

Community-Based Participatory Research (CBPR) Request for Proposal (RFP) Program

Full Proposal

Instructions to Applicants Invited to Submit Full Proposals

Community-Based Participatory Research (CBPR) program

Thank you for your interest in the Community-Based Participatory Research (CBPR) program through Gilead Sciences Inc. For easy reference, this document provides step-by-step instructions to submit a Full Proposal if your LOI has been selected for further review.

1. Login to your G.Optics account.
2. Navigate to your LOI and click on the “Convert to Full Proposal” button in the top right.
3. Refer to this document for guidance filling out the proposal fields for this CBPR program.
4. Contact CREATE@gilead.com if you need further assistance

Converting LOI 1: Receiving an email invitation to submit

1. An invitation will be sent to the email address registered in G.Optics

From: noreply@gilead.com
Date: August 2, 2023 at 11:23:29 AM PDT
To: Archie Kwan <breing@gmail.com>
Subject: G.OPTICS: Invitation to Submit Full Proposal to Test RFP Program for "Convert to a full proposal" RFP Program - L-2023-0410

Dear [REDACTED],

Thank you for submitting a letter of intent (LOI) for your proposal titled Study Title Transfers to Full Proposal to the Gilead Medical Affairs Test RFP Program for "Convert to a full proposal" RFP Program. We received many highly competitive submissions from across the world and we had to select a small number of proposals for further consideration. Your LOI scored well during a formal, cross-functional committee review. We are pleased to invite you to submit a full proposal with detailed budget for further review. The full proposal is due [REDACTED]

3. Click on the link to navigate directly to your LOI. Alternatively, you can login to your G.Optics account at: <https://gileadmedaffairs.appiancloud.com/suite/portal/login.jsp>

To complete the proposal, please return to G.OPTICS [L-2023-0410](#) and select the "Convert LOI to Full Proposal" button. Details from the LOI will be populated automatically, and additional fields including the budget template will be available for you to complete.

In light of the FDA's Patient-Focused Drug Development initiative to gather patients' and family caregivers' perspectives on living with a disease, the symptoms that matter most to them, and their experiences with available therapies, we are interested in supporting proposals that incorporate patient perspectives, patient reported outcomes and other methodologies that meet patient needs and goals and enhance patient outcomes. We encourage proposals that utilize study protocols that reflect patient input and capture data that is meaningful to patients. In addition, if your research center has a Community Advisory Board, which reviews, comments or is involved in your research, please add this information to the application.

Please ensure that your full proposal is submitted by [REDACTED] as proposals received after that time will not be reviewed.

2. Note the due date for submitting a full proposal. The system will not allow submission after this date.

Converting LOI 2: Converting your LOI to a full proposal

My LOI - PI - Investigator Sponsc x

https://gileadmedaffairstest.appiancloud.com/suite/sites/pi-sponsored-research/page/my-lois/record/IQBgv5cFTglcoFbaH5S_U...

Gilead Test Environment

HOME MY PROPOSALS MY AMENDMENTS MY CONCEPTS MY LOI

CONVERT TO FULL PROPOSAL

Summary Review Comments Related Actions

GILEAD | optics ONLINE PORTAL FOR IIS & COLLABORATIVE STUDIES

L-2023-0410 [User Profile] Jul 29, 2023

LOI Status

Draft In-Review Invited for Full Proposal

Principal Investigator

Access your LOI in the MY LOI section

Click this button to convert your LOI

Note: Only LOIs invited for Full Proposals can be converted

Converting LOI 3: Acknowledgement step

Research Proposal

When you have developed a research plan, you can submit a proposal to Gilead for funding and/or study drug through G.OPTICS, using the New Research Proposal form submission.

What is a Research Proposal Submission?

It is a formal application requesting a detailed summary of your proposed research: Principal investigator, sponsor details, scientific rationale, study design, data collection methods, patient/community engagement, complete study budget (if applicable) and publication plan.

If you would like to grant access to others to edit, update, or complete your proposal form entry when further information is requested, please include their email address under "General Research Information" section.

If you are looking to submit a Research Concept for feedback on your research ideas, please go back to the main page and select "New Concept" button. If you need help submitting a Proposal, please refer to the "Help" button on the main page.

