

Clarification Memo # 1 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: 17 May 2013

Summary of Revisions and Rationale

1. A note has been added to the Inclusion Criteria to clarify that participants without HBV immunity at screening will be offered or referred for vaccination.

Implementation

The procedure clarified in this memorandum has been approved by the Division of AIDS (DAIDS) Medical Officer and are to be implemented immediately upon issuance. IRB approval of HPTN 073 Protocol Clarification Memo #1 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.

Revision 1 Section 3.1 Inclusion Criteria

Note: Participants without HBV immunity at screening will be offered or referred for vaccination as indicated in Section 5.1.