**Data entry (Sign) \_\_\_\_\_\_\_\_**

**PrEP demonstration project**

**5B.Clinical data form**

**Follow-up visits through end of month 15**

**Site:**

**Participant unique ID number:**

**TI number: \_\_ (1: FSW1 TI, Mysore, 2: FSW2 TI, Mysore, 3: Rural CC TI, Mysore,**

**4: FSW TI, Mandya)**

**Date:**

**Name and designation of person completing this form:**

**Visit number: 1. End of Month 1, 2. End of Month 3, 3. End of Month 6,**

**4. End of Month 9, 5. End of Month 12 6. End of Month 15**

**Side effects**

Since your last visit, have you experienced any side effects of using PrEP? If yes, then indicate start date and whether it is ongoing or resolved.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Symptoms** | **1. Yes** | **2. No** | **If YES, specify** | | |
|  |  |  | **Start Date**  day/month/year | **1. Ongoing** | **2. Resolved** |
| Nausea |  |  |  |  |  |
| Vomiting |  |  |  |  |  |
| Fatigue |  |  |  |  |  |
| Dizziness |  |  |  |  |  |
| Headache |  |  |  |  |  |
| Rash |  |  |  |  |  |
| Abdominal pain |  |  |  |  |  |
| Weight loss |  |  |  |  |  |
| Other, specify |  |  |  |  |  |

**Acute HIV Infection**

In the past 60 days, have you experienced any ofthe following? If yes, then indicate start date and whether it is ongoing or resolved.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Symptoms** | **1. Yes** | **2. No** | **If YES, specify** | | |
| **Start Date**  day/month/year | **1. Ongoing** | **2. Resolved** |
| Fever |  |  |  |  |  |
| Fatigue |  |  |  |  |  |
| Swollen lymph nodes |  |  |  |  |  |
| Swollen tonsils/tonsillitis |  |  |  |  |  |
| Sore throat |  |  |  |  |  |
| Joint and muscle aches |  |  |  |  |  |
| Diarrhea |  |  |  |  |  |
| Rash |  |  |  |  |  |

If yes to any of the items above, is there self-reported possibility of recent HIV exposure (unprotected sex with someone of HIV-positive or unknown status, or sharing needles with injection drug use) in the past 60 days?

[ ] 1. YES [ ] 2. NO If yes, describe:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Syndromic STI management**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Symptoms** | **1. Yes** | **2. No** | **Start Date**  day/month/year | **If YES, specify** |
| Pain/ burningwith urination |  |  |  |  |
| Vaginal discharge |  |  |  |  |
| Pelvic/lower abdominal pain |  |  |  |  |
| Rash |  |  |  |  |
| Vaginal/vulvalitching |  |  |  |  |
| Genital sore/blister |  |  |  |  |
| Other: |  |  |  |  |

**Clinical findings:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Assessment** | **1. Normal** | **2. Abnormal** | **If abnormal, specify** |
| Genital ulcer disease (GUD) H/NH |  |  |  |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | |  |  |  |  |  | | PID |  |  |  |  | |  | | | | | |  |  |  |
| Other, describe: |  |  |  |

**Disease history and medications**

|  |  |
| --- | --- |
| Is the participant currently taking any medications OTHER THAN PREP, including traditional or alternative medications? | [ ] 1. YES  [ ] 2. NO  Current medications. DO NOT include medications prescribed at this visit:  If yes, what medications? |
| Last menstrual period (date: day/month/year)  If day or month not known, list 99 | \_ \_/\_ \_/\_ \_ |

