**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**