

HPTN PILOT STUDY CONCEPT SOLICITATION

Dear Colleagues:

The HIV Prevention Trials Network (HPTN) is committed to advancing non-vaccine HIV prevention research globally. The Network focuses on the designing and implementing trials for the prevention of HIV acquisition and transmission among all populations at risk for HIV. Its mandate is centered around four scientific aims:

- 1. Identifying **novel antiretroviral (ARV)-based methods and delivery systems** for HIV prevention;
- 2. Developing **multi-purpose technologies** for HIV prevention as well as for contraception, prevention of other sexually transmitted infections or opioid dependence;
- 3. Evaluating **broadly neutralizing antibodies** alone or in a combination that prevent HIV acquisition, in collaboration with the HIV Vaccine Trials Network; and
- 4. Designing and conducting population-specific **integrated strategy studies** that combine biomedical, socio-behavioral, and structural interventions for HIV prevention to maximize their effectiveness.

The purpose of this solicitation is to identify **up to four** concepts for **pilot studies** that can advance the HIV prevention research agenda in the following **priority areas**:

- HIV prevention in heterosexual men in high burden settings
- HIV prevention in stimulant users

The objectives of the pilot studies in these priority areas should be to obtain critical information that will contribute to advancing the work in these specific areas and help inform future HPTN research efforts. Concepts must also be relevant to one of our four HPTN scientific aims.

HPTN and non-HPTN affiliated investigators are welcome to submit concepts. Proposals can include (but are not limited to): identification of specific sub-populations with the greatest need (e.g., age, socioeconomic status, HIV status awareness, other demographics, etc.); engagement of these populations; identification or evaluation of components of a comprehensive prevention package; determination of the feasibility of integrating several interventions, etc.

The study budget for direct costs should not exceed US\$500,000. (The costs for HPTN Central Resources will be calculated separately.) The study must be completed by no later than 30 November 2024.

Future solicitations will include other priority populations or areas of focus.

Concept Lead

All concepts should identify a SINGLE Concept Lead Investigator. If this person intends to be the Protocol Chair, please consider the criteria for assessing suitability for this role.

- Time commitment Must commit to following established HPTN guidelines that include two inperson meetings during the protocol development process, quick responses to team questions, and rapid decision-making to adhere to timelines
- Relevant scientific expertise
- Experience with protocol development
- Experience with study implementation
- Team leadership skills
- Familiarity with the HPTN
- Knowledge of the priority populations and communities

If any gaps are identified, a complementary Protocol Co-Chair may be selected by HPTN Leadership.

Considering the criteria listed above, please indicate **on the concept title page** whether the Concept Lead intends to Chair the protocol.

How to Apply

- Submit a brief letter of intent no later than 31 October 2022 via the Letter of Intent Submission Form. HPTN Leadership will review the letter of intent to ensure that the proposed research is consistent with the priority areas for this solicitation. The letter of intent should include the following:
 - Descriptive title
 - Concept Lead's name and contact information
 - One brief paragraph describing aims, objectives, type of study, and population of focus
- 2. The primary author will receive an email within five working days indicating whether a concept submission is invited.
- 3. Concepts **are limited to five pages** using the template on the <u>Call for Concepts</u> page of the HPTN website and attached to this email.
- 4. Concepts should be uploaded via the <u>Concept Submission Form</u> by no later than **30 November 2022.**
- 5. 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 the end of January 2023.

Should you have any questions, please send your queries to <u>concepts@hptn.org</u>. We look forward to hearing from you.

Sincerely,

Myrn J. Cohen

Myron S. Cohen, MD Co-Principal Investigator HIV Prevention Trials Network

Wafaa M. El-Sadr, MD, MPH, MPA Co-Principal Investigator HIV Prevention Trials Network

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