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| NOVA photostrip 72dpi web | |
| |  |  | | --- | --- | | **HIV NOVA Program:**  NOVel HIV Prevention Research Utilizing F/TAF – Letter of Intent |  | | |
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| Please answer all sections below and submit the completed form as a Word file to [NOVA@gilead.com](mailto:NOVA@gilead.com) **by August 23, 2019**, with the email subject heading “**HIV NOVA LOI – [Principal Investigator Name, Organization Name, Country]**.” If you have any questions about this form, please ask your local Gilead Medical Scientist or email [NOVA@gilead.com](mailto:NOVA@gilead.com). | |
| **Investigator/Institution Information** | |
| Principal Investigator |  |
| Telephone |  |
| Email address |  |
| Legal Sponsor / Primary Site |  |
| Address |  |
| City, State, Zip/Province, Postal code |  |
| Country |  |
| Description of Organization/Institution | Hospital  Academic Research  Government Entity  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Name of Subsite (if applicable) |  |
| Address |  |
| City, State, Zip/Province, Postal code |  |
| Country |  |
| Sponsor IRB/REB | Local IRB/REB Central IRB/REB |
| Name of ethics committee (if applicable) |  |
| Does IRB/REB require a fully executed   contract prior to review? | Yes No |
| Is your organization/institution an existing  Gilead grantee? | Yes  No   |  |  | | --- | --- | | If yes, please explain (including program names if applicable): |  | |
| Has your organization/institution applied for or received funding from Gilead in the past? | Yes No   |  |  | | --- | --- | | If yes, please explain (including program names if applicable): |  | |
| Contact at Gilead (if applicable) |  |
| **Proposal** | |
| Study Title |  |
| Estimated Budget Requested from Gilead  *Any proposal greater than* ***$500,000 USD*** *should be discussed with your Gilead Medical Scientist*  *prior to submission. Must include overhead*  *costs and all taxes if applicable. Overhead in*  *excess of 30% will* ***not*** *be approved.* |  |
| Funding Requested From Other Sources?  *If yes, include name of source and amount in   USD.* | Yes: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  No |
| Study Design (check all that apply) | Prospective  Interventional  Retrospective  Modelling  Observational |
| Study Population (check all that apply) | Black/people of African descent  LatinX  Native Americans  Asian/Pacific Islander  Those engaging in transactional sex  Cisgender women  Those with substance use disorders  Transgender women  Those who are unstably housed  Transgender men  Those in correctional facilities  Adolescents  Those with mental health conditions  Older adults  Other. Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Implementation Strategy (check all that apply) | Testing novel methods of PrEP implementation via telemedicine and technology-driven solutions including PrEP online  HIV screening and PrEP services in non-traditional settings (schools, corrections, mobile units, ED and urgent care, family planning clinics, Native American reservations, substance use treatment facilities, etc…)  Engaging pharmacists, nurses, and other non-MD/DO providers in PrEP care  Evaluating new strategies for adherence maintenance and clinical monitoring of adherence  Evaluating strategies to improve PrEP persistence and re-engagement in PrEP care of at-risk individuals, especially in populations with lower rates of retention in care such as adolescents and women  Evaluating approaches for same-day or rapid-start PrEP initiation  Assessing HIV testing and linkage to care strategies as well as STI prevention strategies in the context of PrEP  Using social media and peer related strategies to connect people at risk to PrEP care  Qualitative research strategies to describe social attitudes, behaviors, and knowledge of HIV prevention among communities and populations described in Objective 2  Evaluating interactions between F/TAF and feminizing or masculinizing hormones in transgender individuals  Other. Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Publication Plan, if applicable (check all that   apply)  *Please specify which Conferences and Journals* | Conference: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Manuscript: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Do you plan to present findings to  Policymakers (local, regional, national)? | Yes No |
| **Research Plan** | |
| **Entire plan overview should not exceed two pages.**  *(Provide an abbreviated proposal overview including background/rationale for study, primary and secondary objectives and endpoints, study design, and a discussion of sustainability and scalability if relevant)* | |
| **Biographical Sketches**   * + *Use the NIH biosketch format in Appendix A below to provide abbreviated bio sketches for the principal investigator and up to two additional key co-investigators or collaborators, if applicable*   + *An example can be provided upon request*   + *Online access to these documents can be found at the following hyperlink:*   [*http://grants.nih.gov/grants/funding/424/index.htm*](http://grants.nih.gov/grants/funding/424/index.htm) | |
| **By entering my name below, I hereby certify that the above statements are true and correct to the best of my knowledge.** | |
| Name & Title Date | |

**APPENDIX A**

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.  
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME:

POSITION TITLE:

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

| INSTITUTION AND LOCATION | DEGREE  (if applicable) | Completion Date  MM/YYYY | FIELD OF STUDY |
| --- | --- | --- | --- |
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*A sample Biographical Sketch may be provided upon request to help complete Sections A, B, C, and D (these forms can also be found at* [*http://grants.nih.gov/grants/funding/424/index.htm*](http://grants.nih.gov/grants/funding/424/index.htm)*):*

1. **Personal Statement**
2. **Positions and Honors**
3. **Contribution to Science**
4. **Research Support**