

HIV Prevention Trials Network

CLARIFICATION MEMO #01 TO:

HPTN 071a – Stigma Ancillary Study

**The Role of HIV-Related Stigma in the Delivery of Universal Test and Treatment
for HIV Prevention**

Version 1.0 / 06 January 2014

Date of Clarification Memorandum: 14 April 2014

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 071a 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 minor wording changes in the informed consent form.

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

Summary of Revisions

This CM provides clarification on the following items:

- 1) Changes the term CARE (Clients at Risk of Exclusion) to Key Populations, at the request of the HPTN 071 (parent study) leadership
- 2) Removes video recording of staff in Zambia, per IRB directive

Implementation

The modifications included in this CM 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.

List of Abbreviation and Acronyms

~~CARES~~ ————— ~~Clients at Risk of Exclusion~~

Section 1.1

~~“clients at risk of exclusion” (CAREs)~~ **Key Populations**

Sections 2.1, 5.2.2, and 6.3

~~CARE~~ **Key Population**

Sections 5.2.2

Data Collection Tools

Interviews will semi-structured and will be digitally recorded and transcribed. Where appropriate to the data collection process, and again with the consent of participants, still photography and video (**video in South Africa only**) will be used to complement the audio data.

Appendix II – Sample Informed Consent

~~Client at risk of exclusion~~ **Key Population**

[insert relevant ~~CARE~~ **Key Population** group]

Where appropriate to the data collection process, and with your consent, still photography and video [**video in South Africa only**] will be used to complement the audio data.

I consent to having photography and video [**video in South Africa only**] of my interview being used to compliment audio data (optional).