

2 RESEARCH SYNOPSIS

This is a prospective interventional study with quarterly visits for up to 12 months of follow up, 480 sexually active girls (by self-report), 16 – 20 years of age, willing to undergo study procedures and willing and able to provide independent informed consent/assent will be eligible for this study. Girls with known plans of relocation from study area for more than 3 consecutive months and with any medical condition that might make study participation unsafe or interfere with study objectives will be excluded.

Eligibility determination and enrollment into the study will be done on the same day (day 1), consenting/assenting (for <18 years) will be done, locator information collected and questionnaires will be administered to obtain demographic information. During subsequent follow up visits up to 12 months, questionnaires will be used to collect information on; sexual history and behavior, STI symptoms, use and attitudes of contraceptive. Urine will be collected to do a pregnancy test and Urine dipstick will be performed to detect urinary tract infections. Blood and genital swabs will also be collected for various laboratory tests such as HPV, HSV, Syphilis, BV, HBV serology etc.

Enrollment: The proposed duration for enrolling the 480 sexually active girls is approximately six months, which means that the last participant will exit the study six months after the first ever enrolled participant has exited the study.

2.1 RESEARCH AIMS/GOALS

- 1.1.1 To determine the prevalence of and factors associated with reproductive tract infections.
- 1.1.2 To determine the incidence of and factors associated with acquisition of reproductive tract infections.
- 1.1.3 To determine the prevalence of contraceptive use and factors associated with contraceptive use among adolescent girls living in informal settlements and other high population density low income settlements.

3 DATA MANAGEMENT OVERVIEW

3.1 GOALS OF DATA MANAGEMENT PLAN

Focus will be given to the following three principles of highest value;

- i. **Data accuracy/validity and completeness.** Accuracy of data is paramount for the simple reason that the age bracket 16-20 is such cohort with nearly similar characteristics and sharing of variables such as names and address. Complete and accurate data collection will ensure that each participant's record is valid and precise with minimized errors.
- ii. **Timeless data (speed of data update).** Timely update of collected data into the system database is vital since generation of summary reports to monitor the study progress in terms of accrued numbers into the study is entirely dependent on available data in the system data base. Scheduling of participants for their subsequent follow up visits and detecting late to follow up & missed visits also greatly relies on the rate at which the program's data base is updated. Turnaround time for laboratory results is crucial for monitoring and reporting HSV2 sero-conversions, STI infections etc.
- iii. **Data integrity and safety.** Safety and integrity of data as pertaining access and use of important aspect of it; protecting system data bases from deliberate bias or manipulation either erroneously or for whatever reason by having independent review of the data to ascertain whether the integrity has been compromised and limiting access to authorized staff only

3.2 DATA MANAGEMENT PROCEDURES

3.2.1 Enrollment/Screening Visit:

Determination of eligibility, screening and enrollment into the study will be performed at the same visit. Parameters measuring eligibility criteria for participants will be recorded in (SELIG), once participant is eligible to participate in the study;

- i. Screening/Enrollment, administration of informed consent for participants who are 18 years and above. For those below 18 years, the parents/guardian will provide consent (permission) while they provide assent.
- ii. After signing of consent/assent, locator information such as name, telephone number, address, names and addresses of contact persons, referral source and name of referring health worker will be

collected and recorded on the locator form; demographic information which includes date of birth, type of residence and socio economic status will be obtained and recorded onto SEDEM form.

- iii. Administration of questionnaires on sexual history and behavior, STI symptoms, use and attitudes to contraceptive (SESX).
- iv. Assigning of a PTID which will be the unique identifier and subsequent enrollment of the subject into the study
- v. HIV Rapid test will be done and results recorded in the (ESLR) form. Blood will be drawn to be used to carryout laboratory tests as outlined in a detailed study procedures table.
- vi. Obtaining medical history, counseling on risk behavior, contraceptive use counseling and provision and record all information of session on a chart note.
- vii. Physical examination and treatment of any medical condition diagnosed during the screening/enrollment visit

Locator information, date of birth and date of enrollment into the study with the PTID as a unique identifier is captured into a local Access data base to ease and allow scheduling of participants for subsequent follow up visits. The laboratory results, SESX, SEGE and PENR is captured onto paper CRF and transcribed into REDCap data base.

3.2.2 Follow up Visits (M1-M12)

Follow up visits will be done quarterly i.e. after every 3 months up a total of 12 months of follow up. The follow up visits will be identical in terms of procedures and questionnaires administered as below.

For every follow up visits (i.e. Month 3, 6, 9 and 12);

- i. Review of previous visit's concern and issues.
- ii. Counselling on risk behavior, contraceptive use and provision.
- iii. Updating of locator information, if different from previous visit.
- iv. Physical examination and obtaining of medical history since previous visit.
- v. Treatment of conditions diagnosed at the visit.
- vi. Administering of follow up visit questionnaires (FSX and FGE).
- vii. Blood draws will be done for outlined laboratory tests.

3.3 DATA COMPLETENESS

Aim is to ensure that the system captures all the information it is supposed to capture without allowing room for missing value, however missing data points more often come up. Likely causes of missing data and how to overcome the challenges:

- i. Uncompleted data points on CRFs – Staff involved in the study and completion of CRFs will be trained on proper source document completion, providing full instructions on CRF back page that outlines how each item should be completed to avoid violation of skip patterns
- ii. Lost to follow up/missed visits – Participants on lost to follow will be contacted before window visit closes to remind them on their scheduled visits and encourage them to attend. Missed visits will be recorded into a missed visit CRF and updated into REDCap.
- iii. Participant declining to undergo procedures – This information will be recorded and indicated in the respective CRF stating reason for decline and offered a chance to undergo the procedures in subsequent visits if they change their mind.
- iv. Laboratory results - Will be recorded in the laboratory CRF weekly and the copies kept on a different binder in the laboratory manager's office for back up and original forms filed together with other study records on the CRF binder.
- v. Data base design (REDCap and Access) – Validation will be done to ensure all key fields are not missed (queries to detect and report missing values) Valid checks (logical algorithm) will be put in place for numerical fields that are required for eligibility confirmation e.g. $16 \leq \text{age} \leq 20$.

