for Tier B and wish to discuss their proposals, Gilead may be able to provide the contact information for a third-party vendor that may offer limited consultations. Topics could include basic research consultations, measuring endpoints, survey development, etc. The request for these vendor services is made at the time of Letter of Intent (LOI) submission. 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.

**Eligibility Criteria**

- Applicant’s organization must provide services including but not limited to health or social services, education or advocacy for populations most impacted by HIV.
- Applicant’s organization must be based in the United States.
- Proposals should directly address a specific research question listed in this RFP.
- Proposal should not include any medications for the treatment of HIV and should not evaluate the safety or efficacy of any medication.

**Research Criteria**

- Have clear scientific objectives based on scientific hypotheses. For proposals that are descriptive only or fully qualitative in nature, where this may not apply, please explain how results will be used to improve programs or generate hypotheses for future studies.
- Collect appropriate metrics using defined, specific, and appropriate data collection methods
- Have a plan to present results in scientific or large community forum and to other organizations,

and to publish results in peer reviewed journals

- Note potential scalability and sustainability of the program once funding is complete (when applicable)
- Highlight generalizability or applicability to other community settings
- The proposed research will not take longer than 12 months to complete
- 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). However, community groups as study leads can propose to partner with an academic institution to bolster research capacity.

## Application Process and Submission Deadlines

To apply for consideration for funding under the CREATE U.S. RFP, please submit a Letter of Intent (LOI) via the [Gilead Optics \(GOptics\) online portal](#).

The LOI should contain a concise overview of your organization, which Tier you are applying for, the proposed project that directly addresses a CBPR topic (above) and a total estimated budget. Instructions on how to submit an LOI with screenshots is here.

### Deadlines:

- **August 15, 2023:** LOI Submission window opens
- **October 3, 2023 (23:59 PDT):** LOI Submission window closes

A review of the LOIs will result in invitations for the top scoring LOI applicants to submit a full proposal with a detailed budget. Below are the timelines for full submissions.

- **October 13, 2023:** Notice of LOI outcome, with invitations for full application submission
- **November 10, 2023 (23:59 PDT):** Full proposals are due

Instructions on how to submit a full proposal is here. All full proposals must be complete and submitted into [GOptics](#) in order for them to be reviewed.

Questions about the RFP or the application process can be submitted to: [CREATE@gilead.com](mailto:CREATE@gilead.com)

Awards shall be for research purposes only. **Requests that include routine medical care or other costs associated with routine medical care will not be considered.**

## Budget Considerations

Gilead plans to award of up to \$800,000 in funds for these research proposals, dependent upon availability of funds and receipt of meritorious applications. Gilead anticipates that up to 10 awards will be granted.

## Review Process

The data gaps and open research questions within the RFP have been discussed with and selected by a panel of community advisors. Each LOI that meets program requirements and is complete, will be assigned to multiple reviewers. Each reviewer will review and score the LOI and will evaluate how well the proposal addresses the RFP, the potential impact and significance of the study, the strength of the

study design and sustainability/scalability/generalizability of the methods under study. Scoring is based on the modified NIH Scoring Tool. High scoring LOIs will be discussed by a multidisciplinary committee. Submitters with the top LOI submissions will be invited to submit a full proposal. All full proposals will be reviewed by a panel consisting of internal reviewers and community advisors drawn from the community and experienced in CBPR.

### **No Guarantee of Funding**

Gilead reserves the right to approve or decline any application at its sole discretion. Submission of an LOI or a full application does not guarantee funding.

### **No Inducement or Reward**

Gilead approval of awards does not take into account the past, present, or future volume or value of any business or referrals between the parties. Awards are not being given, directly or indirectly, as an inducement or reward with respect to the past or potential future purchase, utilization, recommendation or formulary placement of any Gilead product. Furthermore, the awardee is not required to purchase, order, recommend or prescribe to any patients any products manufactured by or available through Gilead

1. Beeson T, Jester M, Proser M and Shin P. Engaging Community Health Centers (CHCs) in Research Partnerships: The Role of Prior Research Experience on Perceived Needs and Challenges. *Clin Trans Sci* 2014;7: 115–120.

GILEAD and the GILEAD Logo are trademarks of Gilead Sciences, Inc.

© 2023 Gilead Sciences, Inc. All rights reserved.