1.0. STUDY TITLE

A LONGITUDINAL COHORT STUDY OF UP TO 12 MONTHS TO ASSESS THE EFFECT HIV-1 DNA VACCINE AMONG HIV INFECTED LACTATING MOTHERS AGE OF 23 – 45 YEARS IN KENYA.

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2.0. SYNOPSIS OF RESEARCH PROJECT

A longitudinal cohort study of up to 12 months to assess the effect Hiv-1 DNA vaccine among HIV infected lactating mothers' age of 23 – 45 years in Kenya.

Specific objectives

i. To describe the profiles of HIV infected lactating mothers in Kenya.
ii. To investigate the socio-economic status of HIV infected lactating mothers in Kenya.
iii. To determine the factors influencing exclusive breastfeeding for twelve months among HIV infected lactating mothers in Kenya.

Protocol synopsis:

Lactating women who are HIV infected in the age bracket of 23-45 years old will be eligible for this study. Subjects will have screening monitor probe in clinic when they are first contacted and monitored up to one week.

3.0. GOALS OF DATA MANAGEMENT PLAN:

Principles of Highest value:

3.1. Data accuracy & completeness

Data accuracy is crucial, especially since different subjects have slightly different characteristics. Complete data reporting, especially with regard to social, biological, emotional dietaries diaries, is crucial for interpretation of how easy and willingness of HIV infected mothers breast feed.

3.2. Speed of reporting

Speed of reporting is important, since observation and interpretation health behavior and social perception that these breast feeding mothers possess may be biased by follow-up HIV-1 DNA vaccine records of these mothers.

3.3. Data 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 angle during data management process.

3.4. Efficiency

Data Efficiency basically will rotate along many processes such as data storage, data access, data filtering, data sharing, data mining etc., and whether or not the processes lead to the desired outcome within resource constraints. Easier ways to promote these processes will be the main goal of this plan.

4.0. DATA MANAGEMENT PROCEDURES

4.1. SCREENING

This will be the first visit for the study; in this visit the main objective is to screen these subjects to help determine whether they are eligible for the study before enrollment. As soon as the HIV positive lactating mothers have been referred to the research clinic through the set referral system, the process of registering will be done at the reception. The study counselor will take a pre-assembled screening binder from data department and initiate the screening process. Consenting must be done before any study procedures have been performed. These breast feeding mothers will be given screening ICFs, demographics will be chronicled on the DEMDF Case Report Form. This will include DoB, age, gender, weight, HIV status, Blood Pressure.

Data collected from screening will be updated into the local access database and into RedCap.

4.2. ENROLMENT

At the enrolment visit, eligibility of the patient will be confirmed, this will be done using Eligibility scoring tool by the eligibility committee which comprises of Data staff, study counsellor, clinician and a Pharmacy technologist. An enrollment binder will be assembled by the data staff onsite which contains laboratory requisition forms, Enrollment CRF, enrollment consent forms are given to the study counsellor. Enrollment consent form will be administered before any other enrollment procedures are executed.

At that point subjects agree whether to participate in the study procedures voluntary this will be after satisfying all the eligibility procedures.
Data personnel will assign these subjects unique PTIDs. After procedures they will be given ART and HIV-1 DNA vaccine.
Data collected from screening will be updated into the local access database and into RedCap where Participant ID will be the unique identifier.

4.3. INTERIM VISIT

After every enrollment visit, patients can willingly anytime come on the research site for interim visit. During this visit no blood draws will be collected. This visit happens only when; they came for blood draws if not done in the scheduled follow up visit, pre-planned adherence counselling on drugs, health issues by participants', or to collect the drugs when confirmed they are over. In this visit only the local Microsoft access database will be updated by data staff/designee.

4.4. FOLLOW UP

There will be a maximum of 4 follow up visits in this study this after every 2 Months. The follow-up Follow up CRF will be filled. ART and HIV-1 DNA vaccine dispensed to the participants. Breast milk and bold plasma EDTA will be done, infant blood plasma sample collected

4.5. STUDY EXIT

An exit to the study, at this visit participants will be terminated from the study
Breast milk and bold plasma EDTA will be done, infant blood plasma sample collected. During this visit participants dissemination done.

4.6. ARCHIVE

Study documents will be archive for 25 years after completion of the study. This will be done in accordance to IRB guidelines. Before records have been archived, data completeness must be confirmed through data cleaning. A database lock must have occurred.

5.0. COMPLETENESS

The main aim of this crucial part is to minimize the degree that missing data can occur and to address the missing data already made.

