

HIV Prevention Trials Network

LETTER OF AMENDMENT #1 TO:

HPTN 071-2

Phylogenetics in HPTN 071:

An ancillary study to “Population Effects of Antiretroviral Therapy to Reduce HIV Transmission (PopART): A cluster-randomized trial of the impact of a combination prevention package on population-level HIV incidence in Zambia and South Africa”

Protocol Version 1.0 dated 15 January 2015

Date of Letter of Amendment: 29 November 2016

Information/Instructions to Study Sites from the Division of AIDS

The information contained in this Letter of Amendment (LoA) impacts the HPTN 071-2 (Phylogenetics) study and must be forwarded to your Institutional Review Board (IRB) and/or Ethics Committee (EC) as soon as possible for their review and approval. This LoA must be approved by all responsible IRBs/ECs before implementation.

The information in this LoA does affect the Sample Informed Consent Forms.

Upon receiving final IRB/EC and any other applicable regulatory entity approval(s) for this LoA, your site should implement the LoA immediately. Your site is still required to submit an LoA registration packet to the DAIDS Protocol Registration Office (PRO) at the Regulatory Support Center (RSC). Your site will receive a registration notification for the LoA once the DAIDS PRO verifies that all the required LoA registration documents have been received and are complete. An LoA registration notification from the DAIDS PRO is not required prior to implementing the LoA. A copy of the LoA registration notification along with this letter and any IRB/EC correspondence should be retained in the site's regulatory files.

If the HPTN 071-2 (Phylogenetics) protocol is amended in the future, this LoA will be incorporated into the next version.

Summary of Revisions and Rationale

The HPTN 071-2 (Phylogenetics) protocol v1.0, 15 January 2015 has been updated to reflect the changes listed in this Summary of Revisions and Rationale. All changes made are indicated in the next section, Implementation of the Protocol Modifications.

- 1) Updates to the protocol team roster and protocol chair university affiliation
- 2) Updates to participant surveys
- 3) An additional sample informed consent form has been added to serve as an addendum to the PC24N consent form. As much of the basic information in both consent forms is the same (e.g.

study background, etc.), a brief phylo addendum will be used for this participants enrolling in both PC24N and phylo during the same visit, to reduce burden on the participant.

Protocol team roster

Roster has been updated to reflect current team. Protocol chair has also moved from Imperial College to Oxford University.

6.3 Population cohort (PC) sampling

Additional questions added to the survey.

6.4 Health care facility (HCF) sampling

Additional questions added to the survey.

7.0 LABORATORY PREPARATION AND TRAIN

Reference to Oxford University added.

12.3 Study Coordination

Reference to Oxford University added.

Appendix 1 - PC24N PARTICIPANT INFORMATION AND CONSENT FORM

Reference to Oxford University added.

Appendix 1B - PC24N PARTICIPANT INFORMATION AND CONSENT FORM

A brief version of the phylo consent was prepared to be used as an addendum to the main PC24N consent form – only for participants who have just enrolled as a part of PC24N. Only the redundant language has been removed.

Appendix 1C - HCF PARTICIPANT INFORMATION AND CONSENT FORM

Typo corrected in title. Also, Appendix 1C was previously 1B before the above change was made.

Reference to Oxford University added.