What is the Difference Between Investigator-Sponsored research (ISR) or Collaborative Research??

In the New Research Proposal form, there is a 'Research Type' question asking whether your research is investigator-sponsored or collaborative research. ISR and Collaborative studies are similar in that Gilead does not act as the Sponsor for either research type. Usually, the investigator's Institution acts as the Sponsor for such research, which is initiated by the investigator alone or in cooperation with Gilead. However, there are some key differences between ISR and Collaborative research:

Investigator-Sponsored Research

- Research must occur after regulatory approval of the study product
- Gilead provides either funding, product or both

Collaborative Research

- Research may be conducted using an investigational product
- Gilead's involvement in the study is beyond providing funding, product, or both
- Gilead may be involved in the study design, development or conduct, providing data/biological samples, data/sample analysis, and/or publication preparation/authorship

I have read the above description and I confirm my choice to submit an Investigator-Sponsored or Collaborative Research Proposal to Gilead Sciences for review.

« GO BACK

Click this
button to
convert your
LOI

» CONFIRM AND PROCEED

Review info on screen
and check this box

Proposal Submission 1: Tips

- We recommend starting a proposal draft and reviewing the submission data fields as a first step.
- It may be easier to draft text for longer fields in a word processing program, noting the character count, and pasting the final version into the submission website fields.
- Please note the deadline for submission of your Full Proposal in your email invitation. The submission window closes automatically by the date shown and cannot accept late submissions.

Note: you can scroll down to the bottom of the submission page and click here to save your work at any time

I hereby certify that the above statements are true and correct to the best of my knowledge



Please note:

*If you have clicked on Submit and you are on the same page, mandatory fields are missing, please scroll up to see the highlighted fields that need addressing.
"Submit" button is only available for Principal Investigator of this study.*

CANCEL

SAVE FOR LATER

SUBMIT

Proposal Submission 2: Filling in the Submission Fields

Study Title, Therapeutic Area, Product, Research Type, Scope of Research

General Research Information

Study Title *

Your study Study title will be automatically transferred from your LOI, but you can edit if you wish

10/255 (max 255 Characters)

Therapeutic Area *

HIV Treatment Select therapeutic area of the CBPR RFP that you are applying to

Please select all applicable Therapeutic Areas if there are more than one.

Research Type *

Investigator Sponsored Select Investigator Sponsored

Difference between investigator-sponsored and collaborative research are described on the 'Research Proposal' landing page (viewed before this page) and the Gilead ISR FAQ document in the 'Help' section (found on the main site). Consider saving your work if navigating away from this page ('SAVE FOR LATER' button at the end of this form).

Product(s) being studied ?

Drug Agnostic Because no drugs are involved in CBPR proposals, select "Drug Agnostic"

Scope of Research

Other

Select Community Research. If none of the choices apply to your proposal, please select "Other"

Proposal Submission 3: Filling in the Submission Fields

Study Lead and additional contacts

Tip: We strongly recommend that the research lead is the requestor/applicant and that any team members are added as assistants

Have you contacted anyone at Gilead regarding this Proposal?

Yes No Answer yes or no. If you answer yes, you will be asked to provide the name of the contact

Will anyone else in your organization be assisting you on this proposal?

Yes No If you would like someone to help you with this proposal, answer Yes.

Please provide their email id(s)

Email

Provide their email address here by clicking on “Add Email Ids”
They will be contacted with further instructions via email on how to create a G.Optics account and access this proposal.



Proposal Submission 4: Filling in the Submission Fields

Principal Investigator Details

Most of these fields will autofill from the LOI. Please refer to notes on this slide for further guidance if needed

Principal Investigator				
Prefix	First Name *	Last Name *	Suffix	Degree(s)
Mr. ▾	First Name 10/255 (max 255 Characters)	Last Name 9/255 (max 255 Characters)	 0/10 (max 10 Characters)	n/a 3/255 (max 255 Characters) Enter your highest academic degree here. If none, put N/A
Institution Name		Institution Type		Specialty
Your Community Organization 27/255 (max 255 Characters)		Charitable/Non-profit Organization ▾ Choose your organization type. If none apply, select Other		Other Choose the area of your studies. If none apply, select Other
Address (Line 1)		Address (Line 2)		
Address of community organization will autofill 47/255 (max 255 Characters)		 0/255 (max 255 Characters)		
City		Country *		
City 4/255 (max 255 Characters)		 		
State/Province		Postal Code		
 		 5/50 (max 50 Characters)		
Email Address *		Phone Number		
email address of principal investigator/research lead/applicant should go here		 		

This should be the email address of the Principal Investigator who would be the primary owner of the proposal.

