DATA MANAGEMENT PLAN

STUDY: A PROSPECTIVE COHORT STUDY OF UP TO 24 MONTHS TO ASSESS THE EFFECT OF PROGESTERONE-BASED HORMONAL CONTACAEPTIVE ON THE VAGINAL MICROBIOME.

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Study Site	FHO KENYA
Users/Audience	Principal Investigator/ FHO Kenya

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1.0. Synopsis of Research Project

A prospective cohort study of 200 young women aged 18-24 years to assess the effect of progesterone-based hormonal contraceptive on the vaginal micro biome.

Specific objectives

i. To prospectively compare changes in the vaginal micro biota before and after successful use of progesterone based hormonal contraceptives.

ii. To investigate the factors influencing decision on choice of family planning method to use in young women.

Protocol synopsis: Non-pregnant, non-breastfeeding, contraceptive naïve women aged 18-24 years will be eligible for this study. Excluded will be young women who will be currently using any hormonal based contraceptives for a period not exceeding 3 months.

2.0. Goals of Data Management Plan:

Principles of Highest value:

2.1. Data accuracy & completeness,

Data accuracy is crucial, especially since different subjects have slightly different characteristics. Complete data reporting, especially with regard to contraception use is crucial for interpretation of how progesterone based hormonal contraceptives interact with the vaginal micro biota.

2.2. Safety,

Safety of information, and who has access to what part of the data and at what time is crucial and essential in ensuring security and avoiding data loss at any stage during the conduct of the study.

2.3. Data safety

Data safety is crucial, data safety monitoring tool will be created to ensure no data loss occurs at any time during data management to fulfill the accuracy and other data management goal discussed above in this research project.

2.4. Confidentiality

Patient records must be confidential. The only identifier between a name and participant id will be the link log that will be kept in secure lockable cabinet. Electronic records must be password protected, and all staff members involved in this study will be trained on GCP before handling research data.

3.0. Description of Procedures:

3.1. Screening

The study counselor or nurse counselor will screen the subject for eligibility, discuss the study, and answer any questions arising before proceeding to administer written informed consent. Once consent is obtained, CRFs will be administered to gather information on demographics, contraception use and sexual history. Urine will be collected to conduct a pregnancy test. An oral HIV test will be done. An endocervical swab in a gene probe tube will be collected to test for etiological testing (STI screening).

3.2. Enrollment

At enrollment visit the study/nurse counselor, study clinician will confirm eligibility. If confirmed positive for any STI the participant is not eligible. Informed consent will be administered and obtained voluntarily from the subject. CRFs will be administered to collect

information on contraception use, and sexual history. A punch biopsy sample will be collected (baseline sample pre contraception use). Participants' will then be put on a progesterone based hormonal contraception.

3.3. Safety Visit

Women will be asked to return back to the clinic after three weeks post contraception use this will act as a safety visit to assess complaints related to contraception use.

3.4. follow up

Women will have quarterly visits there after (after attending the safety visit); a maximum of 7 visits will be scheduled. At this visits' STI testing may be repeated if clinically indicated (presence of symptoms). If during follow up women will be found have an STI or pregnant, discontinuation from the study will follow and will be referred for ANC.

3.5. Exist Visit

Exist visit will be conducted at the 24th month of follow up, a punch biopsy sample will be collected (post contraception use). A disposition form must be filled at the exit visit, and locator information collected for future contact.

4.0. Completeness

4.1. 4.1 Missing Data

Efforts will be made to ensure that all data points necessary to meet the set protocol objectives are met; sources of missing data such as missed appointments will be mitigated by having a robust retention team that will call participants to remind them of upcoming study visits or remind those who are late for their visits to attend. A missed visit form will be completed for each missed appointment to flag the missed data point. Lab results will have a turnaround time of 7 days, reports from the local database will run on daily basis to track overdue results. This report will be emailed to the lab manager who will follow it to its logical conclusion.

5.0. Accuracy/Correctness

We anticipate human errors in this study to include erroneous transcription of results on to paper CRFs and local databases. As thus a regular QA/QC checks will be done routinely as a way of mitigating this, this error will be complied and based on their frequency affected staff will be retrained.

6.0. Verification

There will be three levels of QA/QC. A data officer will enter data in to an electronic database (MS Access Based). An update log will be created; this will be used to record any data entry done on to the database. A second data officer will then review the entries done in to the database against the source document checking for completeness and accuracy. The data manager will be the third level of QC where he/she will also verify these same entries against the source documents.

A contracted site monitor will regularly perform monitoring visits to the site and will review 10% of files randomly as way of confirming compliance with GCP guidelines and site specific SOPs for the study.

7.0. Security/Confidentiality

The databases will be password protected and authorization to access them granted to the P.I, Site coordinator and data management staff. It will be mandatory to change these passwords after every six months of use. Signed consent forms, locators, will be kept under lock and key in a secure location. Data will not be transferred via E-mail.

In addition confidentiality agreements will be created and hired staff will sign and adhere to their stipulation during/after the conduct of the study.

Data captured locally in these databases will be backed up weekly in a computer set aside for this function. No data will be transferred through emails.

8.0. Data Availability and Access

Data collected during the course of the study will be made available through written permission from the study principal investigator to the lead statistician. On completion of analysis and publication of results, findings will be disseminated through medical journals, local media houses and on the official study website.