3.4 DATA ACCURACY AND CORRECTNESS

Describe error management procedures. These are accidental mistakes and could be both human and technical errors. Technical in the essence of design of data base and human bound for instance someone records information inaccurately or enters information into the database incorrectly

3.4.1 Methods to correcting errors

- Entering electronic data twice and checking for inconsistencies (double data entry)
- Peer review of completed CRFS before transcribing into REDCap data base (people based review)
- Conducting random checks on data that have been entered into REDCap data base to check for accuracy and correctness.

- Data base design (good validation, automated ranges & calculation and valid value checks) to ensure correct field values are maintained, detect and report missing values.
- Protect data base systems (password protect) to avoid any manipulation that may arise for any reason.
- Regular data backup, creation of data cleaning queries and reports on data bases (REDCap and Access) to pin point conflicting information and inconsistency on records.

3.5 DATA VERIFICATION (AUDIT PROCEDURES)

To compare paper CRFs (source documents) one on one with electronic CRFs on the data base (REDCap and Access data base), checking if lab results have been accurately transcribed into both paper CRF and into the lab result data base, which will be designed using Access

- Schedule based check will be done weekly to check for missing lab results, monthly to detect any missing data points.
- Comparison of paper CRF and electronic CRF on REDCap will be done on two level QC during data entry. 1st level audits for completeness of paper CRF and enters data into database. 2nd level reviews the 1st level entries and counter checks with REDCap entries for complete process
- Have a computer printout lab result to act as a source document to compare entries on the CRFs entries with corresponding tests.
- 10% of all data entered will be randomly selected for source verification
- External study monitor (during enrollment, follow up and close out visit) will be incorporated to review regulatory and records to further enhance data verification.

3.6 DATA SECURITY AND MAINTAINING CONFIDENTIALITY

To maintain data according to national and/or international standards.

- REDCap data base will contain medical records for baseline visit and all follow up visits, it will not contain any identifiable information, logging in will be required to access the data (user name and password)
- Access data base will password protected/encrypted. It will contain locator information for participants and demographic information. The main purpose of the data base will be to generate schedule visit tracker, late for follow up reports, missed visit reports and also aid in scheduling follow up visits including setting target dates.

- Link log (containing names and PTIDs of all enrolled participant) will be kept under lock and key at a secure location on the site, preferably site coordinator's office.
- Paper CRFs placed in a binder will be in lockable fireproof cabinets within the data department office.
- Regular data backup(weekly) to OneDrive which is a secure cloud storage.
- Staff will be trained on safety SOPs and sign confidentiality agreement not to share information with other clients.

3.7 DATA AVAILABILITY AND ACCESS

Principal investigator, study coordinator, lead clinician and laboratory manager will get access to all medical records and laboratory results. They will hold a meeting bi weekly to review and discuss adverse events and study related injuries to prepare for reporting to local IRB.

Study statistician and senior data manager will export data from REDCap into excel worksheet for preliminary data analysis and generation of summary reports to inform of study progress and easily pull out data as needed.

Study sponsor and funders will receive study updates and summary reports on a weekly basis via e-mail. Dissemination of study results will be done to the public and research participants once the study has been completed and published.

3.8 STUDY COMMUNICATIONS AND COORDINATION

A conference call will be held if need be that will involve the sponsor, funders and participating researchers (research associates and PI) to discuss key information and data/reports pertaining the study.

A regular skype call will be taken between the PI, data manager and statistician to give updates and progress of data management activities and discuss study retention and proposed study analysis plan.

All communication and coordination of day to day study activities among the study staff will be conducted through an alias email address (pistic@ph-rd.org) that will be created at the start of the trial.

APPENDIX

4 TABLE OF CONTENTS

1	Research/Protocol Title	1
2	Research Synopsis.....	2
2.1	Research aims/goals	2
3	Data Management Overview.....	3
3.1	Goals of Data Management Plan.....	3
i.	Data accuracy/validity and completeness.....	3
ii.	Timeless data (speed of data update).....	3
iii.	Data integrity and safety.....	3
3.2	Data Management Procedures.....	3
3.2.1	Enrollment/Screening Visit:	3
3.2.2	Follow up Visits (M1-M12)	4
3.3	Data Completeness	5
3.4	Data Accuracy and Correctness.....	5
3.4.1	Methods to correcting errors	5
3.5	Data Verification (Audit Procedures).....	6
3.6	Data Security and maintaining confidentiality	6
3.7	Data Availability and access	7
3.8	Study Communications and Coordination.....	7

1. List of Abbreviation

HPV	Human papilloma virus
STI	Sexually Transmitted Infection
SEDEM	Screening Enrollment Demographics
SESX	Screening Enrollment Sexual history
ESLR	Enrollment Screening Lab Results
SEGE	Screening Enrollment Genital Exam
CRF	Case Report Form
PENR	Participant Enrollment
FSX	Follow up sexual history
FGE	Follow up Genital Exam
HBV	Hepatitis B virus
QC	Quality Control
PI	Principal Investigator
PTID	Participant ID
REDCap	Research Electronic Data Capture
IRB	Institutional Review Board
SOP	Standard Operating Procedure

