**HIV Prevention Trials Network**

## PILOT STUDY CONCEPT PLAN

 **TITLE**

(No more than 5 pages, starting at the Summary Schema; excluding References and Schedule of Evaluations)

**Indicate priority area of the proposed research:**

[ ]  HIV prevention in heterosexual men in high burden settings

[ ]  HIV prevention in stimulant users

**CONCEPT DEVELOPMENT TEAM**

**(names and affiliations; indicate ONE Concept Lead and whether the Concept Lead intends to chair the study)**

# SUMMARY SCHEMA (one page)

## TITLE

**Purpose:**

**Design:**

**Population:**

**Location/Region (specific sites to be determined later):**

**Study Size:**

**Study Regimen/Intervention:**

**Study Duration and Timeline (enrollment, follow-up, and study completion by 30 November 2024):**

**Primary Objective (no more than one):**

 **Endpoints:**

**Secondary Objective(s) (no more than three):**

 **Endpoints:**

**Budget (not to exceed US$500,000 in direct costs):**

**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, and the overall design

**STUDY OBJECTIVES**

Primary Objective(s) (no more than one)

Secondary Objective(s) (no more than three)

**STUDY DESIGN**

Specify the type of study proposed, randomized clinical trial, observational, nested case control study, etc. Include approximate study duration; about ¼ page.

**Description of the INTERVENTION (if applicable)**

Describe intervention (e.g., drug/regimen, counseling program), specify study arms, including control if applicable; about ½ page.

**ENDPOINTS**

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 ½ page.

**INCLUSION OF PARTICIPANTS ACROSS THE LIFESPAN:**

Individuals of all ages are expected to be considered for all NIH-funded clinical research unless there are scientific or ethical reasons not to include them. If individuals will be excluded based on age, provide a **brief** rationale for this decision.

**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 ½ page.

## *Approximate Sample Size*

## *Demographic and Baseline Characteristics*

## *Primary Efficacy Analysis*

**PARTICIPATION REQUIREMENTS**

Specify the number and type of study visits and, the specimens and data to be collected (including any invasive procedures for specimen collection.); about ½ page. A table showing the planned evaluations and procedures is included in the Appendix (see below).

**OPERATIONAL CONSIDERATIONS**

Specify other collaborating organization(s) and pharmaceutical companies (if any); about ½ page.

**ETHICAL CONSIDERATIONS:**

Identify any special ethical problems that may be associated with study implementation; about ½ page.

**PRODUCT-RELATED CONSIDERATIONS:**

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 of the product for any proposed follow-on studies? About ½ page.

**TIMEFRAME:**

Specify the expected duration of accrual and follow-up, and any contingencies for development/implementation (e.g., final product selection/dosage to await results of the ongoing study); about ½ page. Overall timeline: The study must be completed by 30 November 2024.

**REFERENCES**

***Schedule of Evaluations and Procedures* should be provided. An example is included.**

Appendix I - Schedule of Evaluations and Procedures (Example provided here)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **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 (women); genital exam/swab (men) |  |  |  |  |  |  |  |
| Urine collection (women)  |  |  |  |  |  |  |  |
| Urine collection (men and women) |  |  |  |  |  |  |  |
| Blood collection |  |  |  |  |  |  |  |
| **Laboratory Evaluations/Procedures** |
| HIV-1 diagnostic testing (algorithm to be specified) |  |  |  |  |  |  |  |
| Hematology (CBC with diff, platelets) |  |  |  |  |  |  |  |
| CD4 cell count |  |  |  |  |  |  |  |
| Chemistries (ALT [SGPT] AST, bilirubin, creatinine, CPK, calcium, phosphorous, alkaline phosphatase, total protein, glucose) |  |  |  |  |  |  |  |
| Hepatitis B serology |  |  |  |  |  |  |  |
| Other STI testing (GC, CT, TV, syphilis) |  |  |  |  |  |  |  |
| Urine pregnancy test (women) |  |  |  |  |  |  |  |
| HIV RNA PCR quantitative  |  |  |  |  |  |  |  |
| Serum, plasma for storage |  |  |  |  |  |  |  |

1  Footnotes should be provided where necessary