

# Considerations for a Successful Concept Submission

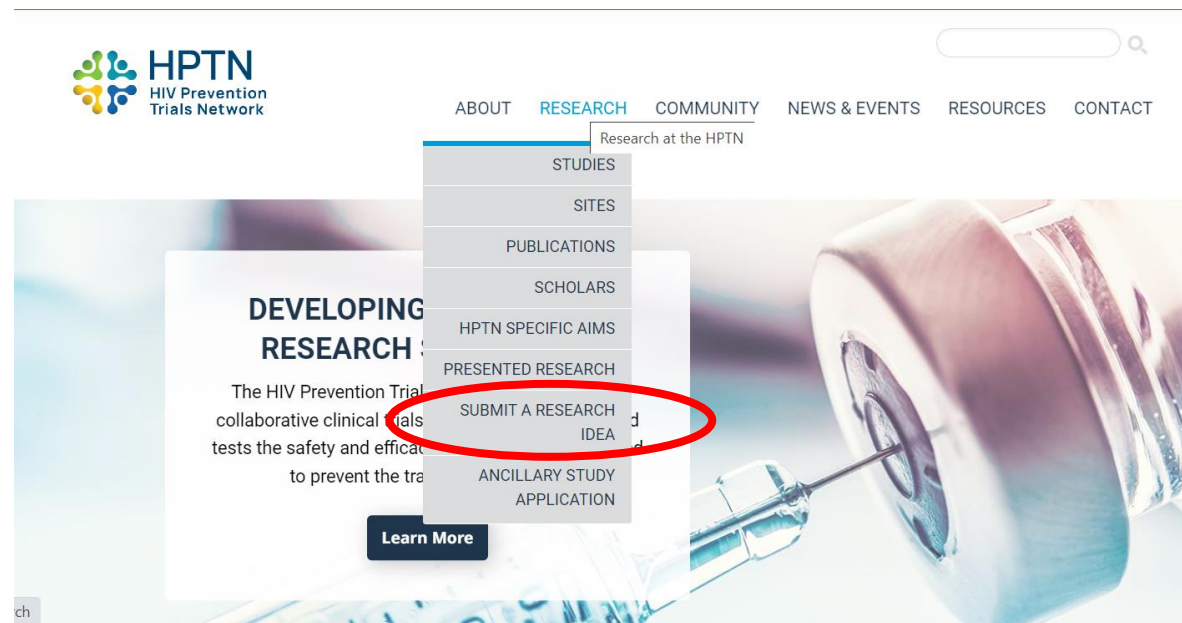
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# How often does the HPTN review concepts?

- Concepts can be submitted at any time
  - HPTN will receive and review concepts at any time



- Calls for concepts are made on occasion and generally target limited specific populations or strategies

# Concept prioritization

- Ensure alignment with HPTN specific aims (HPTN website: Research > Specific Aims):
  - Long-acting antiretroviral (ARV) agents and novel delivery systems for pre-exposure prophylaxis (PrEP)
  - Multipurpose prevention technologies (MPTs) that concurrently prevent HIV and pregnancy, sexually transmitted infections (STIs) or opioid dependence
  - Broadly neutralizing antibodies (bnAbs), alone and in combination, for PrEP
  - Integrated strategies for HIV prevention

# Concept prioritization (cont.)

- Clearly define your primary objectives, endpoints and measurable data.
- Propose ideas consistent with the epidemiology of HIV and gaps in knowledge regarding HIV transmission.
- Clearly explain how your ideas advance research that would have impact on the HIV epidemic.
- Consider ideas that build on vanguard studies already conducted or ongoing by the HPTN or broader prevention community (HPTN protocols are on the website: Research > Studies).
- Large, multi-site, multi-country studies are most desirable but smaller pilot studies with a clear pathway to larger studies will also be considered.

# Lower priority areas

- Surveys without a proposed intervention.
- Studies dependent upon the initiation of other experimental programs.
- Studies with interventions that are not sustainable in public health settings (e.g. cash transfers).
- Proposals primarily focused on addressing broad societal issues (e.g. partner violence, poverty) without a well-defined HIV prevention component.
- Broad ideas without well-defined hypotheses.
- Expanding existing interventions in different populations without clearly identifying/ addressing important differences in contexts or behaviors.
- Early first in human trials that are being done by other research groups.

# Ad hoc concept submission

- Detailed instructions are on the HPTN website (Research > Submit a Research Idea)
- Review Section 9 of the HPTN MOP to best understand the concept and protocol development process
- Unless responding to a specific call for concepts, please submit a **Letter of Intent** prior to submitting a full concept
  - An abbreviated version of the concept template, limited to three pages total (excluding references)
- HPTN leadership will assess the needs and resources of the network for the proposed work and invite submission of a full concept if there is potential for support

# Call for concepts

- A concept template and guidance document will be distributed for every call for concepts
- The target population or strategy will be identified by Network leadership and the Science Committees and Working Groups
- The frequency and timing depends on the needs of the Network and the current epidemiology of the HIV prevention landscape

- Every concept requires fundraising
- Fundraising begins during concept review
  - Network leadership will assess interest and financial support of NIH and other relevant partners
  - HPTN leadership will only approve concepts that have received an expression of interest from funders (expression of interest is NOT a commitment of funding)
- Commitment of funding and funding release generally does not occur until the protocol has reached version 1.0



All concepts should be submitted with a **SINGLE Concept Lead**. If a concept is selected to move forward to protocol development, the ultimate decision for protocol leadership will be made by HPTN leadership. If the Concept Lead chooses to be considered as the Protocol Chair, justification must be provided. The criteria for assessing the proposed Protocol Chair will include:

- Not currently a Protocol Chair or Co-Chair on an active HPTN study
- Time commitment - Must commit to following established HPTN timelines that include two *in-person meetings* at specific timepoints, quick responses to team questions, and rapid decision-making in order to adhere to timelines
- Scientific expertise relevant to the proposed science
- Experience with protocol development
- Experience with implementation of multi-site studies
- Team leadership skills
- Familiarity with the HPTN
- Sensitivity to the target populations and communities

# Protocol chair (cont.)

If any gaps are identified, a complementary Protocol Co-Chair will be selected by HPTN leadership. In this event, protocol leadership discussions will take place with the Concept Lead prior to a final decision on whether to move the concept forward to protocol development.

Protocol chair training is also available and strongly encouraged for new chairs or investigators who have not served as protocol chair in many years.

# Network support for concept development

- Chairs of the relevant Science Committees and Working Groups for guidance
  - Committee descriptions and chairs are on the HPTN website (About > Network Groups & Committees)
- Email questions to [concepts@hptn.org](mailto:concepts@hptn.org)

## Working Groups (WGs)

[Community](#)

[Ethics](#)

[Biomedical Sciences Working Group](#)

[Socio-Behavioral and Structural Working Group](#)

## Science Committees (SCs)

[Adolescent Science Committee](#)

[Sexual and Gender Minority Science Committee](#)

[Substance Use Science Committee](#)

[Women at Risk Science Committee](#)



# Questions?

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