2. DATA MANAGEMENT PROCEDURES/EVENT SUMMARIES.

Visit 1(Screening/Enrolment)	<ul style="list-style-type: none"> ✓ A clinic flow in excel format will be kept that will be updated on a daily basis to capture screened/enrolled numbers. ✓ An excel age calculator will be developed to be used while determining eligibility criteria of age. This will be done by a data officer. ✓ Paper CRFs will then be reviewed for completeness (peer review) by a data officer before data entry into the data bases. ✓ A new visit record is created in the access data base and populated with locator and demographic information including a PTID, date of enrollment into study and age. ✓ The data entry personnel will then do data entry of the relevant CRFs into REDCap data base
Subsequent/Follow up Visits (M3-M12)	<p>Note: <i>These follow up visits will be done quarterly and the clinical procedures will be similar for all quarterly visits</i></p> <ul style="list-style-type: none"> ✓ Participant binder will be retrieved from data archive room, respective CRFs for follow up visits and a locator form will be included ✓ Once the visit is done at clinic, the CRF binder will be reviewed at data office by Data assistant, data officer and finally by the data manager to monitor missing data and correctness of data before handed over to data entry clerk for data entry. ✓ Locator information, if updated on a follow up visit is entered into the local Access database while the clinical data for follow up is captured in REDCap.
Exit/Close out Visit	<ul style="list-style-type: none"> ✓ 10% of the data will be randomly selected for auditing and verification by the monitor who will be externally contracted. ✓ An exit questionnaire will be administered to all study participants to collect views and their experiences into the study ✓ All data will be internally cleaned, data exported to excel format readiness for analysis by the statistician. ✓ All name charts (containing locators and consents) will be archived in a secure location ✓ All softcopy study data available will be stored in an external hard disk for backup and storage

3. SCHEDULE OF STUDY PROCEDURES

Procedure/Test	Screening/Enrollment	Quarterly visits (M3-M12)
Informed consent/parental permission and assenting	X	
Obtain locator information	X	
Updating of locator information		X
Demographic information questionnaire(SEDEM)	X	
sexual history and behavior questionnaire(SX)	X	X
STI symptoms, use and attitudes to contraceptive use questionnaire(FSX)	X	X
HIV testing	X	X
Blood draws for; Syphilis test, HSV-2 ELISA and HBV serology	X	X
Genital swabs for; Gen-Probe, Bacterial vaginosis and Human Papilloma Virus (HPV)	X X	X
Urine sample for; Pregnancy test and Urine dipstick for urinary tract infections	X	X
Counselling; Risk behavior and Contraception counseling with provision	X	X
Physical examination, Medical history and treatment of conditions diagnosed at this visit	X	X

*Follow up Visits will occur(Quarterly) i.e. at Months 3, 6,9 and 12

4. TABLE OF PROCEDURES

Visits	Event
Screening/Enrollment	<p>Determination of eligibility is done and a new file binder is created;</p> <p><i>Administrative, Behavioral and Regulatory procedures</i></p> <ul style="list-style-type: none"> ✓ Administration of informed consent for participants who are 18 years and above. For those below 18 years, the parents/guardian will provide consent, while they provide assent. ✓ Locator information will be obtained ✓ Demographic information will be obtained by questionnaires <p><i>Clinical Procedures</i></p> <ul style="list-style-type: none"> ✓ Medical history ✓ Questionnaire will be administered to obtain information on sexual history and behavior, STI symptoms, use and attitudes to contraceptive use ✓ Contraception counseling with provision ✓ Physical examination ✓ Risk behavior counseling ✓ Genital examination with genital swabs collection ✓ HIV testing - based on the Kenyan national guidelines - serial testing using the Determine HIV-1/2 (Abbott Diagnostic Division. If this is positive, the participant will be tested with First response test kit. ✓ Blood collection ✓ Urine collection ✓ Treatment of conditions diagnosed at this visit <p><i>Laboratory Procedures</i></p> <p>The blood sample collected will be separated and aliquots of serum prepared at the on-site laboratory in PHRD. The aliquots will then be shipped to CTRL lab in KNH Nairobi for the following tests:</p> <ul style="list-style-type: none"> ✓ Syphilis - the RPR test will be done ✓ HSV-2 - HSV-2 antibodies will be detected using Focus HSV-2 IgG ELISA, with a positive test defined as index value of at least 2.2. ✓ HBV serology – HBsAg will be measured on the sample

	<p>The <u>urine</u> sample collected will be used for the following tests</p> <ul style="list-style-type: none"> ✓ Pregnancy test – will be performed using a rapid hCG kit ✓ Urine dipstick will be performed to look for urinary tract infections <p>The <u>genital</u> swabs collected will be tested as follows</p> <ul style="list-style-type: none"> ✓ Gen-Probe swab for Neisseria gonorrhoea, Chlamydia trachomatis, Trichomonas vaginalis – these will be stored at 2-8°C in the CTRL. ✓ Bacterial vaginosis – diagnosis will be based on Amsel's criteria – (if any three of the following are present: (1) vaginal pH ≥ 4.7, (2) clue cells >20% of vaginal epithelial cells on microscopy, (3) fishy odor with KOH and (4) abnormal vaginal discharge (increased amount, differing from usual consistency, or malodorous). Thus swabs will be collected for pH, wet mount with saline and KOH. A swab will also be collected for Nugent scoring ✓ Human Papilloma Virus (HPV) – a swab will be collected for assessment of high-risk HPV types 16,18, 31 and 33
Follow up (Month 3,6,9 and 12)	<p><i>Clinical Procedures</i></p> <ul style="list-style-type: none"> ✓ Medical history ✓ Questionnaire will be administered to obtain information on sexual history and behavior, STI symptoms, use and attitudes to contraceptive use ✓ Contraception counseling with provision ✓ Physical examination ✓ Risk behavior counseling ✓ Genital examination with genital swabs collection ✓ HIV testing - based on the Kenyan national guidelines - serial testing using the Determine HIV-1/2 (Abbott Diagnostic Division. If this is positive, the participant will be tested with First response test kit. ✓ Blood collection ✓ Urine collection ✓ Treatment of conditions diagnosed at this visit <p><i>Laboratory Procedures</i></p>

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Interim Visits	Participants will be asked to come to the clinic for review if they have any STI symptoms. Participants' symptoms will be managed at the clinic and samples will be collected for definitive diagnosis.