**Test results**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Test** | **Date of sample drawn**  day/month/year | **Date of result received**  day/month/year | **Result** | **Notes** |
| HIV test | \_ \_/\_ \_/\_ \_ | \_ \_/\_ \_/\_ \_ | [ ] 1. Negative [ ] 2. Positive  *Note:* If HIV-positive, refer for care  and treatment |  |
| PregnancyTest:  (Urine) | \_ \_/\_ \_/\_ \_ | \_ \_/\_ \_/\_ \_ | [ ] 1. Negative [ ] 2. Positive  *Note:* if pregnant and not attending ANC, refer to ANC. |  |
| Hepatitis B  (HbSAg) | \_ \_/\_ \_/\_ \_ | \_ \_/\_ \_/\_ \_ | [ ] 1. Negative [ ] 2. Positive  [ ] 99. NA |  |
| Hepatitis C  (AbHCV) | \_ \_/\_ \_/\_ \_ | \_ \_/\_ \_/\_ \_ | [ ] 1. Negative [ ] 2. Positive  [ ] 99. NA |  |
| Syphilis  (RPR) | \_ \_/\_ \_/\_ \_ | \_ \_/\_ \_/\_ \_ | [ ] 1. Non- reactive [ ] 2. Reactive  [ ] 99. NA |  |
| Cervical cancer screen  (VIA) | \_ \_/\_ \_/\_ \_ | \_ \_/\_ \_/\_ \_ | [ ] 1. Negative [ ] 2. Positive  [ ] 99. NA |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Test** | | **Date of sample drawn**  day/month/year | **Date of result received**  day/month/year | **Result** | **Recommended Ranges** |
| Liver function (ALT) | | \_ \_/\_ \_/\_ \_ | \_ \_/\_ \_/\_ \_ | U/L  [ ] 99. NA | 7 to 55 units per liter (U/L) |
| Liver function (AST) | | \_ \_/\_ \_/\_ \_ | \_ \_/\_ \_/\_ \_ | U/L  [ ] 99. NA | 8 to 48 units per liter (U/L) |
| Kidney function (serum creatinine) | | \_ \_/\_ \_/\_ \_ | \_ \_/\_ \_/\_ \_ | mg/dL  [ ] 99. NA | 0.6-1.2 milligrams per deciliter (mg/dL) |
| Urine Routine | Albumin | \_ \_/\_ \_/\_ \_ | \_ \_/\_ \_/\_ \_ | [ ] 99. NA |  |
| Sugar | \_ \_/\_ \_/\_ \_ | \_ \_/\_ \_/\_ \_ | [ ] 99. NA |  |
| Microscopy | \_ \_/\_ \_/\_ \_ | \_ \_/\_ \_/\_ \_ | [ ] 99. NA |  |
| Stool Routine | Ova | \_ \_/\_ \_/\_ \_ | \_ \_/\_ \_/\_ \_ | [ ] 99. NA |  |
| Cyst | \_ \_/\_ \_/\_ \_ | \_ \_/\_ \_/\_ \_ | [ ] 99. NA |  |
| Occult blood | \_ \_/\_ \_/\_ \_ | \_ \_/\_ \_/\_ \_ | [ ] 99. NA |  |
| Fat globules | \_ \_/\_ \_/\_ \_ | \_ \_/\_ \_/\_ \_ | [ ] 99. NA |  |
| Hemoglobin | | \_ \_/\_ \_/\_ \_ | \_ \_/\_ \_/\_ \_ | g/dL  [ ] 99. NA | 12.0 to 15.5 grams per deciliter (g/dL) |

**Blood draw for drug levels (10% sample)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Test** | **Date of sample drawn**  day/month/year | **Date of result received**  day/month/year | **Result** | **Notes** |
| TDF levels | \_ \_/\_ \_/\_ \_  99. NA |  |  |  |

**Does the participant have any of the following conditions that would make the participant ineligible to continue in the demonstration project?**

HIV-infection: [ ] 1.YES [ ] 2. NO

Hepatitis B infection [ ] 1.YES [ ] 2. NO

Currently pregnant: [ ] 1.YES [ ] 2. NO

Serum creatinine >1.2 mg/dL: [ ] 1.YES [ ] 2. NO

**Overall assessment of theparticipant including any conditions that couldmake the participant ineligible for the demonstration project.Note anymedicationsprescribed or referrals made to other services.**

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