5.1. Likely causes of Missing data

Lost CRFs/ not administered CRFs: Forms may get lost or not administered during the time of study procedures or during data entry to the local Microsoft access database and or RedCap.

Missed Visits: This cause of missing data may occur due to missed appointments. Subjects may miss their study visit and if will not be contacted or have a lost contact and fall outside the follow-up study window there will be a cause of missing data.

Communication with outside laboratories: Suppose that the samples collected are sent to the outside laboratories and they are delayed leading to pending results and Incomplete results.

Breakdown in Technology: Breakdown or lack of clinic and Lab Instrument like weighing machine, thermometers, and microscopes etc

5.2. Data completeness optimization

For likely missed visits, data team will generate report on late for follow up on a daily basis from the local Microsoft access database like with excel export work sheet tool. This follow-up report will be sent to the retention staffs via e-mail. A phone call will be made a day after missing the target date, and there after a home visit will be planned. Participants whose visit window closes before visiting the clinic for that follow-up procedures, will have a missed visit CRF completed and an update made into local Microsoft access database RedCap.

For study clinic, laboratories, data department technological tools like, UPS, Internet, computers, thermometers, power supply etc, there will be a back-up onsite. This is to serve as a back-up when there is breakdown etc.

Communication with outside laboratories. After sample has been sent to outside Lab. They will be given 7 days to send the results back for RedCap update. Pending results will be discovered by use of daily reports generated from the local database by the data staff and the emailed to the laboratory manager a day prior to the day the pending results are to be sent back to the study local laboratory.

To optimize the level of missing data reduction. All the study staff will be taken through training on regular basis to make them aware of necessary things to do when feeling the chart notes and CRFs. After training refresher trainings will be done after every 2 weeks. Training will be organized by the training coordinator who will designate training on CRFs to be conducted by the data staff/designee**.**

Timely data entry. This allows earlier detection of problems with missing data. During data entry data staff will implement a verification process requiring fields to be checked for accuracy and all discrepancies resolved before data entry

6.0. ACCURACY/CORRECTNESS

Reports will be generated from RedCap queries to show the degree of estimated errors that have been realized.

Height, weight, temperature, blood pressure are baselines characteristics that may contribute largely to high level of errors due to investigator error, bias etc.

Validation rules is created in RedCap by use of data dictionary and an online designer to fix the possible ranges expected. This will help in error checking and detection.

Double entry will detected since all data entry clerks will be needed to type their signature or initial after entering, reviewing data in study logs, and RedCap.

QC/QA procedures will be people-based reviewed and will involve all the study staff responsible in filling the source documents CRFs, they will be instructed to do so by the data officer checking for accuracy, correctness and completeness of the source document.

7.0. DATA VERIFICATION: AUDIT PROCEDURES

There will must exist a study HIV-1 DNA IN BREAST FEEDING study log data captures the clinic flow of participants as they arrive to the study clinic, schedules, local report and summaries and all study procedures.

The data officer will review whether the entries whether the entries are the correct parameters required. If there exists an error, data officer will inform the respective person who filled the CRF to correct. At this step the RedCap comment on the respective participant records will be ‘Unverified’.

The second Quality Control data officer will review the entries in RedCap against the paper CRFs to check whether they are correct. The RedCap comments in this step will be “Incomplete”.

The third level of Quality Control/ Quality Assurance will be done by a third data review personnel who will check accuracy, completeness. If all the data in RedCap is consistent will the CRFs information, he/she will change the forms status to “complete”.

All the data will be corrected as per the Good Clinical Practice guidelines.

Monitoring of data management procedures will be monitored by site monitor and or Coordinating Center. Also, Principal Investigator will review the files at 10% randomly selected basis of participant CRFs.

8.0. SECURITY/CONFIDENTIALITY

All computers, local databases in the data room will be protected by passwords. This will ensure security and confidentiality of data.

RedCap data entry and data review personnel will have personal user account to RedCap all will have personalized passwords set for the study.

Electronic data, databases will have back-ups on one drive or and hard disks.

All participants will be assigned PTID which will only be contained in the CRFs binder and spring files containing documents with participant names that will be stored in the data cabinets in the data room under lock and key.

Link logs will be kept in the principal investigator's office under lock and key.

No other study staff except data personnel will be allowed to access data cabinets. Also, no file will leave data room filling the file movement log that is stored by the data personnel in the data review table.