PREVALENCE AND INCIDENCE OF SEXUALLY TRANSMITTED INFECTIONS AND CONTRACEPTIVE USE AMONG
FEMALE ADOLESCENTS IN CENTRAL KENYA - A PROSPECTIVE STUDY

LOCATOR INFORMATION

SUBJECT INFORMATION: _____ Date _____ (dd/mm/yyyy)

Full Name:	
Address	
Primary Telephone Number:	
Alternative Telephone No:	
Institution:	
Email Address:	
Place of Birth:	

CONTACT INFORMATION FOR FRIEND/ROOM MATE

Full Name:	
Relationship to Subject:	
Hostel/Village:	
Institution:	
Town:	
Primary Telephone Number:	
Alternative Telephone Number:	
Email Address:	

CONTACT INFORMATION FOR PARENT/GUARDIAN

Full Name:	
Relationship to Subject:	
Address1:	
Address2:	
Primary Telephone Number:	
Email Address:	
Head of Household	

Referral source: _____

Name of referring Health worker: _____

Description of participant/guardian area of residence

Nearest points

Nearest shopping centre _____

Nearest Church/mosque _____

Nearest school _____

Nearest bar/ Kiosk _____

Describe how to get to participants/guardian house in writing and/or drawing a map

.....
.....
.....
.....
.....

Does the subject or her parent/guardian intend to remain at this address throughout the duration of the study?

Yes

No

If no, will the subject still be able to return to the clinic for all required visits?

Yes

No

Screening and Enrollment Demographics Form

(SEDEM)

Screening ID	Participant ID	Visit Date
<input type="text"/> -- <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>	<input type="text"/> <input type="text"/> -- <input type="text"/> <input type="text"/> <input type="text"/> -- <input type="text"/> <input type="text"/> <input type="text"/>
		dd mmm yyyy
Screening Demographics <i>This is an interviewer administered form. Read each item aloud to the participant</i>		
1.	When were you born? <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd mmm yyyy	
2.	How many years of school have you completed? (Do not count repeat levels) <input type="text"/> <input type="text"/> Years	
3.	3a. Do you have a regular source of income/money? <input type="checkbox"/> Yes <input type="checkbox"/> No	
	3b. How much income/money do you get monthly (average over last 3 months) Ksh. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
4.	4a. Do you live in a rural or urban area? <input type="checkbox"/> Rural <input type="checkbox"/> Urban	
	4b. Is the place of residence a formal or <input type="checkbox"/> Formal <input type="checkbox"/> Informal <input type="checkbox"/> Not sure an informal settlement?	
5.	In the participant's house:	
	Yes No	
	5a. Is there running water? <input type="checkbox"/> <input type="checkbox"/>	
	5b. Is there a concrete floor? <input type="checkbox"/> <input type="checkbox"/>	
	5c. Is there electricity? <input type="checkbox"/> <input type="checkbox"/>	
	5d. Is the roof made of tile or metal? <input type="checkbox"/> <input type="checkbox"/>	
	5e. How many rooms are there in the house? _____	
	5f. How many people live in the house? _____	

Completed by (initials/date) _____

Screening and Enrollment Eligibility Form

(SELIG)

Screening ID:	Participant ID:	Visit Date:
<input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/>	<input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
1.	1a. Did the participant provide informed consent?	Yes <input type="checkbox"/> No <input type="checkbox"/> → Go to item 2
	1b. Date when informed consent for screening was marked or signed?	<input type="text"/> dd <input type="text"/> mmm <input type="text"/> yyyy <i>(Then go to item 4)</i>
2.	2a. Was the participant's guardian/parent willing and able to provide independent, written, informed consent for screening?	Yes <input type="checkbox"/> No <input type="checkbox"/> → Ineligible(End of Form)
	2b. Date when informed consent for screening was marked or signed?	<input type="text"/> dd <input type="text"/> mmm <input type="text"/> yyyy
3.	3a. Was the participant willing and able to provide independent, written, informed assent for screening?	Yes <input type="checkbox"/> No <input type="checkbox"/> → Ineligible(End of Form)
	3b. Date when informed assent for screening was marked or signed?	<input type="text"/> dd <input type="text"/> mmm <input type="text"/> yyyy
<i>Question 4-7 should be answered 'yes' for the participant to be eligible</i>		
4.	Is the participant 16 – 20 years?	Yes <input type="checkbox"/> No <input type="checkbox"/>
5.	Is the participant/ participant's guardian/parent willing and able to provide adequate locator information?	Yes <input type="checkbox"/> No <input type="checkbox"/>
6.	Is the participant willing and able to undergo genital examinations?	Yes <input type="checkbox"/> No <input type="checkbox"/>
7.	Is the participant willing to remain in follow up for 3 years?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Exclusion Criteria Questions 8-11 should be answered 'no' for the participant to be eligible</i>		
8.	Has the participant ever had sex?	Yes <input type="checkbox"/> No <input type="checkbox"/> → Go to item 9
	8a. if yes in item 8 specify number of life time partners	<input type="text"/> (if >1 participant ineligible)
9.	Does the participant have any condition that, in the opinion of the Site Investigator or designee, makes participation in the study unsafe, complicates interpretation of the study outcome data, or otherwise interferes with achieving the study objectives?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>If participant is still eligible continue with blood draws. If ineligible at this point, end form.</i>		
10.	Is the participant HIV positive?	Yes <input type="checkbox"/> No <input type="checkbox"/>
11.	Is the participant HSV 2 positive?	Yes <input type="checkbox"/> No <input type="checkbox"/>
12.	Based on the information from item 1-11, is the participant eligible for enrollment?	<input type="checkbox"/> Eligible <input type="checkbox"/> Not eligible
<i>If participant is eligible but does not enroll, continue, otherwise end of form.</i>		
13.	Reason eligible participant did not enroll: <input type="checkbox"/> Declined Enrolment <input type="checkbox"/> Investigator decision <input type="checkbox"/> Did not return for enrollment <input type="checkbox"/> Other Specify _____	

Completed by (Initials/date) _____

Participant ID: - - Date:
 dd mmm yyyy

**Screening and Enrolment Sexual History and Behavior
(SESX)**

CRF not administered

Screening and Enrolment Sexual History and Behavior This is an interviewer administered form. Page 1

Now I'm going to ask you about your sexual practices. While some of the information may be embarrassing or difficult to remember, please try to give your best answers and be as honest as you can. Whenever sex or sexual intercourse is stated, it includes vaginal and anal sex, but not oral sex. The term 'condom' refers to either a male or a female condom.

