

FINAL 21Nov06

Date: 21 November 2006
To: HTPN 059 Study Sites
From: HPTN 059 FHI CORE

Alternate Condoms

During a previous PSRT conference call, we discussed the fact that two participants voiced complaints about the study provided condoms (Alatech brand). Three other types of condoms have been tested with 1% tenofovir gel and the matched placebo gel and all were found to be compatible. These condoms are:

Trojan Latex w/Aqueous Lubricant
Durex Latex w/Aqueous Lubricant
Durex Latex w/Silicone Lubricant

Participants who ask about the use of non-study provided condoms should be informed that we prefer that they and their partner(s) use the study provided condoms. However, should they ask about alternatives, they may be provided with the names of the condoms listed above. Additionally, participants should be counseled that it is always better to use any condom rather than no condom.

Use of Vaginal Lubricants

The PSRT also discussed the use of lubricants during intercourse in response to a query from a study participant. To date, there have been no lubricants that have been tested with study gel or placebo. Therefore, all participants should be advised to avoid the use of all vaginal products (except study gel) within two hours before and two hours after insertion of the study product (as stated in the protocol). If, during queries about the use of concomitant medications, a participant mentions use of a lubricant, please list the lubricant on the appropriate DataFax CRF page.

Note:

This document should be filed in study file binder # 12: Other Study-Related Communications, item 37 (Study-Related Communications to and from HPTN CORE)