9.0. DATA AVAILABILITY AND ACCESS

Data will be entered in RedCap, all data personnel including statisticians will have access to it. This data will be available in the paper CRFs and RedCap online CRFs. RedCap will be used for easy retrieval of data. Since RedCap have export and import tools, excel can be used to obtain data.

STATA 1.3, R and SAS statistical softwares will be used to analyze data. Data weekly reports will be generated every Friday from RedCap or as needed and sent to the Principal Investigator.

Local Microsoft access database onsite and will be used to generate late for follow-ups, study summaries and will be shared in the computers over the network in the data room.

Data will be archived in a lockable cabinets in the data archive room and will be available if needed to be reviewed by WHO, coordinating center.

10.0. STUDY COMMUNICATION AND COORDINATION FUNCTIONS

There will be a working webmail created for all the study staff. Communication between study data management department will be through this webmail designed for every data staff. There will be a general email for all the data staff created by the data manager which is datamanager@bftrial.com

There will be frequent departmental meeting lead by the data manager/designee to assess and review the data management policies and updating on various new data management

procedures.

Conference calls between the coordinating center, Principal investigator and team leaders will be done on the Friday of every month. While teleconference team calls will be done every month.

11.0. APPENDIX

TABLE OF CONTENTS

ACRONYMS

CRF	**Case Report Form**
ENRBF	**Enrolment Breast feeding form**
SELIGBF	**Screening eligibility Breast feeding form**
DEMBF	**Demographics breast feeding form**
QC/QA	**Quality Control/Quality Assurance**
WHO	**World Health Organization**
RedCap	**Research Electronic Data Capture**
HIV	**Human Immunodeficiency Virus**
DNA	**Deoxyribonucleic acid**
CD4	**Cluster of Differentiation 4**
DoB	**Date of Birth**
ART	**Antiretroviral therapy**
ISP	**Internet Service Provider**
IT	**Information Technology**
ICFs	**Informed Consent Forms**
CC	**Coordinating Center**
KEMRI	**Kenya Medical Research Institute**
SERU	**Scientific and Ethics Review Unit**
Ksh.	**Kenya Shilling**
EDTA	**Ethylene diaminetetraacetic acid**
LRFs	**Laboratory Requisition Forms**
PTID	**Participant Identifier**

LIST OF EVENTS

		Study Counsellor	Study Clinicians	Data Officer
Screening	Signing of Screening ICFs	X		
	Feeling of Participant Locator form by the counsellor	X		
	Filling of Screening medical chart notes by clinicians		X	
	HIV testing	X		
	Filling of Screening Counsellor chart notes by study counsellors.	X		
	Baseline characteristics		X	
	Filling of Screening DEMBF,SELIGBF CRFs	X	X	
	Blood Draws, Breast Milk sample, Blood Plasma EDTA.		X	
	Infant plasma sample collection		X	
	HIV testing		X	
	Filling LRF		X	
	Entering into RedCap Screening			

	Participant data			X
Enrolment	Eligibility Committee			
	Signing of Enrolment ICFs	X		
	Assigning of PTID			X
	Filling of the enrolment medical chart notes		X	
	Filling of enrolment counsellor Chart notes	X		
	Baseline activities		X	
	Blood Draws, CD4, VL		X	
	Filling of ENRBF CRFs	X	X	
	Entering data into RedCap & Local Microsoft access database			X
	Scheduling Participants for first follow up Visits			X
Follow-up	Filling of the follow-up medical chart notes		X	
	Filling of follow-up counsellor Chart notes	X		
	Baseline activities			

	Blood Draws, CD4, EDTA test plasma blood samples		X	
	Filling of FBF CRF	X	X	
	Entering data follow-up into RedCap & Local Microsoft access database		X	
	Scheduling Participants for the next follow up Visit and clinic flow			X
	Note: this is an observation study			X
InterimVisit	Filling of follow-up Counsellors chart notes	X		
	Filling of Medical chart notes		X	
	Updating Interim visit in Local Microsoft access database only			X
Study Exit	Updating participant locators form	X		
	End of study medical chart notes		X	
	End of study Counsellor chart notes	X		
	Blood draws CD4, VL		X	
	Filling FBF CRF	X	X	
	Dissemination of Participants		X	
	Updating RedCap participant data &			

	on Microsoft access databases and clinic flows			X

PRESECREENING QUESTIONAIRE

INSTRUCTIONS

1) Please tick or answer as required.
2) Do not indicate your name.
3) This questionnaire is for the study and all information provided will remain confidential

SECTION 1: MATERNAL PROFILE/DEMOGRAPHIC AND SOCIO-ECONOMIC STATUS

1. **Age** [ ]