1.	a. Have you ever had sex?	<input type="checkbox"/> Yes <input type="checkbox"/> No → End of form
	b. When did you first have sex? <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR Already reported at visit <input type="text"/> . dd mmm yyyy	
	c. Was a condom used the first time you had sex?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	d. Was the sexual act your choice and with your agreement?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	e. Were you offered a reward/ money for sex?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	f. How old was the person you first had sex with?	<input type="text"/> Years
	g. How long had you known the person before having sex?	<input type="text"/> Days <input type="checkbox"/> Months <input type="checkbox"/> Years
2.	a. In the past 3 months, how many times have you had sex?	<input type="text"/> times → If 00, go to item 3
	b. How many times did you use a condom?	<input type="text"/> times
	c. How many sexual partners have you had in the past 3 months?	<input type="text"/>
	d. How many new sexual partners have you had in the past 3 months?	<input type="text"/>

Completed by: (initials/date) _____

Participant ID: - - Date:
dd *mmm* *yyy*

(SESX)

CRF not administered

Screening and Enrolment Sexual History and Behavior		Page 2	
3.	a. In the past 3 months have you had anal sex?	<input type="checkbox"/> Yes <input type="checkbox"/> No → Go to item 4	
	b. How many times did you have anal sex?	<input type="text"/> <input type="text"/> times	
	c. How many times did you use a condom?	<input type="text"/> <input type="text"/> times	
4.	a. In the past three months, have you used any method of contraception?	<input type="checkbox"/> Yes <input type="checkbox"/> No → End of form	
	b. Which method do/did you use? <i>Mark all that apply</i>		
	<input type="checkbox"/> Oral	<input type="checkbox"/> Implant	<input type="checkbox"/> Safe days
	<input type="checkbox"/> IUD	<input type="checkbox"/> Emergency pills	<input type="checkbox"/> Other,(specify) _____
	<input type="checkbox"/> Injectable	<input type="checkbox"/> Condoms	
Completed by: (initials/date) _____			

Participant Enrollment

(PENR)

Participant ID:	Visit Date:		
<table border="1" style="width: 100px; height: 30px;"></table> <table border="1" style="width: 100px; height: 30px;"></table> <table border="1" style="width: 30px; height: 30px;"></table>	<table border="1" style="width: 30px; height: 30px;"></table>	<table border="1" style="width: 30px; height: 30px;"></table>	
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1.	Did the participant meet all the eligibility criteria? Yes <input type="checkbox"/> No <input type="checkbox"/> Investigator/Designee signature: _____ <table border="1" style="width: 100px; height: 30px;"></table> <table border="1" style="width: 100px; height: 30px;"></table> <table border="1" style="width: 100px; height: 30px;"></table> <i>dd</i> <i>mmm</i> <i>yyyy</i>		
2.	2a. Did the participant/guardian provide independent, written, informed consent/parental permission for enrollment? Yes <input type="checkbox"/> No <input type="checkbox"/> 2b. When was the informed consent for enrollment marked or signed? <table border="1" style="width: 30px; height: 30px;"></table> <table border="1" style="width: 30px; height: 30px;"></table> <table border="1" style="width: 30px; height: 30px;"></table> <i>dd</i> <i>mmm</i> <i>yyyy</i> 2c. Consented under protocol version # <table border="1" style="width: 30px; height: 30px;"></table> . <table border="1" style="width: 30px; height: 30px;"></table>		
3.	3a. Did the participant provide independent, written, informed assent for enrollment? Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> 3b. When did the participant sign or mark the assent form for enrollment? <table border="1" style="width: 30px; height: 30px;"></table> <table border="1" style="width: 30px; height: 30px;"></table> <table border="1" style="width: 30px; height: 30px;"></table> <i>dd</i> <i>mmm</i> <i>yyyy</i> 3c. Assented under protocol version # <table border="1" style="width: 30px; height: 30px;"></table> . <table border="1" style="width: 30px; height: 30px;"></table>		
4.	4a. Did the participant/guardian provide informed consent or assent/parental permission for specimen storage? Yes <input type="checkbox"/> No <input type="checkbox"/> 4b. When was the informed consent or assent for specimen storage marked or signed? <table border="1" style="width: 30px; height: 30px;"></table> <table border="1" style="width: 30px; height: 30px;"></table> <table border="1" style="width: 30px; height: 30px;"></table> <i>dd</i> <i>mmm</i> <i>yyyy</i>		
5.	Date participant ID assigned: <table border="1" style="width: 30px; height: 30px;"></table> <table border="1" style="width: 30px; height: 30px;"></table> <table border="1" style="width: 30px; height: 30px;"></table> <i>dd</i> <i>mmm</i> <i>yyyy</i>		

Completed by (initial/date) _____

Screening and Enrollment Genital Exam page 1

(SEGE)

