**HIV Prevention Trials Network**

## HPTN Study Concept Plan

(No more than 10 pages, starting at the Summary Schema)

## Concept Title

## Date

## HPTN Study Concept Plan

## Concept Title

**Lead Concept Author**

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 below. 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

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. HPTN Protocol Chair Training is required for new chairs or investigators who have not served as protocol chair within the last three years.

**Please indicate whether the Concept Lead should be considered for Protocol Chair, and if so, provide justification based on the criteria above**:

**Concept Design Support:**

The HPTN Executive Committee may, in collaboration with the concept lead, assign a representative from one of the HPTN Science Committees or Working Groups to provide guidance and support and ensure consistency across HPTN studies.

**HPTN Study Concept Plan**

## Concept Title

**Concept Development Team**

**(names and affiliations; indicate ONE Concept Lead)**

# SUMMARY SCHEMA

# (one page)

## Concept Title

**Purpose:**

**Design:**

**Population:**

**Study Size:**

**Study Duration (including enrollment and follow-up periods):**

**Study Location/Region (specific sites not selected at this time):**

**Study Regimen/Intervention:**

**Primary Objective(s):**

 **Endpoints**

**Secondary Objective(s):**

 **Endpoints**

**STUDY TITLE:**

**SUMMARY OF PURPOSE AND RATIONALE**: This should include introduction and background literature to set the context of the proposed research. Specify the principal aim(s), rationale, relevant background, overall design for Phase I/II trials describe critical pathway to efficacy evaluation; indicate relevance to the long-term global goals of HPTN.

**STUDY AIM:**

**STUDY OBJECTIVES:**

 Primary Objective(s)

 Secondary Objective(s)

**STUDY DESIGN**: Specify the type of study proposed, e.g., whether it is a Phase I, IIA, IIB, or III randomized clinical trial, observational, nested case control study, etc. Include approximate study duration; about 1/2 - 1 page.

**Description of the INTERVENTION:** Describe intervention (e.g., drug/regimen, counseling program), specify study arms, including control if applicable; about 1/2 to 2 pages.

**ENDPOINTS:** Specify the primary and secondary endpoint(s) such as seroconversion, dose-limiting toxicity, specific behavioral outcomes; about ¼ page. The endpoints should address and parallel the objectives.

*Restate Primary Objective(s)*

Primary Endpoint(s)

*Restate Secondary Objective(s)*

Secondary Endpoint(s)

**STUDY POPULATION:** Specify sample size, recruitment source(s), appropriateness of the proposed study population for the proposed concept, and other salient characteristics; about 1/2 - 1 page.

**STATISTICAL CONSIDERATIONS:** For each study objective (or for groups of objectives where appropriate) justify statistical design characteristics (e.g., sample size, comparison groups, estimate of effect size, etc.); about 1 page.

## *Approximate Sample Size*

## *Demographic and Baseline Characteristics*

## *Primary Efficacy Analysis*

**PARTICIPATION REQUIREMENTS:** Specify the number and type of study visits, as well as the specimens and data to be collected (including any invasive procedures for specimen collection.); about 1/2-1 page. A table showing the planned evaluations and procedures is included in the Appendix.

**OPERATIONAL CONSIDERATIONS:** Specify other collaborating organization(s) and pharmaceutical companies (if any); about 1/2 -1 page.

**ETHICAL CONSIDERATIONS:** Identify any special ethical problems that may be associated with study implementation; about 1/2 page.

**PRODUCT-RELATED CONSIDERATIONS (as applicable):** Is an IND needed? Are the product and placebo available in sufficient quantity for the proposed study? From whom? Is there a plan to manufacture sufficient quantities for any proposed follow-on studies? About 1/2 page.

**TIMEFRAME:** Specify expected duration of accrual and follow-up, and any contingencies for development/implementation (e.g. final product selection/dosage to await results of ongoing study); about 1/2 page.

**REFERENCES:**

Appendix I – Example Schedule of Evaluations and Procedures

|  | **Screening**1 | **Enrollment/****Randomization** | **Week 2** | **Monthly (every 4 weeks) until study Participation completed)** | **Quarterly only****(every 12 weeks) until study participation completed** | **Every six months (24 weeks) only** | **Exit visit** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Administrative and Behavioral Evaluations/Procedures**  |
| Screening informed consent |  |  |  |  |  |  |  |
| Enrollment informed consent |  |  |  |  |  |  |  |
| Locator information |  |  |  |  |  |  |  |
| Demographic information |  |  |  |  |  |  |  |
| Social harms assessment |  |  |  |  |  |  |  |
| Behavioral risk assessment |  |  |  |  |  |  |  |
| HIV risk reduction counseling |  |  |  |  |  |  |  |
| Self-reported study drug adherence assessment |  |  |  |  |  |  |  |
| Study drug supply and associated counseling  |  |  |  |  |  |  |  |
| Enhanced Risk Reduction Counseling |  |  |  |  |  |  |  |
| **Clinical Evaluations/Procedures** |
| Complete medical history including medications |  |  |  |  |  |  |  |
| Interim medical history including concomitant meds |  |  |  |  |  |  |  |
| Full physical exam |  |  |  |  |  |  |  |
| Symptom-directed physical exam |  |  |  |  |  |  |  |
| Pelvic exam/swab (female); genital exam/swab (male) |  |  |  |  |  |  |  |
| Urine collection – male and female |  |  |  |  |  |  |  |
| Blood collection |  |  |  |  |  |  |  |
| **Laboratory Evaluations/Procedures** |
| Hematology (CBC with diff, platelets) |  |  |  |  |  |  |  |
| CD4 cell count |  |  |  |  |  |  |  |
| Chemistries (ALT [SGPT] AST, bilirubin, creatinine, CPK, calcium, phosphorous, alkaline phosphatase, total protein, glucose) |  |  |  |  |  |  |  |
| HIV-1 diagnostic testing (algorithm to be specified) |  |  |  |  |  |  |  |
| Hepatitis B serology |  |  |  |  |  |  |  |
| Other STI testing (GC, CT, TV, syphilis) |  |  |  |  |  |  |  |
| Urine pregnancy test (women) |  |  |  |  |  |  |  |
| HIV-1 RNA PCR quantitative (on stored plasma) |  |  |  |  |  |  |  |
| Resistance testing (on stored plasma) |  |  |  |  |  |  |  |
| Viral subtyping and characterization (on stored plasma) |  |  |  |  |  |  |  |
| Truvada concentration (on stored plasma or PBMC) |  |  |  |  |  |  |  |
| Serum, plasma for storage |  |  |  |  |  |  |  |

1 Footnotes should be provided where necessary