

HPTN PILOT STUDY CONCEPT SOLICITATION FAQ

Q1. What is the submission due date?

A. Letters of intent must be [uploaded](#) by **COB 31 October 2022**. Concepts must be [uploaded](#) by **COB 30 November 2022**.

Q2. What criteria are considered in evaluating an HPTN concept?

A. The criteria listed below are used for evaluation of HPTN concepts.

Scientific Merit (50%)	<ul style="list-style-type: none"> hypothesis is scientifically sound and answerable by the proposed design study design and methods will yield the proposed outcomes plan for analysis of data is adequate and appropriate populations is appropriate for the research; relevance of research to the community is considered
Public Health Impact (30%)	<ul style="list-style-type: none"> relevance of the planned research to the prevention of HIV infection proposed study could provide key information and is part of a critical path of research
Research Advantage of the HPTN (20%)	<ul style="list-style-type: none"> study is aligned with the HPTN scientific agenda and priorities for this solicitation

Q3. Where can I locate a template of the concept form for submission? Is this the normal template used for concept submissions?

A. A copy of the template for this solicitation can also be found on the HPTN website: [Call for Concepts](#). The standard concept template has been modified for this specific solicitation.

Q4. Who can submit a concept? Can different individuals from the same group/organization submit more than one concept?

A. Concepts are welcome from either HPTN or non-HPTN investigators. Individuals within the same organization can submit concepts.

Q5. What is the review process for these concepts?

A. Concepts will undergo review by HPTN Leadership and topic area experts as directed by the HPTN Leadership. This process is anticipated to be completed by end of January 2023.

Q6. How can I get input for a concept under development?

A. Concept authors can solicit input from the HPTN [scientific committees](#) and [working groups](#) or from topic area experts within and outside the HPTN.

Q7. Do all concepts need HIV as an endpoint?

A. For these pilot study concepts, HIV incidence is not expected as the endpoint. However, the concept should describe how the data obtained will inform the design of a potential future study evaluating HIV prevention.

- Q8. *Can I withdraw my concept after it has been approved to move forward to protocol development?*
 A. Concepts can be withdrawn at any time. Concept Leads should inform the HPTN promptly, if they decide to withdraw a concept from consideration.
- Q.9. *Are biosketches and letters of support required with the submission?*
 A. The concept template describes everything that is required for submission. No additional supporting documentation like biosketches or letters of support are required at the time of submission.
- Q.10. *Can individuals submitting concepts get statistical and design support from the HPTN?*
 A. Investigators may request support from the HPTN Statistical and Data Management Center (SDMC). Requests for support should be submitted to concepts@hptn.org.
- Q11. *Can proposals include products that do not have GMP manufacturing or is the Network entertaining only purely research products?*
 A. Proposals involving new or investigational products must be GMP manufactured to allow use in human trials. While products should be scalable for use in subsequent clinical studies, this is not required at the time of solicitation. This solicitation is not intended for pre-clinical trial work.
- Q12. *Can an investigator submit more than one concept or be part of an investigative team on more than 1 concept?*
 A. Yes, an investigator can have multiple submissions, as an individual or as part of a team.
- Q13. *What is the timeline for communicating whether my proposal has been approved?*
 A. The following timeline is tentative and is a guide for planning purposes.

Disseminate concept solicitation	10 October 2022
Submit letter of intent	31 October 2022
Receive concept proposals	30 November 2022
Review and prioritization by HPTN Leadership and delegated reviewers	December 2022 - January 2023
Communications to all concept authors	Early Feb 2023