

**Community REseArch To End the HIV Epidemic (CREATE)
Request for Proposals (RFP) for Australia, Canada and Europe (ACE)
CREATE-ACE**

Community-based organizations, community-based health centers and other organizations providing support or care to people with HIV 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 organizations, 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 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.¹

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 (RFP), Gilead is making a specific request for community-based participatory research study proposals in the therapeutic area of HIV care.

Through the CREATE-ACE Program, Gilead will evaluate and potentially support proposals which help communities reach and maintain the UNAIDS 95-95-95 targets and achieve long term success in the management of HIV. This includes proposals that aim to help people with HIV to know their HIV status, be on lifesaving antiretroviral treatment and people who are on treatment achieve and sustain viral suppression. Proposals that aim to close gaps in achieving the UNAIDS 95-95-95 goals and long-term success of key affected communities and subpopulations of PWH will be prioritized. Research proposals should address one or more of the following open research questions and topic areas:

1. How do innovative programs designed and delivered by the community improve testing and linkage to care, reduce late diagnoses, support rapid ART initiation, support adherence, and improve long-term management of HIV in key populations*?
2. Understanding the impact of peer services on the individual's treatment journey (diagnosis, deciding to start treatment, adherence, treatment decisions, staying in care, quality of life).
3. Given the impact of stigma in obtaining 95-95-95 goals, describe and evaluate a strategy, approach, or program that can empower people with HIV to live their best lives.
4. What innovations can increase collaboration between the community and clinicians and other local stakeholders?

*Examples of key priority populations include (but are not limited to): Gay, bi, and other men who have sex with men; trans and gender diverse people; migrants/immigrants; Indigenous communities; individuals ≥50 years of age; underserved populations; cisgender women; youth; homeless/marginally housed; sex workers; persons who use drugs or other substances; those with mental health challenges and/or clinical co-morbidities; people in custodial settings; and low socioeconomic status/uninsured populations.

Community Research

The intent of the CREATE-ACE 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, and 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, hospitals, etc), but the community organization must enter the research agreement, and the funds will go directly to this entity as the party 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-ACE RFP is intended to provide the community with the results of the funded research so that those results may benefit others providing care for people with HIV.

For this CREATE-ACE RFP, there will be two award tiers. Applicants should select which Tier to apply for carefully as there will be a limited number of Tier A rewards available.

Tier A (award up to USD\$120,000)

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

-Proposed study involves a larger scale, more involved/intensive intervention, or high impact of proposed research on a wider population

Tier B (award up to USD\$30,000)

-Applicants from all other community-based organizations

As the study sponsor, the principal investigator will be responsible for compliance with all laws and regulations applicable to research sponsors, including satisfying local requirements and obtaining all necessary regulatory approvals prior to beginning the study.

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 Australia, Canada or Europe and serve a population in one of these regions.
- Community based organizations must have the legal capacity to conduct research.
- 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.
- Proposal should originate from a community entity and be led by a non-academic individual (e.g., one who has neither a paid academic appointment nor is employed at a higher learning institution, hospital, or healthcare center on a full-time basis). However, community groups as study leads can propose to partner with an academic institution or healthcare institution to bolster research capacity.

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 a 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 18-24 months to complete.

Application Process and Submission Deadlines

To apply for consideration for funding under the CREATE ACE 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 one or more of the open research questions (above) and a total estimated budget. Instructions on how to submit an LOI with screenshots are [here](#).

A review of the LOIs will result in invitations for the top scoring LOI applicants to submit a full proposal with a detailed budget. For applicants who are invited to submit a full proposal based on their LOI, instructions on how to submit a full proposal are [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
We also advise interested applicants to reach out to their local Medical Scientist/Community Partner.

Q&A sessions

For interested applicants, Gilead will be holding Q&A sessions for CREATE-ACE to answer general questions about the RFP and the application process on August 8, 2024, 7am and 5pm PDT. Please send an email to CREATE@gilead.com for a Zoom invitation. A summary of the discussions will be posted on this RFP here when available for applicants who could not attend.

Key Dates:

- **July 22, 2024:** LOI Submission window opens.
- **October 15, 2024 (23:59 PDT):** LOI Submission window closes
- **November 1, 2024:** Notice of LOI outcome, with invitations for full application submission extended to successful LOI applicants.
- **December 2, 2024 (23:59 PST):** Full proposals are due.
- **By February 28th, 2025:** Notice of full application outcome

Budget Considerations

Gilead plans to award up to \$1.2 million 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. Proposed overhead costs should not exceed 30% of the total budget.

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.**

Review Process

The data gaps and open research questions within the RFP have been discussed with 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, evaluating the proposal fit to RFP, rationale, methodology, community impact, and feasibility according to the guidelines linked [here](#). 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. Proposals that are funded will primarily be investigator-sponsored research study proposals. However, collaborative research study proposals (developed in conjunction with Gilead) will also be considered.

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.

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