2. **Marital status**
   a. Single [ ] c. Widowed [ ]
   b. Married [ ] d. Divorced [ ]

3. **Have ever been tested for HIV**
   a. Yes [ ] b. No [ ]

4. **If yes result was?**
   a. Negative [ ] b. Positive [ ]

5. **Level of education**
   a. Primary [ ] b. Secondary [ ] c. Tertiary [ ]

6. **Residence**……

7. **Occupation**
   a. Self-employment [ ] c. Unemployed [ ]
   b. Formal employment [ ] d. Casual laborer [ ]

8. **Any Multiple Births in the family**
   a. Yes [ ] b. No [ ]

9. **Date of birth of breastfeeding child**_____dd/mm/yyyy

10. **Sex of Child**
    a. Male [ ] b. Female [ ]

11. **Age of Child in months**……Months

SECTION 2: PERINATAL HISTORY

1. **Place of Delivery**

a. Home [ ] b. Health Facility [ ]

2. **Type of Delivery**

a. Normal [ ] b. Caesarean [ ]

SECTION 3: BREASTFEEDING PRACTICES

1. **Initiation of Breastfeeding**

a. Immediately after Delivery [ ]
b. After 30 minutes [ ]
c. More than 30 minutes [ ]

2. **Has your baby been given anything to eat other than breast milk since birth?**

a. Yes [ ] b. No [ ]

3. **If Yes, what liquid has she been given?**

a. Glucose water [ ]
b. Formula milk [ ]
c. Medicine [ ]
d. Plain boiled water [ ]

4. **Has the infant been fed anything else other than breast milk since breastfeeding was initiated?**

a. Yes [ ] b. No [ ]

5. **Are you still breastfeeding?**

a. Yes [ ]
b. No [ ]

6. **If Yes, how frequent do you breastfeed?**

a. On demand [ ] b. On schedule [ ]

7. **After how long to you stop breast feeding?.....Months**

SECTION 4: MATERNAL CHILD HEALTH

1. Has the child been unwell in the last one month?

a. Yes [ ] b. No [ ]

2. If Yes, what condition was the baby suffering from?

a. Diarrhea [ ]
b. Vomiting [ ]
c. Fever [ ]
d. Cough [ ]
e. Malaria [ ]
f. Others (specify) ……..

3. Did you seek medical care?

a. Yes [ ] b. No [ ]

4. Has the illness interfered with the baby's breastfeeding?

a. Yes [ ] b. No [ ]

5. Have you experienced any problems in breastfeeding?

a. Yes [ ] b. No [ ]

6. If Yes, what problem have you experienced?

a. Inadequate breast milk [ ]
b. Baby refusing to breastfeed [ ]
c. Painful breasts [ ]
d. Others (specify)

7. Have you been sick in the last one month?

a. Yes [ ] b. No [ ]

8. If Yes, what have you been suffering from? _____

9. Does your spouse support exclusive breastfeeding?

a. Yes [ ]

b. No [ ]

HIV-1 DNA VACCINE
BREASTFEEDING STUDY
Specimen Tracking (ST)

Maternal ID: ☐☐-12-☐☐ Form ☐ N/A Infant ID: ☐☐-12-☐☐

Site Study CHECK M/I Chk

Visit Day: ☐☐ ART Dose #: ☐☐

Time HIV-1 VACCINE DOT Taken (24hrs) ☐☐☐☐

Collection Type: ☐ TROUGH ☐ PEAK

Date Specimens Collected: ☐☐ DD ☐☐ MM ☐☐ YY

Date Specimens Received at Lab: ☐☐ DD ☐☐ MM ☐☐ YY

MATERNAL ST LABEL

1: MATERNAL SAMPLES:

Serial ID: ☐☐☐☐☐☐☐☐ Specimen Code: ☐☐ Aliquot ID#: ☐☐☐☐

Specimen Type: Plasma EDTA ☐ Time Collected (24hrs): ☐☐☐☐ Time Frozen (24hrs): ☐☐☐☐

Serial ID: ☐☐☐☐☐☐☐☐ Specimen Code: ☐☐ Whole BM Aliquot ID#: ☐☐☐☐

Specimen Type: Breast Milk ☐ Time Collected (24hrs): ☐☐☐☐ BM plasma Aliquot ID#: ☐☐☐☐

Time Frozen (24hrs): ☐☐☐☐

Infant sample collected today?

