***Study 1: Black MSM in Africa: A behavioral feasibility study for recruitment, retention, and measurement of social impacts.***

1. **General Site Information (Research Experience/ Network Affiliation/ Recruitment/Retention/ Regulatory) (40% of total score) (LOC votes on this category)**
2. Experience recruiting and retaining in previous related research trials (1-5, 5 being the ‘best’ score) **(75% of category score)**

* Experience enrolling target population within a (X) month period and retaining at a high rate (90% at 1 year) (5)
* Experience enrolling target population within a (X) month period and retaining at a high rate (85% at 1 year) (4)
* Experience enrolling target population within a (X) month period and retaining at a high rate (80% at 1 year) (3)
* Experience enrolling and retaining target population (2) with less than 80% retention at 1 year (2)
* No experience or evidence that the target population can be enrolled or retained (1)

1. Current HPTN affiliation **(12.5% of category score)**

* Network Site (5)
* Not a network site (CRS), but previous NIH trials experience and can be easily linked to a CTU (4)
* Not a network site (CRS), but previous NIH trials experience; cannot easily be linked to a CTU (3)
* Not a network site; research experience in the required field but no NIH experience (2)
* Not a network site (CRS), little clinical trials experience in the required field (1)

1. Timing of Regulatory Approvals (evidence based) **(12.5% of category score)**

* MOH and IRBs expected within 4 months of submission (5)
* MOH and IRB approvals expected within 6 months of submission (4)
* MOH and IRB approvals expected within 9 months of submission (3)
* MOH and IRB approvals expected within 12 months of submission (2)
* MOH and IRB approvals expected more than 12 months from submission (1)

1. **Risk/ Incidence/Prevalence (10% of total score) (LOC votes on this category)**
2. HIV infection risk; proportion of HIV-infected population in the target community who may be HIV infected (e.g. prevalence >30% and/ or incidence greater than 3 person years) **(50% of category score)**

* Prevalence >30% and/ or incidence > than 3 (5)
* Prevalence >25% and/ or incidence > 2.5 (4)
* Prevalence <25% and incidence <2.5 (3)
* Prevalence <20% and incidence <2.0 (2)
* Prevalence <20% and incidence <1.5 (1)

1. Evidence of high risk behaviors among population **(50% of category score)**

* Lack of use of condoms > 30% and more than 5 sexual partners in previous 6 months and/or some substance use in targeted population (5)
* Lack of use of condoms > 30% and more than 1 sexual partners in previous 6 months and/or some substance use in targeted population (4)
* Lack of use of condoms > 25% and more than 1 sexual partners in previous 6 months and/or some substance use in targeted population (3)
* Lack of use of condoms > 20% and more than 1 sexual partner in previous 6 months (2)
* Lack of use of condoms >10% and/or 1 sexual partner in previous 6 months (1)

1. **Laboratory (15% of total score) (LC votes on this category)**
2. Laboratory capacity to conduct a network level randomized clinical trial **(100% of category score)**

* All required panels/ assays (see supplemental laboratory sheet for listings) are currently being processed by the local laboratory and no EQA, etc. panels must be performed (SMILE, etc). Leadership is adequate; demonstrated ability to process and export samples (5)
* 80% or higher of the required panels/ assays are currently being processed by the affiliated laboratory or minor leadership or other issues such as some samples might not be able to be exported (4)
* 70% or higher of the required panels/ assays are currently being processed by the affiliated laboratory or leadership or other issues (3)
* 50% or higher of the required panels/ assays are currently being processed by the affiliated laboratory or leadership or other issues (2)
* Less than 50% of the required panels/ assays are currently being processed by the affiliated laboratory or leadership or other issues (1)

1. **Data (5% of total score) (SDMC votes on this category)**
2. DataFax potential/IT infrastructure/Quality of Data Management **(100% of category score)**

* Internet faxing equipment available, tested, good high speed internet connectivity; ability to send in CRFs within 48 hours; QC Rate lower than average (5)
* Internet faxing equipment available, tested, good high speed internet connectivity; ability to send in CRFs within 48 hours; QC Rate average (4)
* Internet faxing equipment available, but some previous issues, needs new equipment or Internet connectivity issues; QC Rate average (3)
* Internet faxing equipment not available, needs new equipment or Internet connectivity issues which can be easily resolved; QC Rate greater than average (2)
* Internet faxing equipment not available, needs new equipment; other internet infrastructure problems which cannot be easily resolved; QC Rate greater than average (1)

1. **Other (30% of total score) (Example questions below- each study to tailor to specific needs) (Protocol Chair votes on this category)**
2. Current political landscape allows for such a trial to be conducted **(100% of category score)**

* Access to services for MSM in an environment that will not be targeted by police or protests/ riots in the community (5)
* Homosexuality illegal, but necessary assurances are in place that the clinic and participants will not be targeted (4)
* Homosexuality illegal, unclear as to whether assurances will be in place to adequately protect participants (3)
* Homosexuality illegal, Ethics Committee and police working together to limit targeting of MSM behavior and participants (2)
* Homosexuality illegal; no assurances that clinic/ participants will not be targeted (1)

***Study 2: Utilizing PrEP in PWID in central Asia. Enrolls 1,000 HIV negative persons with at least one confirmed HIV positive injection sharing partner. Primary endpoint is a reduction of HIV incidence.***

1. **General Site Information (Research Experience/ Network Affiliation/ Recruitment/Retention/ Regulatory) (20% of total) (LOC votes on this category)**
2. Experience in previous related research trials (1-5, 5 being the ‘best’ score)  **(75% of category)**