Proposal Submission 5: Filling in the Submission Fields Sponsor and Site Information

1. Please review the sponsor definition

2a. Check this box if your community organization will be the sponsor of the research project

2b. If your community organization will NOT be the sponsor, please give the sponsor name here and provide explanation in the box below

3. Please answer these questions about the sponsor. If No is chosen, a text box will appear to allow you to provide additional detail.

4. If the research will be conducted at a location that is different from that of the organization, please check this box and provide additional detail

Sponsor Details

A Research Sponsor refers to a person or entity that takes responsibility for the initiation, management and setting up a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. Gilead Sciences cannot be the Sponsor of an Investigator-Sponsored Research project.

Check if same as Principal Investigator's Institution?

Name of Sponsor

0/255 (max 255 Characters). A study sponsor refers to a person or entity that takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. This includes designing the study or analysis, interpretation and ownership of data. Gilead cannot be the sponsor of ISR and collaborative studies.

Explain why the sponsor is outside of your institution

0/255 (max 255 Characters)

I confirm that the above sponsor is responsible for:

Entering into research contract with Gilead

Yes No Can your organization review and sign a contract with Gilead?

"Sponsor" obligations under regulations

Yes No Can your organization act as the sponsor of this research, according to local regulations as applicable?

Design and conduct of the research project

Yes No Is your organization leading the design and conduct of this research?

Oversight of sites, study personnel and participants

Yes No Will your organization be responsible for the sites, personnel, and participants involved in this research?

Primary Site Information

Check this box if Primary Site Information is different from Principal Investigator

Proposal Submission 6: Filling in the Submission Fields

Research Details

Scientific Basis/Rationale

Tell us about the overall main concern that your proposed study will address. Tell us briefly what is already known and short descriptions of the key elements of your proposal. Then tell us the main thing that is unknown or the unmet need that you would like to investigate. Provide references if you have them

0/6000 (max 6000 Characters)

Primary Objective

Describe in a sentence or two your main plan to investigate (for example, the goal of your proposed program or intervention)

0/4000 (max 4000 Characters)

Trial/Study Design

--- Select all that apply--- Select Community Research. If no options apply, choose Other

Number of Sites

Answer "1" for your primary organization site. Answer "2" or more if there will be additional locations gathering data for your study.

Hypothesis

Provide a specific research question this study will answer or hypothesis that this study will test.

0/4000 (max 4000 Characters)

Secondary Objectives

Describe in a sentence or two any additional goals of your proposed program or intervention

0/4000 (max 4000 Characters)

Study Design and Research Methods

Tell us the details of how you plan to study this research question. Give details of your proposed program or intervention, what data you will collect, how it will be collected, and how it will be analyzed

0/4000 (max 4000 Characters)

List all countries where study activities will occur

Start typing the Country...

Proposal Submission 7: Filling in the Submission Fields

Research Details

Priority Populations

Select options that would describe study participants that apply and if no options apply, choose Not Applicable

Inclusion Criteria

List the characteristics that you will require of your study participants

0/2500 (max 2500 Characters)

Primary Endpoint

Describe exactly what you will be measuring for your main study objective (Examples could be, but are not limited to: Average change in quality-of-life questionnaire scores, difference in percentage of participants fully adhering to HIV treatment)

0/4000 (max 4000 Characters)

Sample Size Justification/Statistical Analysis

Provide details of what statistical analysis you have planned and how many study participants you estimate you will need, in order to collect enough data for it to be statistically meaningful.