☐ **Yes** ☐ **No**

INFANT ST LABEL

2: INFANT PLASMA SAMPLE:

Serial ID: ☐☐☐☐☐☐☐☐ Specimen Code: ☐☐ Aliquot ID#: ☐☐☐☐

Time Collected (24hrs): ☐☐☐☐ Time Frozen (24hrs): ☐☐☐☐

3: Comments: _____

Completed by: _____ Clinic (initials/date) _____ Lab (initials/date)

COMMUNICATION FOLLOW-UP LOG

PTID	DATE	TIME	COMMUNICATION	ACTION TAKEN	INITIALS

LOCATOR INFORMATION

Date_____ (dd/mm/yyyy)

SUBJECT INFORMATION:

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

FRIENDS CONTACT INFORMATION

Full Name:	
Relationship to Subject:	
Town:	
Primary Telephone Number:	
Alternative Telephone Number:	
Email Address:	

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 house in writing and/or drawing a map

……

……

……

……

Does the subject 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

Referral source: _____

Name of referring Health worker: _____

COUNSELOR CHART NOTES

Maternal ID:							Infant ID:							Visit Date:		
		0	2						0	2						
Site		Study		Pair	M/I	Chck	Site		Study		Pair	M/I	Chck	dd	mm	yy

_____

_____

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_____

BREAST FEEDING COUNSELING_____

_____

PROCEDURES DONE:

_____

_____

_____

PLAN: _____

_____

_____

_____

_____

_____

_____

_____

COUNSELOR INITIAL: _____**DATE:** _____

HIV-1 DNA VACCINE IN BREAST FEEDING WOMEN IN KENYA

FOLLOW UP CASE REPORT FORM

Maternal ID: ☐☐ 1 2 ☐☐ HIV status ☐

Site *Study* *Check*

Infant ID: ☐☐ 1 2 ☐☐ HIV status ☐

Site *Study* *Check*

	Visit Date (dd/mm/yy) ☐☐ ☐☐ ☐☐ ***Visit Month*** ☐☐
1.	Since your Last visit, have you experienced any of the following symptoms? *Mark all that apply* ☐ *Diarrhea* ☐ *Nausea* ☐ *Reduced urine volume* ☐ *Bone pain* ☐ *Muscle pain* ☐ *Vomiting* ☐ *Abdominal pain* ☐ *Others (specify) ……* ☐ *None reported*
2.	Since your Last visit, has your study infant had any of the following symptoms? *Mark all that apply* ☐ *Diarrhea* ☐ *Vomiting* ☐ *Reduced urine volume* ☐ *Others (specify)……* ☐ *None reported*
3.	3a. Other than breast milk, did you give your child any other feeds in the past one day? ☐ Yes ☐ No (refers to the last 24 hours) ***If No go to item 3d*** 3b. If yes above, how much feeds other than breast milk did the child get in the past one day? ☐☐☐ mL *(use a demonstration bottle to help mother estimate the volume of feeds the child received)* 3c. If yes in 3a above, in your own estimate how much of the total daily child feeding was from breast milk only? *(use say 7 in 10 to assist the mother make this estimate and covert to %)* ☐☐ 3d. In the past one day (last 24 hours), how many times have you breastfed your child? ☐☐ 3e. On average, how many times do you breastfeed your child per day? ☐☐
	FOR CLINICIANS ONLY: ITEMS 4 TO 9.
4	4a. Observed participant take HIV-1 DNA Vaccine today? Yes ☐ No ☐ 4b. If Yes, time of HIV-1 DNA Vaccine medication (*24hrs*) ☐☐ ☐☐ 4c. HIV-1 DNA VACCINE Dose No. ☐☐
5	Was blood or breast milk sample for drug levels collected today? ☐ Yes ☐ No **If NO go to 9**
6.	6a. Maternal trough blood sample collected today? Yes ☐ No ☐ Collection time ☐☐ ☐ 6b. Maternal trough breast-milk sample collected today? Yes ☐ No ☐ Collection time ☐☐ *MINS*
7.	7a. Maternal peak blood sample collected today? Yes ☐ No ☐ Collection time ☐☐ 7b. Maternal peak breast-milk sample collected today? Yes ☐ No ☐ Collection time ☐☐ *MINS*
8.	8a. Infant peak blood sample collected today? Yes ☐ No ☐ Collection time ☐☐ *MINS*
9	comment.....

