KENYA MEDICAL RESEARCH INSTITUTE

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KEMRI/RES/7/3/1 **May 8, 2009**

TO: **JOANNA CRICHTON (PRINCIPAL INVESTIGATOR)**

THRO': **DR. ELIYA ZULU,**
AFRICAN POPULATION & HEALTH RESEARCH CENTER,
NAIROBI

RE: **NON-SSC PROTOCOL No. 065: RESEARCH AND FEASIBILITY STUDY TO EXPLORE MENSTRUAL PRACTICES AND INVESTIGATE THE SUITABILITY OF MENSTRUAL CUPS FOR ADOLESCENT GIRLS AND WOMEN IN KENYA**

Dear Madam,

Make reference to your letter dated May 8, 2009.

It is now clear that the requested amendments are for the next review period and have not been implemented as yet. They are:

1. The addition of the Division of Public Health who has become a partner with the following additional investigators:
    a. Dr. Josephine Kibaru - Co-Principal investigator
    b. Dr. Chi-Chi Undie, Dr. Eliya Zulu and Dr. Lucy Musyoka – Co-investigators
2. Expanded plans for dissemination to involve 3 levels of dissemination (policy, local and national)
3. Korogocho slum will be the informal settlement that will be under study
4. The increase of IDIs and FGDs for Phase I from 14 to 20 and 14 to 16 respectively
5. Sample size increased from 30 to 75 for phase II of the study
6. The IDI and structured interviews will be held at both 0 months and 4 months to yield greater comparative data on participants experiences with and assessments of menstrual cups
7. Three target groups for Phase 2 have been altered as follows:
    a. The second group has been changed from APHRC staff to students to keep reduce the chances of bias

b. The site for the school girls aged 15-17 has been changed from a single sex secondary boarding school to mixed day school to ensure that the participants targeted are from an urban informal settlement
8. Changes to the nurse's sensitization of participants about the practical requirements necessary for using menstrual cups
9. Instruments and consent forms for Phase 2 in English and Kiswaili have been added, Appendix Five.
10. The expansion of the Inclusion criteria to include active RTIs and UITs and current use of IUCD, diaphragm or cap
11. Added detail on measures to ensure confidentiality for study participants
12. Added detail on measures to manage risk from any reproductive tract infections that could ocurr during the trial independently of the device.

The Committee is satisfied with your response to the issues raised at the meeting of 14th April 2009. The study is hereby granted **annual** approval for implementation effective this **8th day of May 2009,** for a period of twelve (12) months.

Please note that authorization to conduct this study will automatically expire on **Thursday, 7th May 2010.** If you plan to continue with data collection or analysis beyond this date, please submit an application for continuing approval to the ERC Secretariat by **Thursday, 27th March 2010**.

You are required to submit any amendments to this protocol and other information pertinent to human participation in this study to the SSC and ERC prior to initiation. You may embark on the study.

Yours sincerely,

RCTKithinji

R. C. KITHINJI,
FOR: SECRETARY,
KEMRI/NATIONAL ETHICS REVIEW COMMITTEE