**HIV Prevention Trials Network**

## LETTER OF INTENT FOR STUDY CONCEPT PLAN

 **TITLE**

(**No more than 3 pages**, starting at the Schema; excluding References)

**Indicate alignment with HPTN scientific 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 DEVELOPMENT TEAM**

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

# SCHEMA (one page)

## TITLE

**Purpose:**

**Design:**

**Population:**

**Location/Region:**

**Study Size:**

**Study Regimen/Intervention:**

**Study Duration (estimated time for accrual and follow-up):**

**Primary Objective(s):**

 **Endpoints (the endpoints should address and parallel the objectives):**

**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, and the overall design; about ½ page.

**STUDY DESIGN**

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

**STUDY POPULATION**

Specify approximate sample size, recruitment source(s), appropriateness of the proposed study population for the proposed concept, and other salient characteristics; 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.

**OPERATIONAL CONSIDERATIONS**

Specify other collaborating organization(s) and pharmaceutical companies (if any); about ¼ 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 subsequent studies or post-trial access, if effective? About ¼ page.

**REFERENCES**