Concepts for the NIH HIV Prevention Trials Network
Frequently Asked Questions (v. 0.2)

Q1. What are the two aims for the HPTN that serve as the foundation for new concepts?

A. The HIV Prevention Trials Network (HPTN) is engaged in a large number of studies with the goal of reducing the transmission and acquisition of HIV. The mandate for the HPTN is broadly focused on non-vaccine HIV prevention with two pillars for its work: 1) identifying new agents for pre-exposure prophylaxis (PrEP) and 2) identifying integrated strategies designed to maximize the effectiveness of available HIV prevention tools.

Q2. Is the HPTN call for concepts geared toward a specific population or research area?

A. This call for research concepts is broad and can focus on any non-vaccine prevention approach. It is important to note that the concepts should focus on the aims of the HPTN as noted in Q1. Concepts could propose either: 1) vanguard studies (preparatory studies that aim to identify feasibility of recruitment and retention of potential study population, feasibility and acceptability of intervention or combination of interventions or exploring HIV incidence rates in specific population) or 2) phase 1, 2 or 3 clinical trials. Concepts that propose a vanguard study should describe how the findings from the study will inform potential future phase 2 or 3 study.

Q3. What is the due date for submission?

A. All concepts must be submitted to Kathy Hinson by COB **August 15, 2018**.

Q4. What criteria are considered in evaluating an HPTN concept?

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

Scientific Merit (50%)	• 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 • population is appropriate for the research; relevance of research to the community is considered
Public Health Impact (30%)	• relevance of the planned research to the prevention of HIV infection • proposed study is part of a critical path of research • proposed study is or would potentially lead to an efficacy trial
Research Advantage of the HPTN (20%)	• study is aligned with the scientific agenda and priorities of the Network (i.e., integrated strategies and PrEP) • proposed research will benefit from a multi-site, multidisciplinary collaboration involving different populations either in the initial phase or in a subsequent phase

Q5. 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 is attached and can also be found on the HPTN website: Call for Concept Template. This five-page template is slightly shorter than the routine ten-page template. This abbreviated version focuses on the scientific aspect with the following key sections: title, purpose/rationale, study aim, objectives, design, description of intervention(s), endpoints, study population, product-related considerations, and timeframe.

Q6. Who can submit a concept? Can different individuals from the same group/organization submit more than one concept? If yes, would we compete against each other?

A. Concepts are welcome from either HPTN or non-HPTN investigators. Individuals within the same organization can submit concepts. See the response below about the review process in terms of the competition.

Q7. What is the review process for these concepts?

A. Concepts will be received by Kathy Hinson (khinson@fhi360.org) **by August 15, 2018.** These concepts will then be forwarded to the relevant HPTN scientific committee for review and prioritization. Following the scientific committee review, the concepts will undergo the Network review by the HPTN Executive Committee as per HPTN's established process. This process is anticipated to take place during the Fall of 2018. The process will include feedback to the concept authors. The feasibility and funding for the approved concepts will be discussed with NIH partners.

Q8. Can I receive the template in a word document?

A. See the attached announcement and template as a word document (see below).

Q9. How can I get input for a concept under development?

A. Concept authors can solicit input from the existing scientific committees (see committee and working group information on the HPTN website (HPTN Committees) or from topic area experts within and outside the HPTN.

Q10. Do all concepts need HIV as an endpoint?

A. The endpoint(s) for specific concept will be dependent on the nature of the proposed study. For vanguard and phase 1 studies, HIV incidence is not required as the endpoint. However, for phase 2 and phase 3 studies, HIV incidence is the preferred endpoint.

Q11. Do all concepts have to be a randomized controlled trial (RCT)?

A. Proposed concepts should propose the preferred methodology to answer the research question.

Q12. Can I withdraw my concept after it has been approved to move forward to protocol development?

A. Concepts can be withdrawn at any time. However, the concept chair should inform the HPTN promptly, if they decide to withdraw a concept from consideration.

Added 27 June 2018

Q.13. Are biosketches, budgets, and letter of support required with the submission?

A. Please use the concept template for the information provided. No additional supporting documentation like biosketches, letters of support, or budgets are required at the time of submission.

Q.14. Can individuals submitting concepts get statistical and design support from the HPTN?

A. Network resources including statistical, laboratory or operational support are not provided for concept submission. Should the concept be approved, dedicated Network resources will support continued development.