0/4000 (max 4000 Characters)

Treatment Regimen

As CBPR is drug agnostic, please enter "Not Applicable"

0/4000 (max 4000 Characters)

Exclusion Criteria

List the characteristics that will make prospective participants ineligible for your study

0/4000 (max 4000 Characters)

Secondary Endpoint

Describe exactly what you will be measuring for each of your additional study objectives

0/4000 (max 4000 Characters)

Additional Comments

Please use this field to add any additional information you feel is relevant to your application

0/4000 (max 4000 Characters)

Proposal Submission 8: Filling in the Submission Fields

Data Collection and Community Engagement

Select “yes” if you plan to follow participants forward in time, from study beginning to study end.

Participant Screening/Enrollment

Do you plan to enroll and/or screen participants prospectively?

Yes No

Select “yes” if you plan to analyze data that has already been collected (for example, from medical records)

Retrospective Data Collection

Do you plan to collect and analyze existing retrospective data?

Yes No

Click Yes or No for the first two questions, and select all that apply for the third question

Do you plan to engage patients/community (including caregivers, patient organizations) in your study?

Yes No

Will you ensure that patients/community are informed about the data generated by the study?

Yes No

How will you gather patient/community input?

--- Select---

Proposal Submission 9: Filling in the Submission Fields

Publication Plan and Attachments


Publication Plan ▼

Publication Type	Publication Name	Year Estimate	
<input type="radio"/> Conference <input type="radio"/> Journal		--- Select a Year ---	✖
+ Add Publication Details			

Please enter each planned publication on an individual line. Provide your best estimate for the publication name and year with the understanding that publication plans often change

Attachments ▼

Please upload your curriculum vitae and any supporting documents that may be relevant for this research proposal

Type	File ?	
---Select---	UPLOAD  Drop file here	✖
+ Add New Attachment		

The CV (or resume) you uploaded in your LOI will be listed here. You can delete and update with a new CV (or resume) if you wish. Please also upload any additional documents that you feel are relevant (for example, published reports of previous research studies)

Proposal Submission 10: Filling in the Submission Fields

Study Support and Submitting Full Proposal

Study Support

Type of Support

Select **Select "Funding Only"** ▼

Are you requesting any other type of support from Gilead or other entities?

Yes No Click Yes or No. If Yes is selected, a field will appear to allow you to provide more detail

⚠ Please note:

*If you have clicked on Submit and you are on the same page, mandatory fields are missing, please scroll up to see the highlighted fields that need addressing.
"Submit" button is only available for Principal Investigator of this study.*

CANCEL

SAVE FOR LATER

SUBMIT

Click here when finished!



Proposal Submission 11: Troubleshooting an incomplete submission

If you are returned to this page after you confirm submission, scroll up, find all the red-highlighted fields that need your attention, and fill in the required information. Then click SUBMIT again.



The screenshot shows a web form with several elements:





- A red-bordered box at the top contains the text "CV is required". A red arrow labeled "Example" points to this box.
- A blue header bar labeled "Study Support" contains a red warning triangle icon.
- Below the header, the "Type of Support" field is highlighted with a red border and contains the text "Select". A red arrow labeled "Example" points to this field.
- Below the "Type of Support" field, the text "A value is required" is displayed in red. A second red arrow labeled "Example" points to this message.
- The question "Are you requesting any other type of support from Gilead or other entities?" is followed by radio buttons for "Yes" and "No".
- Below the radio buttons, the text "A value is required" is displayed in red.
- A yellow warning box contains a red triangle icon and the text: "Please note: If you have clicked on Submit and you are on the same page, mandatory fields are missing, please scroll up to see the highlighted fields that need addressing. 'Submit' button is only available for Principal Investigator of this study."
- At the bottom left is a "CANCEL" button.
- At the bottom right are "SAVE FOR LATER" and "SUBMIT" buttons.

↑
Scroll up to find them all

Proposal Submission 12: Thank you!

Summary | Review Comments | Email History | Related Actions

  ONLINE PORTAL FOR IIR & COLLABORATIVE STUDIES

2022-18678   Aug 16, 2022  HIV Treatment  Collaborative - Other Org.

Proposal Status

Draft **In-Review** Decision

General Research Information

Study Title

- After submission, status bar should change to In-Review
- Please direct questions to CREATE@gilead.com