Template instructions

Throughout this template, instructions are in **red** text and can be replaced with the requested information (font color should be changed to black) or deleted.

Formatting requirements

Applications must be in English.

All currency values must be in US dollars.

This application must be written in 11-point font or larger in a standard font (e.g., Arial, Calibri, Times New Roman).

Tables and charts can be in 10-point font.

Pages must be on US letter-sized paper (8.5 x 11 inches or 22 x 28 cm) with 1-inch margins (2.54 cm).

Pages must be numbered using an X of Y format in the lower left-hand corner (e.g., 3 of 5).

This file must be submitted as a single PDF.

If confidential data or information are contained in the application, the phrase “Confidential—do not disseminate” must be placed in the footer of each page.

This file must be labeled *RFA2024-003\_main narrative\_PI name*.

Delete this page.

V1.0

Graphical user interface

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Your project name

Request for Applications 2024-003

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This project is made possible by the generous support of the American people through the United States Agency for International Development (USAID) through the United States President’s Emergency Plan for AIDS Relief (PEPFAR), under the terms of Cooperative Agreement #AID-OAA-A-17-00015. The contents are the responsibility of PATH and do not necessarily reflect the views of USAID, PEPFAR, or the United States government.

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1 Technical application

Section 1 should be no more than five pages total.

Technical applications that exceed five pages will be returned without review.

|  |  |
| --- | --- |
| Principle investigator: |  |
| Title: |  |
| Organization: |  |
| Department: |  |
| Country: |  |
| Email address: |  |

1.1 Project overview

Section 1.1 should be no more than one page.

Provide a brief overview of your project and how your application addresses the objectives of the request for applications (RFA)—specifically, how your project is:

An innovative primary HIV prevention concept in the form of a product, drug delivery system, or drug that is in need of seed funding for demonstration of feasibility, proof of concept, or value added.

Congruent with the Microbicide R&D to Advance HIV Prevention Technologies through Responsive Innovation and eXcellence (MATRIX) consortium’s scientific goals to strengthen the capacity of students, young/early investigators, and established teams.

Succinctly summarize the technical application. Describe how your project and innovation are important/novel, and define your goals, objectives, and strategies. List one to three specific aims. Describe how the specific aims are responsive to the areas of research interest as stated in the RFA and how they will help obtain your research objective.

Note: Proof of concept is defined as evidence generated through experimental methods that a concept meets preestablished criteria for feasibility, such as milestones and/or go/no-go criteria.

1.2 Project management and roles of project team

Section 1.2 should be no more than one page.

Describe the oversight and project management structure for your project. Describe the principal investigator’s (PI’s) training and managerial expertise to direct and manage the project.

Detail how the team has the expertise necessary to complete the proposed work. Detail how the funds will provide an advantage to the PI or institution to build research capacity.

Refer to the “Biosketches”, biographical sketches (separate attachment), and the “Personnel” section in the budget narrative (separate attachment) as necessary.

1.3 Significance and innovation

Section 1.3 should be no more than one-half page.

Describe the significance of the proposed work and how it is innovative. This description should provide a narrative of the expected principal results that the project will achieve and how those results relate to the primary HIV prevention objectives of the RFA. Address how the proposed project will address a critical need for HIV prevention. What makes the proposed project original, innovative, and potentially a game changer?

Applicants should devote a portion of this section’s narrative to specifically highlight how the proposed work will contribute to the field of HIV prevention by the development of their primary HIV prevention product or strategy.

1.4 Technical approach

For each specific aim, describe your study design and methods, and how your data will be analyzed. How will this approach help achieve the project objectives and deliverables of the project? How will you incorporate mentoring components into the project work?

1.5 Timeline to meet deliverables

Create a timeline with projected completion dates for activities. The timeline must include a table or graphic. Ensure that dates align with any stipulations in the RFA announcement. Ensure that the project includes proper time-bound milestones and benchmarks and has realistic timelines. At minimum, you should include milestone(s) or go/no-go criteria at the halfway point and end of your project.

The timeline should be a chronological arrangement of critical activities, milestones, and go/no-go criteria. It is preferred that the timeline is depicted as a graphical representation (e.g., Gantt chart), although timelines in a table format will also be acceptable.

Note these key definitions:

**Activity:** A discrete event that will be performed to achieve a specific goal or milestone. An activity must begin with an active verb.

**Milestone:** A measure of progress. Milestones identify critical junctures/steps in the research process that must be accomplished/completed in order to successfully complete the research. A milestone may also incorporate go/no-go criteria in its description as measures of progress in attaining the milestone.

**Go/no-go criteria:** Critical decision points stated as quantitative absolutes in the development pathway of a product. Go and no-go statements/criteria are an integral part of defining a milestone. Go is a decision to continue development. No-go is a decision to stop development. A single milestone may have multiple go/no-go criteria depending upon its complexity. A go decision allows the research program to proceed to the next milestone.

***Examples***

*Activity: Obtain necessary approvals and conduct a safety and rat pharmacokinetic study.*

*Milestone: Complete safety and rat pharmacokinetic study.*

*Go: There are no safety issues and the prespecified pharmacokinetic parameters were met.*

*No-go: There are safety concerns and/or the pharmacokinetic parameters were not met.*

*Activity: Develop suitable packaging. Perform accelerated stability testing on product.*

*Milestone: Packaging provides sufficient barrier to humidity.*

*Go: Humidity ingress at 3 months is sufficient for product stability with <5% product degradation.*

*No-go: Humidity ingress at 3 months leads to >5% product degradation.*

The examples are provided for clarity purposes only and are not meant to be required wording for describing these critical application components.

1.6 Anticipated problems and solutions

Describe any anticipated problems and solutions or risks to the project and how you plan to overcome them.

1.7 Major internal and external resources

Identify any internal or external resources that can be leveraged in aid of the project. You can include factors such as facilities and equipment, but be brief.

2 Mentorship support statement

Section 2 should be no more than one page.

Note: The level of mentoring must be appropriate to the PI’s level of tenure. Early-stage PIs should identify appropriate mentors while established PIs should indicate how they will mentor younger scientists in their lab.

2.1 Institutional support

Identify the PI’s mentor and their qualifications. Also indicate what support will be provided through the institution, including what capacities and expertise will be provided to support the PI. Examples could include regular meetings with a senior researcher or department chair, structures to assist with financial administration, etc.

2.2 Needed support

Briefly describe what support MATRIX could provide to strengthen the research environment for the PI. This section is to ensure that MATRIX can supply the support as needed, but it does not require MATRIX to provide such support. Refer to these websites for the expertise within MATRIX <https://matrix4prevention.org/> or within PATH <https://www.path.org/>. Examples could include study design, product development, etc.

3 Future funding

Section 3 should be no more than one page.

Describe the potential impact of the proposed research on the field of primary HIV prevention and how successful completion of the research will be leveraged for career advancement and/or access to additional funding by the applicant.