Participant ID: _____ _____ _____		Visit Date: _____ _____ _____		
<i>dd mmmyyyy</i>				
1.	Last Menstrual Period	_____ _____ _____	dd	mmmyyyy
2.	a. Was a genital exam done?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
	b. If genital exam was not done, please provide a reason	_____		
3.	Is the participant circumcised?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
4.	Were any of the following signs noted?			
	a. Redness	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	b. Abnormal vaginal discharge	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	c. Swelling	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	d. Ulcers	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	Location of ulcers:	<input type="checkbox"/> Mons <input type="checkbox"/> Perianal <input type="checkbox"/> Labia <input type="checkbox"/> Buttock <input type="checkbox"/> Perineal <input type="checkbox"/> Leg/hip/back		
	e. Other	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	Specify:	_____		

Completed by (initial/date) _____

Screening and Enrollment Genital Exam

page 2

(SEGE)

Participant ID:		Visit Date:					
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>					
		<i>dd</i>	<i>mmm</i>	<i>yyyy</i>			
5.	Was a HSV-PCR swab collected?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	N/A
6.	Was a vaginal swab for BV gram stain collected?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	N/A
7.	Was a vaginal swab for BV storage collected?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	N/A
8.	Was a vaginal swab for GC, CT, TV collected?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	N/A
9.	Was cervicovaginal lavage done?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	N/A
10.	Was an archive sample for HSV testing taken?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No		
11.	Was a host DNA sample taken?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No		
Etiologic Diagnosis							
12.	Laboratory tests done for etiological diagnosis of STDs?	<input type="checkbox"/>	Not done	→(end of form)			
a.	Gonorrhea:	<input type="checkbox"/>	not done	<input type="checkbox"/>	done	→	Result: <input type="checkbox"/> negative <input type="checkbox"/> positive
b.	Chlamydia:	<input type="checkbox"/>	not done	<input type="checkbox"/>	done	→	Result: <input type="checkbox"/> negative <input type="checkbox"/> positive
c.	Trichomoniasis:	<input type="checkbox"/>	not done	<input type="checkbox"/>	done	→	Result: <input type="checkbox"/> negative <input type="checkbox"/> positive
d.	Bacterial Vaginosis:	<input type="checkbox"/>	not done	<input type="checkbox"/>	done	→	Result: <input type="checkbox"/> negative <input type="checkbox"/> positive

Completed by (initials/date) _____

**PREVALENCE AND INCIDENCE OF SEXUALLY TRANSMITTED INFECTIONS AND CONTRACEPTIVE USE AMONG FEMALE
ADOLESCENTS IN CENTRAL KENYA - A PROSPECTIVE STUDY**

Participant ID: - - Date: Visit code:

dd mmm yyyy

Participant Follow-up Sexual History and Behavior and Behavior
(FSX)

CRF not administered

Participant Follow-up Sexual History and Behavior *This is an interviewer administered form.* **Page 1**

Now I'm going to ask you about your sexual practices. While some of the information may be embarrassing or difficult to remember, please try to give your best answers and be as honest as you can. Whenever sex or sexual intercourse is stated, it includes vaginal and anal sex, but not oral sex. The term 'condom' refers to either a male or a female condom.

1.	a. Have you ever had sex?	<input type="checkbox"/> Yes <input type="checkbox"/> No	→ End of form
	b. When did you first have sex? <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd mmm yyyy	<input type="checkbox"/> OR Already reported at visit <input type="text"/> . <input type="checkbox"/>	→ Go to item 2
	c. Was a condom used the first time you had sex?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	d. Was the sexual act your choice and with your agreement?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	e. Were you offered a reward/ money for sex?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	f. How old was the person you first had sex with?	<input type="text"/> <input type="text"/> Years	
	g. How long had you known the person before having sex?	<input type="text"/> <input type="text"/> Days <input type="checkbox"/> Months <input type="checkbox"/> Years	
2.	a. In the past 3 months, how many times have you had sex?	<input type="text"/> times	→ If 00, go to item 3
	b. How many times did you use a condom?	<input type="text"/> times	
	c. How many sexual partners have you had in the past 3 months?	<input type="text"/> <input type="text"/>	
	d. How many new sexual partners have you had in the past 3 months?	<input type="text"/> <input type="text"/>	

Completed by: (initials/date) _____

**PREVALENCE AND INCIDENCE OF SEXUALLY TRANSMITTED INFECTIONS AND CONTRACEPTIVE USE AMONG FEMALE
ADOLESCENTS IN CENTRAL KENYA - A PROSPECTIVE STUDY**

Participant ID: - - **Date:** / / **Visit code:**

dd *mmm* *yyy*

**Participant Follow-up Sexual History and
Behavior (FSX)**

CRF not administered

Participant Follow-up Sexual History and Behavior		Page 2									
3.	<p>a. In the past 3 months have you had anal sex? <input type="checkbox"/> Yes <input type="checkbox"/> No → Go to item 4</p> <p>b. How many times did you have anal sex? <input type="text"/> times</p> <p>c. How many times did you use a condom? <input type="text"/> times</p>										
4.	<p>a. In the past three months, have you used any method of contraception? <input type="checkbox"/> Yes <input type="checkbox"/> No → End of form</p> <p>b. Which method do/did you use? <i>Mark all that apply</i></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; text-align: center; padding-bottom: 5px;"><input type="checkbox"/> Oral</td> <td style="width: 33%; text-align: center; padding-bottom: 5px;"><input type="checkbox"/> Implant</td> <td style="width: 33%; text-align: center; padding-bottom: 5px;"><input type="checkbox"/> Safe days</td> </tr> <tr> <td style="text-align: center; padding-bottom: 5px;"><input type="checkbox"/> IUD</td> <td style="text-align: center; padding-bottom: 5px;"><input type="checkbox"/> Emergency pills</td> <td style="text-align: center; padding-bottom: 5px;"><input type="checkbox"/> Other,(specify) _____</td> </tr> <tr> <td style="text-align: center; padding-bottom: 5px;"><input type="checkbox"/> Injectable</td> <td style="text-align: center; padding-bottom: 5px;"><input type="checkbox"/> Condoms</td> <td></td> </tr> </table>	<input type="checkbox"/> Oral	<input type="checkbox"/> Implant	<input type="checkbox"/> Safe days	<input type="checkbox"/> IUD	<input type="checkbox"/> Emergency pills	<input type="checkbox"/> Other,(specify) _____	<input type="checkbox"/> Injectable	<input type="checkbox"/> Condoms		
<input type="checkbox"/> Oral	<input type="checkbox"/> Implant	<input type="checkbox"/> Safe days									
<input type="checkbox"/> IUD	<input type="checkbox"/> Emergency pills	<input type="checkbox"/> Other,(specify) _____									
<input type="checkbox"/> Injectable	<input type="checkbox"/> Condoms										
Completed by: (initials/date) _____											