9.0. Study Coordination and Communication

Progress reports will be sent weekly to the study Principal Investigator to update on study progress. Priority emails will be sent to the site to gather most urgent data or to communicate new guidelines on specific areas.

10.0. Appendix A to the plan:

Project Investigators will secure and maintain this document as part of the project's regulatory records.

Table of Contents

2. List of Acronyms

GCP	Good Clinical practice
HIV	Human Immunodeficiency Virus
STI	Sexually Transmitted Infection
CRF	Case Report Forms
ANC	Antenatal Clinic
QA/QC	Quality Assurance/Quality Control
SOP	Standard Operating Procedure
PI	Principal Investigator
MS	Microsoft
ICT	Information Communication Technology

3. Table of Procedures

Tests and Procedures	Screening	Enrolment	Week 3	Quarterly visits	Month 24 /Exit
Informed Consent	X	X			
Inclusion/ Exclusion	X	X			
Locator Information	X				X
Medical history	X	X	X	X	X
BIOPSY		X			X
HIV TEST	X	X			
Urine Preg-test	X	X	X	X	X
STI testing	X	[X]	[X]	[X]	[X]

[X]- if indicated

4. Sample Forms

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Informed consent process

Screening ID _____

Date and time participant signed informed consent form _____

The following were completed in the informed consent process and form	☐	Participant or legal representative printed name, signed and dated the consent form
	☐	Person who obtained consent personally printed name, signed and dated consent form
	☐	Participant or legal representative initials "use of specimens in future research"
	☐	Participant or legal representative initials "future contact"
Was a copy of consent given to participant?	○	Yes
	○	No

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Demographics

Date of Visit _____

Personal Information

Participant Initials _____

Date of Birth _____ (Eligible if born between 1992 and 1998(inclusive))

Ethnicity
- ○ Kikuyu
- ○ Kamba
- ○ Luo
- ○ Luhya
- Kisii
- Other

Other _____

Education (total years completed) _____

Additional Comments _____

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InclusionCriteria

Is the participant between 18 and 24 years of age?	○ Yes ○ No
Is the participant willing to give voluntary consent, sign an informed consent form and comply with study procedures as required by the protocol?	○ Yes ○ No
Per volunteer history and investigator discretion, is the participant in general good health without any clinically significant systemic disease?	○ Yes ○ No
Is the participant able and willing to provide locator information?	○ Yes ○ No
Is participant willing and able to undergo speculum examination (approximately 5 minutes)?	○ Yes ○ No
Is participant HIV-uninfected based on testing performed by study staff during screening procedures?	○ Yes ○ No
Was participant diagnosed with BV by Amsel's criteria?	○ Yes ○ No

Participant does not meet Inclusion Criteria if *"NO"* is ticked as an option. Do not enroll in to the study.

ExclusionCriteria

Does the participant have a known bleeding disorder that could lead to prolonged or continuous bleeding with biopsy?	○ Yes ○ No
Is the participant intending to become pregnant during the period of study participation?	○ Yes ○ No
Is the participant currently pregnant?	○ Yes ○ No
Is the participant currently breast feeding?	○ Yes ○ No
Does the participant have a positive test for Trichomonas, Neisseria gonorrhea, or Chlamydia	○ Yes ○ No

Does the participant have evidence of a clinically detectable genital abnormality (i.e., mucopurulent discharge, cervicitis, lesion) or vaginitis other than BV?	○ Yes ○ No
Is the participant allergic to silver nitrate and Monsel's solution?	○ Yes ○ No

5. Budget

The study will enroll a maximum of 200 subjects for a period of 24 months.

DESCRIPTION	COST (USD)
Personnel	22,925
Equipment	5,000
Supplies	850
Softwares	3,000
Participants Reimbursement	16,000
Indirect Costs	7,000
GRAND TOTALS	54,775

6. Budget Justification

Personnel

1. **Recruitment Personnel Cost,**

   Field coordinator:

   He/She will be responsible for all recruitment and retention activities, hire field officers and institute community entry strategies that will be used to mobilize the target group for the study.

2. **Data management personnel cost,**

   Data Manager:

   The holder of this post will over see the formulation of case report forms, design and programming of databases, coordinate and supervise data entry clerks and advice the PI on ICT matters.

3. **Statistician personnel cost;**

   A statistician will be hired to assist in study design, analysis, interpretation and dissemination of study outcomes.

4. **Clinician personnel cost;**

   Lead clinician/Physician

   A certified clinician will be hired to cater for the medical aspect of this study; she will be responsible for the clinic.

Equipment

i. Desktop pc (2*1200), laptop computers (2*500)

   This will be used to assist staff carry out tasks such as, data entry, correspondence, report compiling and administrative duties.

Printers @ 850

Label printer @750

Supplies

i. Monies will be set aside to purchase office supplies such as;

Printing papers (@ 500),

Other stationaries (@350)

Softwares

i. Under the recommendation of the staff, we will strive to purchase genuine copies of application softwares that will assist in execution of outlined duties.

Firewall and antivirus for computer systems (@1000)

Office suite, accounting software (@2000)

Participants Reimbursement

Participants will receive reimbursement for each clinic visit attended; they will each receive USD 10 per visit. This will be inclusive of transport and a token of appreciation.

Indirect costs

i. Staff members will also be provided with a medical cover for them and three members of their family. One team building event per year will also be planned with the aim of improving staff cohesiveness. Regular trainings will also be planned to improve the skills of the workers.