HIV Prevention Trials Network

CLARIFICATION MEMO #02 TO:

HPTN 071

DAIDS Document ID #11865

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

Version 1.0 / 26 October 2012

Date of Clarification Memorandum: 17 October 2013

The items clarified in this Clarification Memorandum (CM) have been approved by the DAIDS Medical Officer and are to be implemented immediately upon issuance. IRB/EC approval of this CM is not required by the sponsor; however, investigators may submit the CM to the IRB/EC overseeing the study at their site for information. This CM is official HPTN 071 (PopART) documentation and is effective immediately.

This CM and all related IRB/EC correspondence must be retained in the site regulatory file and in other pertinent files. Protocol registration approval is not required by DAIDS for CMs.

This CM includes a minor clarification in the informed consent form.

If the full HPTN 071 (PopART) protocol is amended in the future, the changes in this CM will be incorporated into the next version of the protocol.

Summary of Revisions and Rationale

This CM serves to clarify:

1) that all HIV infected, pregnant or breastfeeding women are eligible for lifelong ART per government policy in Zambia and the Western Cape of South Africa
2) that field staff will not solicit enrollment into the *Population Cohort* of community members living in the same household as an employee of Zambart or the Desmond Tutu TB Center

3) that the age provided in the study information sheet is for consent to HIV testing, rather than the age of consent for participation in the intervention

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Changes in the protocol are summarized below by section. Added text appears in **bold face** and deleted text appears with a ~~strike-through~~.

Section 3.7- Prevention of Mother-to-Child Transmission

In Arms A and B, the CHiP team will encourage women who may be pregnant to receive pregnancy testing at the health center. As well CHiPs will encourage pregnant women who are encountered during regular household visits in their zone to attend an ANC. **If CHiPs encounter women who are HIV infected and pregnant or breastfeeding, they will refer them for PMTCT. In both Zambia and the Western Cape of South Africa the "B+" option for PMTCT has been adopted as government policy, promoting lifelong ART for pregnant women with HIV infection. Because of this, the requirement to obtain written informed consent from clients who have CD4 cell count above 350 cells/µl or are at an early WHO stage in Arm A clinics before initiating ART will not apply for HIV infected pregnant or breastfeeding women; such women will be automatically eligible per government policy.** ~~In Arm A, all HIV-infected women should be offered immediate initiation of lifelong ART, and t~~**T**he CHiP team will be responsible for ~~checking this and for~~ assisting **these women** with linkage to care, if this has not taken place. ~~For women in Arm B who according to national standard guidelines are not eligible for ART and women in Arm A who decline immediate treatment, the CHiP team will ensure that they are offered standard PMTCT services according to national policy. National policies in Zambia and South Africa may change during the period of this study to initiate lifelong ART among pregnant women with HIV infection. If this occurs, then all pregnant women in both Arms A and B will be linked to care for immediate ART in the country or countries where it is the national policy.~~

Section 5.1.1 – Sampling/Recruitment of *Population Cohort*

Only one adult will be randomly selected from each **randomly selected** household to participate in the *Population Cohort* for outcome evaluation. This is to avoid the distortion of the trial results which might occur if whole households or several members of a household were to be evaluated, since this would in itself constitute a mass testing and counseling intervention. **To avoid the possibility of coercion or biased study data, field staff will not enumerate a randomly selected household if someone in that household is an employee of Zambart or Desmond Tutu TB Centre.** If the person selected for the cohort from a given household is ineligible or refuses participation, the team will move on to the next household on the list. As described in Section 7, the

statistical analysis will take into account the different sampling probabilities resulting from the selection of one individual irrespective of household size.

APPENDIX VI - SAMPLE INFORMED CONSENT FORM – CHIP TEAM ACTIVITIES SUBJECT INFORMATION SHEET

- The CHiPs will ask individuals to consider having an HIV test. Individuals do not have to have a test unless they wish to do so. Household members aged below 16 can only ~~join the study~~ **receive an HIV test** if their parents or guardians give their consent.

> ***Note about this revision****: This language is from the sample information sheet. The actual age will be adjusted by the site teams to reflect local guidelines when they create the site-specific version of this document*.