Participant ID: - - Date: Visit code:

dd

mmm

yyyy

**Participant Follow-up Genital
Exam (FGE)**

CRF not administered

Participant Follow-up Genital Exam		Page 1
1.	a. Date of Last menstrual Period	<input type="text"/> <input type="text"/> <input type="text"/> <i>dd</i> <input type="text"/> <input type="text"/> <i>mmm</i> <input type="text"/> <input type="text"/> <i>yyyy</i>
	b. Was a genital exam done?	<input type="checkbox"/> Yes <input type="checkbox"/> No (if no complete item 1 c then skip to 4g)
	c. If a genital exam was not done, please provide a reason:	_____
2.	i. Were any of the following abnormalities noted on external genital examination?	
	a. Abnormal vaginal discharge	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not examined
	b. Genital warts	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not examined
	c. Other:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not examined
	Specify:	_____
	ii. Was a speculum exam done?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
	On speculum exam were any of the following abnormalities noted?	
	a. Cervical mucopus	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not examined
b. Other:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not examined	
Specify:	_____	
3.	Does the participant have genital lesions consistent with herpes?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not examined
		→ Complete SGHE Form and collect HSV culture swab
4.	a. Was a HSV-PCR swab collected?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
	b. Was a vaginal swab for BV gram staining collected?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
	c. Was a vaginal swab for BV storage collected?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
	d. Was a vaginal swab for GC, TV and Chlamydia collected?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
	e. Was a cervicovaginal lavage done?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
	f. Was a HSV culture swab collected?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
	g. Was a HIV/HSV ELISA sample collected?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Completed by (Initials/date) _____

Participant ID: - - Date: Visit code: .
 dd mmm yyyy

Participant Follow-up Genital Exam (FGE)

CRF not administered

Participant Follow-up Genital Exam		Page 2
Etiologic Diagnosis		
5.	Laboratory tests done for etiological diagnosis of STDs?	<input type="checkbox"/> Not done (skip to 6)
	a. Gonorrhea: <input type="checkbox"/> not done <input type="checkbox"/> done → Result: <input type="checkbox"/> negative <input type="checkbox"/> positive	
	b. Chlamydia: <input type="checkbox"/> not done <input type="checkbox"/> done → Result: <input type="checkbox"/> negative <input type="checkbox"/> positive	
	c. Trichomonas: <input type="checkbox"/> not done <input type="checkbox"/> done → Result: <input type="checkbox"/> negative <input type="checkbox"/> positive	
	d. Bacterial Vaginosis: <input type="checkbox"/> not done <input type="checkbox"/> done → Result: <input type="checkbox"/> negative <input type="checkbox"/> positive	
6.	Since the last visit, has the participant sero-converted to HSV? <input type="checkbox"/> Yes <input type="checkbox"/> No → Go to item 8	
	6a. Date sero-conversion: <input type="text"/> <input type="text"/> <input type="text"/> dd <input type="text"/> mmm <input type="text"/> yyyy confirmed	OR already reported <input type="text"/> . <input type="text"/> at visit:
7.	Is participant eligible for HSV shedding sample collection at home? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A → Go to item 8	
	7a. Was participant trained on self-collection of genital swabs? <input type="checkbox"/> Yes <input type="checkbox"/> No	
	If "No" specify the reason then go to item 8 _____ _____	
	7b. Was participant provided with a 2 week self-collection home kit and given a return date for returning the swabs? <input type="checkbox"/> Yes <input type="checkbox"/> No → Complete PSIS Form	

Completed by (Initials/date): _____

PREVALENCE AND INCIDENCE OF SEXUALLY TRANSMITTED INFECTIONS AND CONTRACEPTIVE USE AMONG FEMALE ADOLESCENTS IN CENTRAL KENYA - A PROSPECTIVE STUDY

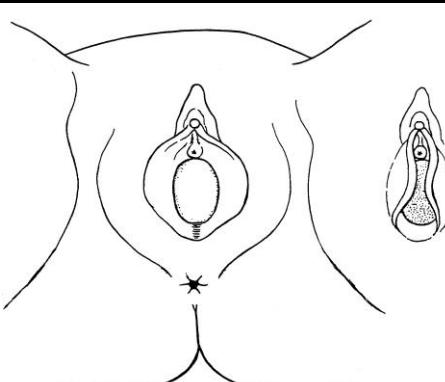
Participant ID: - - Date: Visit code: .
 dd mmm yyyy

Participant Follow-up Genital Exam (FGE)

CRF not administered

Participant Follow-up Genital Exam

Page 3

8.	8a. Is the participant eligible for vulvar biopsy collection? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A  End of form
	8b. Did participant provide independent , written informed consent for biopsy collection? <input type="checkbox"/> Yes <input type="checkbox"/> No  End of form
	8c. When was the informed consent marked or signed? <input type="text"/> <input type="text"/> <input type="text"/> dd mmm yyyy
9.	Was a vulva biopsy collected at this visit? <input type="checkbox"/> Yes <input type="checkbox"/> No  End of form If "Yes: mark the appropriate box Sample 1 (Pre- HSV acquisition) <input type="checkbox"/> Sample 2 (3 months post-HSV acquisition) <input type="checkbox"/> Sample 3 (12 months post-HSV acquisition) <input type="checkbox"/>
10.	Was a photo of the vulva taken before the biopsy ? <input type="checkbox"/> Yes <input type="checkbox"/> No
11.	 Mark on the diagram the site of biopsy
12.	Was a photograph taken after biopsy? <input type="checkbox"/> Yes <input type="checkbox"/> No