HIV-1 DNA VACCINE IN BREAST FEEDING WOMEN IN KENYA

FOLLOW UP CASE REPORT FORM

PTID: ☐☐-☐☐-☐☐ **DATE**: ☐☐ ☐☐ ☐☐ **Visit code**: ☐☐☐
SEX: _____ **WEIGHT**: _____ **BLOOD PRESSURE**: _____ **PULSE RATE**: _____
HEIGHT: _____ **TEMPERAGE**: _____**RESPIRATION** _____

_____

_____

_____

Any medication taken? ☐ Yes ☐ No

If yes, list medications, date started and stopped

_____

_____

HIV status_____

Comments_____

_____

PROCEDURES DONE:

_____

_____

_____

_____

_____

IMPRESSION: _____

_____

_____

PLAN: _____

TCA: _____

INITIAL: _____ DATE: _____

HIV-1 DNA VACCINE IN BREAST FEEDING WOMEN IN KENYA

ENROLLMENT CASE REPORT FORM

Maternal ID: ☐☐ 1 2 ☐☐ HIV status ☐

Site *Study* *Check*

Infant ID: ☐☐ 1 2 ☐☐ HIV status ☐

Site *Study* *Check*

	Visit Date (dd/mm/yy) ☐☐ ☐☐ ☐☐ ***Visit Month*** ☐☐
1.	Since your Screening visit, have you experienced any of the following symptoms? *Mark all that apply* ☐ *Diarrhea* ☐ *Nausea* ☐ *Reduced urine volume* ☐ *Bone pain* ☐ *Muscle pain* ☐ *Vomiting* ☐ *Abdominal pain* ☐ *Others (specify) ……* ☐ *None reported*
2.	Since your Screening visit, has your study infant had any of the following symptoms? *Mark all that apply* ☐ *Diarrhea* ☐ *Vomiting* ☐ *Reduced urine volume* ☐ *Others (specify)……* ☐ *None reported*
3.	3a. Other than breast milk, did you give your child any other feeds in the past one day? (refers to the last 24 hours) ☐ Yes ☐ No ***If No go to item 3d*** 3b. If yes above, how much feeds other than breast milk did the child get in the past one day? ☐☐☐ mL *(use a demonstration bottle to help mother estimate the volume of feeds the child received)* 3c. If yes in 3a above, in your own estimate how much of the total daily child feeding was from breast milk only? *(use say 7 in 10 to assist the mother make this estimate and covert to %)* ☐☐ 3d. In the past one day (last 24 hours), how many times have you breastfed your child? ☐☐ 3e. On average, how many times do you breastfeed your child per day? ☐☐
	FOR CLINICIANS ONLY: ITEMS 4 TO 9.
4	4a. Observed participant take HIV-1 DNA Vaccine today? Yes ☐ No ☐ 4b. If Yes, time of HIV-1 DNA Vaccine medication (*24hrs*) ☐☐ ☐☐ 4c. HIV-1 DNA VACCINE Dose No. ☐☐
5	Was blood or breast milk sample for drug levels collected today? ☐ Yes ☐ No **If NO go to 9**
6.	6a. Maternal trough blood sample collected today? Yes ☐ No ☐ Collection time ☐☐ ☐ 6b. Maternal trough breast-milk sample collected today? Yes ☐ No ☐ Collection time ☐☐ *24HRs*
7.	7a. Maternal peak blood sample collected today? Yes ☐ No ☐ Collection time ☐☐ 7b. Maternal peak breast-milk sample collected today? Yes ☐ No ☐ Collection time ☐☐ *24HRs*
8.	8a. Infant peak blood sample collected today? Yes ☐ No ☐ Collection time ☐☐ *MINS*
9	comment.....

Version 1.0, 01-03-2016 **English** **Completed by: _____** (initials/date)

HIV-1 DNA VACCINE Breast Feeding Study

ORIGINAL	LAB
COPY 1	LAB
COPY 2	CLINIC

Laboratory Requisition Form

visit code | | |

Version 1.0

PARTICIPANT DEMOGRAPHICS

ID LABEL HERE:

MATERNAL ID: | | | | | | |

INFANT ID: | | | | | | |

SAMPLING DATE:

DAY		MONTH			YEAR	

TIME:

24 HOUR CLOCK			

SPECIMEN COLLECTED BY:_____

SAMPLING SECTION				**CLINIC USE ONLY**	**LAB USE ONLY**
TYPE OF TUBE	**TEST**	**COMMENT**			
MOTHER SECTION					
6.0 mL EDTA	**Archive sample (Trough)**	**Time(24HRS)**			
6.0 mL EDTA	**Archive sample (Peak)**	**Time(24HRS)**			
Conical tube (15mL)	**Breast milk (Trough)**	**Time(24HRS)**			
Conical tube (15mL)	**Breast milk (Peak)**	**Time(24HRS)**			
INFANT SECTION					
2.0 ml EDTA	**Archive sample**				

