

Sample Letter to Ethics Committee Requesting Review of Materials Needed for Dissemination



SOUTH
AFRICAN
MEDICAL
RESEARCH
COUNCIL



HIV PREVENTION RESEARCH UNIT

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Chair: Biomedical Research Ethics Committee
Westville Campus
University of KwaZulu-Natal

**PROTOCOL: An international multi-centre, randomised, double-blind, placebo-controlled trial to evaluate the efficacy and safety of 0.5% and 2% PRO 2000/5 gels for the prevention of vaginally acquired HIV infection (MDP 301). G Ramjee, MRC MRC Ref: T267/05
Africa Centre Ref: T111/05**

RE: Approval of Trial Results Dissemination Presentation, Q & A Document and MDP Backgrounder

Dear _____,

The above-mentioned trial is now closed to participant follow-up and data has been locked. We are expecting the results to be released sometime in December 2009, depending on the review of the data analysis in late November 2009.

As we have done in the past, please find enclosed a Powerpoint presentation, which will be used to provide the information to communities and trial participants. We would appreciate your feedback on this. We also enclose the Q & A document and study backgrounder for your information.

As we are blinded to the data and we have no results, we have some slides which do not have final data and there are three outcome scenarios each with a possible explanation. Once the trial results are available, this data and the final outcome scenario will be added for your expedited review at a later stage.