Clarification Memo # 2 to:

HPTN 073: Pre-Exposure Prophylaxis (PrEP) Initiation and Adherence among Black Men who have Sex with Men (BMSM) in Three U.S. Cities, Version 1.0, dated February 21, 2013

Final Version: 9 December 2013

Summary of Revisions and Rationale

This notice serves as clarification that at least some portions of the protocol are not clear for the conduct of study procedures:

1. The ACASI is conducted at every visit from Enrollment through Termination. This is not a change to any of the protocol procedures, but rather a consolidation of procedures/terminology previously written separately. At least some portion of the procedures/terminology is conducted at each visit under the "ACASI" label. As an example, the PrEP Adherence Self Regulation Questionnaire is a part of the ACASI.
2. STI testing measurements are listed incorrectly in the statistical section of the protocol.

Implementation

The procedures clarified in this memorandum have been approved by the Division of AIDS (DAIDS) Medical Officer. **IRB approval of HPTN 073 Protocol Clarification Memo #2 to HPTN 073 V. 1.0 is not required by the sponsor**; however, sites may submit the clarification memo to the responsible IRBs for their information.

No change in the informed consent forms is necessitated by or included in this Clarification Memo.

The modifications included in this Clarification Memo will be incorporated into the next full protocol amendment. Text noted below by ~~strikethrough~~ will be deleted; text appearing below in **bold** will be added.

Clarification 1 Section 5.3 Enrollment

Administrative and Behavioral Evaluations/ Procedures (clinical team)

- Verify locator information
- ~~Behavioral and Psychosocial Risk Survey (ACASI)~~ **Behavioral, Psychosocial, Adherence and C4-related survey (ACASI) (see Appendix II)**
- HIV/ STI behavioral risk-reduction counseling
- PrEP discussion
- Offer condoms and other prevention supplies

Note: Indication and Usage for Pre-exposure Prophylaxis will be reviewed with participants as part of a comprehensive package of risk reduction services. In general, sites must refer to the CDC interim guidelines for PrEP administration (http://www.cdc.gov/hiv/prep/pdf/PrEPfactsheet.pdf) and to the guidelines for PrEP Indication (https://www.truvadapreprems.com/#). A manual will be created for all sites to follow when introducing PrEP to participants based on safety and efficacy language found in the ICF under "Study Purpose".

If initiating PrEP:

- Assess participant's initial readiness for PrEP adherence (may be conducted at any time through Week 48)
- Study product supply
- Autonomy supportive adherence counseling
- PrEP adherence-goal setting
- ~~**PrEP Adherence Self-Regulation Questionnaire (participant self-administered)**~~

C4 including:

- C4 Case Conference (by staff prior to enrollment)
- Care Coordination Measurement Tool **(as needed)** ~~(recorded by providers)~~

Section 5.4 Weeks 4 and 8

Administrative and Behavioral Evaluations/ Procedures

- Review and update locator information
- **Behavioral, Psychosocial, Adherence and C4-related survey (ACASI) (see Appendix II)**
- Social Harms
- HIV/STI behavioral counseling (pre- and post-test), including risk-reduction counseling
- PrEP discussion
- Offer condoms and other prevention supplies

Note: Indication and Usage for Pre-exposure Prophylaxis will be reviewed with participants as part of a comprehensive package of risk reduction services. In general, sites must refer to the CDC interim guidelines for PrEP administration (http://www.cdc.gov/hiv/prep/pdf/PrEPfactsheet.pdf) and to the guidelines for PrEP Indication (https://www.truvadapreprems.com/#). A manual will be created for all sites to follow when introducing PrEP to participants based on safety and efficacy language found in the ICF under "Study Purpose".

If initiating or on PrEP:

- Assess participant's initial readiness for PrEP adherence (only if initiating)
- Self-reported study product adherence assessment
- Study product supply
- Autonomy supportive adherence counseling
- PrEP adherence goal setting

- ~~**PrEP Adherence Self-Regulation Questionnaire (participant self-administered)**~~

- C4 including:
  - Care Coordination Measurement Tool (**as needed** ~~recorded by providers~~)
  - ~~**Health Care Climate Questionnaire (participant self-administered)**~~

Section 5.5 Week 13

Administrative and Behavioral Evaluations/ Procedures (clinical team)

- Review and update locator information
- Social Harms
- ~~Behavioral and Psychosocial Risk Survey (ACASI)~~ **Behavioral, Psychosocial, Adherence and C4-related survey (ACASI) (see Appendix II)**
- HIV/ STI behavioral risk-reduction counseling (pre- and post-test), including risk-reduction counseling
- PrEP discussion
- Offer condoms and other prevention supplies

If initiating PrEP:

- Assess participant's initial readiness for PrEP adherence (may be conducted at any time through Week 48)
- Study product supply
- Autonomy supportive adherence counseling
- PrEP adherence-goal setting
- ~~**PrEP Adherence Self-Regulation Questionnaire (participant self-administered)**~~

- C4 including:
  - C4 Case Conference (by staff preferably prior to the Week 13 visit)
  - ~~Health Care Climate Questionnaire (participant self-administered)~~
  - ~~Client Perception of Coordination Questionnaire (participant self-administered)~~
  - Care Coordination Measurement Tool **(as needed)** ~~(recorded by providers)~~

Section 5.6 Weeks 26, 39 and 52

Administrative and Behavioral Evaluations/ Procedures

- Review and update locator information
- Social Harms
- Behavioral, Psychosocial**,** ~~and~~ **Adherence (if applicable) and C4-related** ~~Risk~~ Survey (ACASI) **(see Appendix II)**
- Qualitative Interview (Week 52 only)
- Adherence goal setting (except Week 52)
- HIV/STI behavioral counseling (pre- and post-test), including risk-reduction counseling

- PrEP discussion
- Offer condoms and other prevention supplies
- Informed Consent for individual interview (Week 52 only)

  Note: Indication and Usage for Pre-exposure Prophylaxis will be reviewed with participants as part of a comprehensive package of risk reduction services. In general, sites must refer to the CDC interim guidelines for PrEP administration (http://www.cdc.gov/hiv/prep/pdf/PrEPfactsheet.pdf) and to the guidelines for PrEP Indication (https://www.truvadapreprems.com/#). A manual will be created for all sites to follow when introducing PrEP to participants based on safety and efficacy language found in the ICF under "Study Purpose".

  If initiating or on PrEP:
  - Assess participant's initial readiness for PrEP adherence (only if initiating; initiation not allowed to start after Week 48)
  - Self-reported study product adherence assessment
  - Study product supply (except Week 52)
  - Autonomy supportive adherence counseling (except Week 52)
  - ~~PrEP Adherence Self-Regulation Questionnaire (participant self-administered) (except week 52)~~

- C4 including:
  - C4 Case Conference (commencing discharge/transition planning for weeks 39 and 52)
  - ~~o~~ Care Coordination Measurement Tool **(as needed)** ~~(recorded by providers)~~
  - ~~o Health Care Climate Questionnaire (participant self-administered)~~
  - ~~o Client Perception of Coordination Questionnaire (participant self-administered)~~
  - ~~o Care Transition Measure (Week 52 only or study exit)~~
  - ~~o Front Line Administrative Staff Satisfaction Survey (week 52 only or study exit)~~

Clarification 2 Section 7.1 Review of Study Design

Sexually transmitted infections (STIs)

STIs will be measured at ~~baseline~~ **Screening and Weeks 26 and 52**~~onthly for the first three months and then at quarterly visits~~. Tests will include rectal and urine **NAAT** GC/CT, and ~~NAAT for~~ **plasma for** syphilis ~~and chlamydia.~~