TRANSPORTED TO MOMBASA LAB BY:

DAY		MONTH			YEAR		24 HOUR CLOCK				INITIALS

RECEIVED AT MOMBASA LAB BY:

DAY		MONTH			YEAR		24 HOUR CLOCK				INITIALS

DETAILED BUDGET

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY					FROM 6th Sept 2016	THROUGH 5th Dec 2017
PERSONNEL (Applicant organization only)	Role on Project	% EFFORT ON PROJECT	INST. BASE SALARY For 12 Months	KENYAN SHILLING AMOUNT REQUESTED (omit cents)		
TITLE				SALARY REQUESTED For 12 Months	FRINGE BENEFITS For 12 Months	TOTAL For 12 Months
Principal Investigator	Study Coordination	Full time 100				
Data Manager	Data Lead Management	Full time 100	1 440 000	1 221 000	114 000	1 335 000
Data Entry Officer	Data Entry	Full time 100	720 000	660 000	90 000	750 000
Statistician	Data Analysis & reporting	1Full time 100	1 200 000	1 080 000	99 000	1 179 000
Computer & IT assistant	IT support, Programming	Full time 100	1 080 000	900 000	93 000	993 000
Data Officer	Data management	Full time 100	1 200 000	1 044 000	99 000	1 143 000
SUB TOTALS →						Ksh. 5 400 000
CONSULTANT COSTS Data Consultant						 150 000
EQUIPMENT (itemize) Desktop Computers (6) Lockable Cabinets (4) Integrated Network Printer 2 Fax & Photocopier 1 Routers Network Server Brady Label Printer & Back-up Hard Phones 2 Power Generator						 210 000 200 000 900 000 200 000 50 000 100 000 200 000 9 000 350 000
SUPPLIES (itemize by category) CRFs Binders 140 Spring files 140 A4 Printing Papers Pens and Diaries Network Cables Other Stationaries ISP Softwares Anti Virus						 84 000 5 600 20 000 25 000 25 000 200 000 600 000 250 000 70 000
TRAVEL						

All travels		700 000
PATIENT CARE COSTS	INPATIENT Study druds	1 000 000
	OUTPATIENT Re-imbursement & study drugs	 2 000 000
ALTERATIONS AND RENOVATIONS (itemize by category) Service Contracts for Printers, Servers, Photocopier Lockable Cabinets repairs Computer repairs & Maintenance		 2 000 000 150 000 450 000
OTHER EXPENSES (itemize by category) Internet Back-up 9 port UPS		 600 000 67 000
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		Ksh. 10 435 600
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD →		Ksh. 15 835 600

BUDGET JUSTIFICATION

DATA MANAGEMENT WORKFORCE COSTS

Data Manager 12x111 250= Ksh. 1 335 000

Coordination of all the data management activities, some of his/her responsibilities will be;

- Implement policies and guidelines for data management and hiring, training junior data personnel on refreshers and new standards of operation
- Develop standard operating procedures for data handling and archiving, implementing error detection audits.
- Maintaining data management plans and providing a technical oversight for integrating new technology for new initiatives into data standards and structures.

Data Officer: 12x87 000= Ksh. 1 044 000

- He/she will be helping data manager in maintaining internal data asset library, ensure the integrity, confidentiality and security of all datasets.
- Review source documentation, presentations, tables and graphs to ensure accuracy and quality.

Statistician: 12x 98 250= Ksh. 1 179 000

- He/she will be organizing, analysing, interpreting and reporting of statistical data in order to identify significant differences in relationships among different participants/study data.
- Develop and initiate innovative statistical techniques, protocol etc.
- Communicate and advice on necessary update/ initiative with the CC and the PI that will help in gaining accurate study data results after analysis
- Will be contacted for help with trial design and data analysis before publications.

Data entry Clerk: 12x62 500= Ksh.750 000

- He/she will be responsible for entering data from source documents into the local database and RedCap
- He/she will be needed to help in reviewing the databases entry to promote accuracy and completeness of CRFs.

Computer & IT assistant: 12x82 750= Ksh. 993 000

- Database maintenance and computer repair & maintenance, equipment and software debugging and this individual will also be in charge of regular updates of this equipment on the study data room.
- Configuring internet and contacting the respective companies that sold the specific equipment to service and review the service contracts.

Consultation costs: Ksh. 150 000

- Consultations on policies and regulations that will help data management process efficient, safe, and effective.