Completed by (Initials/date): _____

**PREVALENCE AND INCIDENCE OF SEXUALLY TRANSMITTED INFECTIONS AND CONTRACEPTIVE
USE AMONG FEMALE ADOLESCENTS IN CENTRAL KENYA - A PROSPECTIVE STUDY**

Missed Visit (MV)

PARTICIPANT ID

6	3			
---	---	--	--	--

Visit Month

--	--	--

Form Completion

--	--	--

 dd

--	--	--

 mmm

--	--	--

 yy

Missed Visit

Instructions: Complete this form when the window has closed for the visit.
For Visit Month, enter the visit code of the scheduled visit that was missed.

1

Reason visit missed:

- School commitments
- Work issues
- Parental refusal
- Travelling or out of area
- Illness or hospitalized
- Transport/fare issues
- Refused visit
- Relocated or moved
- Unknown/unable to contact
- Incarcerated
- Other, specify _____

2

Comments:

Version 1.0, 03-Mar-2016

English

Completed by: _____(initials/date)

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY				FROM 09-Mar-2016	THROUGH 20-October-2017	
PERSONNEL (Applicant organization only)		% EFFORT ON PROJ.	INST. BASE SALARY	AMOUNT IN DOLLAR REQUESTED PER MONTH		
NAME	ROLE ON PROJECT			SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Personnel 1	Biostatistician	19	\$2,500	\$2,100	\$120	\$2,220
Personnel 2	Data Manager	37	\$1,800	\$1,500	\$100	\$1,600
Personnel 3	Data Officer	23	\$1,000	\$850	\$83	\$933
Personnel 4	Data Entry	21	\$550	\$500	\$48	\$548
SUBTOTALS				\$ 4,950	\$ 351	\$ 5,301
EQUIPMENT						
i.	Desktop computers (2 pieces)					
ii.	All in one printer, copier and scanner					
iii.	Internet Backup (Fly box modem)		→			\$7,800
SUPPLIES						
i.	2 ring binder (480 pieces)					
ii.	A4 printing papers					
iii.	Office Point sticky note pads	→				\$7,100
iv.	Ring binder separator					
TRAVEL						
ALTERATIONS AND RENOVATIONS						
Service contract for all in one Printer						\$400
OTHER EXPENSES						
i.	External Hard disk					
ii.	Cloud storage(OneDrive)					
iii.	Ink toners and labels					\$1,600
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD						\$ 22,201

Budget Justification

The study will enroll 480 sexual active girls (by self-report).

1. Data management personnel cost:

1.1. Biostatistician

The statistician will decide on what data point are needed (to be collected) in order to answer the specific outline objectives as well as designing the trial. He/she will analyze, interpret and report conclusions from the analyses. The statistician will work full time 8 hours a day for the study period.

Salary Pay: \$2,220 per month, **Total: 2,220 x 18months = \$39,960**

1.2. Data Manager

The data manager will design data collection tools such as CRFs and data bases. He/she will be in charge of hiring the data officer and data entry clerk and ensure that all data management systems and audit procedures are effectively working to establish data quality standards. He/she will also provide technical consultation and assistance. The data manager will work full time 8 hours a day for the study period.

Salary Pay: \$1,600 per month, **Total: 1,600 x 18months = \$28,800**

1.3. Data Officer/Assistant

The data officer will be in charge of the overall quality control and quality assurance processes during data collection and transcription. He/she will work with the study PI and the data manager to formulate, implement, and enforce proper data collection policies and procedures as well day to day maintaining/troubleshooting of trial data bases and electronic equipment. The data officer will work full time 8 hours a day for the study period.

Salary Pay: \$933 per month, **Total: 933 x 18months = \$16,794**

1.4. Data Entry staff

Duties will be to oversee the day to day data entry of trial data into appropriate data bases. He/she will work with the data officer to implement error detection audits and regular data cleaning and generation of summary reports. He/she will be the point person to prepare participants' file binders by assembling correct forms for various visits. The data officer will work full time 8 hours a day for the study period.

Salary Pay: \$548 per month, **Total: 548 x 18months = \$9,864**

2. Equipment

Two desktop computers @ \$1600 per unit, \$800 x 2 = \$3,200 – To be used for data entry of clinical trial data into REDCap, preparing summary reports, conducting data analysis and also sending reports for printing into the printer. These pcs will also be used for e-mail communication.

All in one printer, scanner and copier @ \$4,500. For use in making copies of consent forms and CRFs, scanning of paper e-mail communications, printing of study records such as locator forms and schedule visit trackers. The printer will be key for all paper works during the entire study period.

Internet backup (fly box modem) @ \$100 To be used for internet connectivity (Wi-Fi hotspot) for e-mail communication, REDCap data management and entry processes for the web based data base as well for cloud upload of data backup/storage

3. Stationary

2 ring binders (480 pieces) to act as CRF binders for research paper records, A4 printing papers (500 reams) for printing CRFs, chart notes and consent forms, sticky notes (1000 pieces) for flagging errors detected on CRF binder and separators to separate records on a binder per visit type at a total cost of **\$7,100**

4. Other Expenses

Service contract for the printer for 24 months @ **\$400**

Data storage back-up costs (external hard drive for disaster prevention) and cloud storage cost (OneDrive for offsite back up purpose) at a cost of **\$ 100**, printer toners and laboratory specimen L\labels **\$1,500**

Total Cost

Budget Category	Cost in US\$
Personnel cost	\$95,418
Equipment cost	\$7,800
Stationary cost	\$7,100
Other category expenses	\$2,000
TOTAL BUDGET	<u>\$112,318</u>