* Experience enrolling target population within a (X) month period and retaining at a high rate (90% at 1 year) (5)
* Experience enrolling target population within a (X) month period and retaining at a high rate (85% at 1 year) (4)
* Experience enrolling target population within a (X) month period and retaining at a high rate (80% at 1 year) (3)
* Experience enrolling and retaining target population (2) with less than 80% retention at 1 year (2)
* No experience or evidence that the target population can be enrolled or retained (1)

1. Current HPTN affiliation **(12.5% of category)**

* Network Site (5)
* Not a network site (CRS), but previous NIH trials experience and can be easily linked to a CTU (4)
* Not a network site (CRS), but previous NIH trials experience; cannot easily be linked to a CTU (3)
* Not a network site; research experience in the required field but no NIH experience (2)
* Not a network site (CRS), little clinical trials experience in the required field (1)

1. Timing of Regulatory Approvals (evidence based) **(12.5% of category)**

* MOH and IRBs expected within 4 months of submission (5)
* MOH and IRB approvals expected within 6 months of submission (4)
* MOH and IRB approvals expected within 9 months of submission (3)
* MOH and IRB approvals expected within 12 months of submission (2)
* MOH and IRB approvals expected more than 12 months from submission (1)

1. **Risk/ Incidence/Prevalence (40% of total) (LOC votes on this category)**
2. HIV infection risk; proportion of HIV-infected population in the target community who may be HIV infected (e.g. prevalence >30% and/ or incidence greater than 3 person years) **(70% of category total)**

* Prevalence >30% and/ or incidence > than 3 (5)
* Prevalence >25% and/ or incidence > 2.5 (4)
* Prevalence <25% and incidence <2.5 (3)
* Prevalence <20% and incidence <2.0 (2)
* Prevalence <20% and incidence <1.5 (1)

1. Evidence of high risk behaviors among population **(30% of category total)**

* Lack of use of condoms > 30% and more than 5 sexual partners in previous 6 months and/or some substance use in targeted population (5)
* Lack of use of condoms > 30% and more than 1 sexual partners in previous 6 months and/or some substance use in targeted population (4)
* Lack of use of condoms > 25% and more than 1 sexual partners in previous 6 months and/or some substance use in targeted population (3)
* Lack of use of condoms > 20% and more than 1 sexual partner in previous 6 months (2)
* Lack of use of condoms >10% and/or 1 sexual partner in previous 6 months (1)

1. **Laboratory (15% of total) (LC votes on this category)**
2. Laboratory capacity to conduct a network level randomized clinical trial **(100% of category total)**

* All required panels/ assays (see supplemental laboratory sheet for listings) are currently being processed by the local laboratory and no EQA, etc. panels must be performed (SMILE, etc). Leadership is adequate; demonstrated ability to process and export samples (5)
* 80% or higher of the required panels/ assays are currently being processed by the affiliated laboratory or minor leadership or other issues such as some samples might not be able to be exported (4)
* 70% or higher of the required panels/ assays are currently being processed by the affiliated laboratory or leadership or other issues (3)
* 50% or higher of the required panels/ assays are currently being processed by the affiliated laboratory or leadership or other issues (2)
* Less than 50% of the required panels/ assays are currently being processed by the affiliated laboratory or leadership or other issues (1)

1. **Data (5% of total) (SDMC votes on this category)**
2. DataFax potential/IT infrastructure/Quality of Data Management **(100% of category total)**

* Internet faxing equipment available, tested, good high speed internet connectivity; ability to send in CRFs within 48 hours; QC Rate lower than average (5)
* Internet faxing equipment available, tested, good high speed internet connectivity; ability to send in CRFs within 48 hours; QC Rate average (4)
* Internet faxing equipment available, but some previous issues, needs new equipment or Internet connectivity issues; QC Rate average (3)
* Internet faxing equipment not available, needs new equipment or Internet connectivity issues which can be easily resolved; QC Rate greater than average (2)
* Internet faxing equipment not available, needs new equipment; other internet infrastructure problems which cannot be easily resolved; QC Rate greater than average (1)

1. **Other (Example questions below- each study to tailor to specific needs) (20% of total) (Protocol Chair votes on this category)**
2. Access to ART and OST for current PWID including agreement to provide ART for use during the study and post study for those who are or become HIV positive **(50% of category total)**

* Access to ART during study for those with CD4 counts >350 as well as guaranteed post study access for HIV infected study participants; universal access to OST (5)
* Access to ART during study for those with CD4 counts >350 but data needed in order to guarantee continued treatment post study for all that were HIV positive during the trial; universal access to OST (4)
* Limited access to ART and OST (3)
* Limited access to ART and no access to OST (2)
* No access of ARTs or OST during the study or post study provided by local authorities (1)

1. Access to sterile injection equipment **(25% of category total)**

* Universal availability and uptake of syringe exchange program or legal pharmacy sales (5)
* Universal availability but mixed uptake of syringe exchange program or legal pharmacy sales (4)
* Limited availability of syringe exchange program or legal pharmacy sales
* (3)
* Availability of syringe exchange program or legal pharmacy sales in the near future (2)
* No availability of either (1)

1. Expertise in behavioral change or adherence interventions with PWIDs **(25% of category total)**

* Evidence based behavioral change and adherence interventions with PWIDs and research experience and appropriate staff available to conduct the study (5)
* Behavioral change or adherence interventions with PWIDs with research experience and appropriate staff available to conduct the study (4)
* Limited behavioral change and/or adherence intervention experience with PWIDs (3)
* No behavioral change OR adherence intervention experience (one lacking but not both) with PWIDs (2)
* No behavioral change and no adherence intervention experience with PWIDs (1)