

PB54 Preventing co-enrolment in multiple clinical trials in Durban, South Africa

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ABSTRACT TEXT

Issue:

Several microbicide trials funded by HPTN, MDP, CONRAD and Population Council are currently underway by the HIV Prevention Research Unit of the Medical Research Council in KwaZulu-Natal, South Africa. In addition, the MIRA Phase III diaphragm clinical trial is ongoing between two sites. Since many of these studies are based in low income communities, a major factor could influence recruitment is the stipulation by MCC to reimburse women with R150 for each visit during trial participation. We recognize that multiple trial enrolment may be considered by women in the community as a means to generate an income. A strategic plan by the Unit has been implemented to prevent the co-enrolment of women in multiple trials conducted by the Unit.

Description:

As all clinical trial staff are bound by confidentiality agreements in the Unit, a HPRU trial participants enrolled log has been created on a Microsoft Excel spreadsheet for circulation among project leaders of existing trials. Every study has an allocated worksheet on this database. This log contains the participants South African identity number and date of enrolment in a particular trial. This enrolled log is updated daily and Search and Find computer functions are used to identify if women are concurrently participating in other trials conducted by the HPRU. The identity numbers of eligible women scheduled for enrolment at each site are crosschecked on this database prior to randomization into respective clinical trials. Through this system we have identified several women who have attempted to join multiple trials for monetary gain. These women are counselled and reminded of exclusion criteria of the trial in which they are already enrolled.

Conclusion:

Co-enrolment in clinical trials can be successfully avoided using the log developed by the MRC.

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