- Consultations with KEMRI, CC, SERU, MOH, IRB, County government to obtain permit of work.
- There will be consultations made on how data will be archived and on which supplies and equipment to be bought.

EQUIPMENT

6 Desktop Computers: 6x35 000= Ksh. 210 000

- This computers are needed to be used by the data personnel for data entry, data review on RedCap, Data Back-upm Facilitate communication via webmail.
- Computers will be used for data analysis, organization and reporting and scientific simulations.
- Computers will be needed for instrumentation control

4 Lockable Cabinets: 4x50 000= Ksh. 200 000

- This will be used to securely store participant binders separately with the consents & name charts. This will ensure safety and confidentiality.

2 Integrated Network Printer: 2x450 000= Ksh 900 000

- This printer will be used for printing paper CRFs, consents, for printing e-mails for references, referral notes etc.
- They will be used as Photocopiers for photocopying required papers

Fax & Photocopier 1: Ksh 200 000

- This will be used for faxing necessary documents to e-mails, CC etc.
- It will have also capabilities of photocopier.

Routers Ksh 50 000

- This routers will function to as a booster for the server to support internet connectivity within the study site and especially in the data room.

Network Server: Ksh. 100 000

- Network server will be used to provide and support internet connections within the study site. This will enhance communication and easy coordination.

Brady Label Printer: Ksh. 200 000

- This will be used in printing Laboratory labels. It will be integrated with one of the computers in the data room.

Hard Phones 2: 2x4 500=Ksh.9 000

- This phones will be used in communication will the PI and during teleconferencing with the CC

Power Generator: Ksh. 350 000

- This will serve as power back-up when there is power off.

SUPPLIES

CRFs Binders 140: 140x600= Ksh. 84 000

- Will be needed to hold the paper CRFs for 140 participants who will be enrolled in the study

Spring files 140: 140x40= Ksh. 5 600

- Will be needed to hold name charts, ICFs for 140 participant who will be enrolled to the study

A4 Printing Papers: Ksh. 10 000

- A4 printing papers will be bought for daily printing of CRFs, ICFs, e-mail reference papers, referral notes, note to files, etc.

Pens and Diaries: Ksh. 5 000

- Pens & diaries will be bought. Pens will be used for data verification, data audit, Quality Control etc Diaries will help data personnel to organize their daily activities.

Network Cables: Ksh. 25 000

- Will be used to supply internet between all computers onsite.

Other Stationaries: Ksh. 200 000

- Such as sticky notes, Fountain Pens, paper clips, staple pins, staple pin remover etc. to help in daily data management procedures and sticky notes for processing of flagging errors in the paper CRFs, ICFs

ISP: Ksh. 600 000

- This amount will be used to pay for the chosen Internet Service Provider which will be majorly Orange & Safaricom Internet Providers for the Internet bandwidth supplied to the study site.

Softwares: Ksh.250 000

- Softwares will be bought regularly especially when a new version is released by the production companies. Eg the label printing softwares, OS, STATA, SAS, Printers drivers etc

Anti-Virus: Ksh. 70 000

- This anti-virus must be bought and installed in every data department computers because it will be used for protecting computers from any kind virus that may destroy data.

TRAVEL

All travels: Ksh. 700 000

- This will cater for team building travelling, site monitors travelling, outside site trainings, travels for consultations. Procurement travelling

PATIENT CARE COSTS

Study drugs: 1 000 000

- Study drugs will be bought e.g ART. For inpatients

Re-imbursement Study drugs: Ksh. 2 000 000

- There will be re-imbursement of 600 per participant per visit and study drugs e.g ART for outpatients

ALTERATIONS AND RENOVATIONS

Service Contracts for Printers, Servers, and Photocopier: Ksh. 2 000 000

- There will be service control semi-annually that is, after 6 months of service, this amount will be used to renew service contracts and for servicing.

Lockable Cabinets repairs: Ksh. 150 000

- Brocken or loose lockable cabinets will be repaired immediately, this money will be kept emergent to help facilitate storage and archiving of the source documents and manuscripts.

Computer repairs & Maintenance: Ksh. 450 000

- Brocken keyboards, spoilt mouse, corrupted hard disks, spoilt monitors etc. will be repaired and where necessary unrepaired parts will be bought and replaced.

OTHER EXPENSES

Internet Back-up: Ksh. 600 000

- Internet Modem must be bought and locate it in the data room that will serve as back up for data management process.

9-port UPS: Ksh. 67 000

Will be bought to help support computers and internet as power back-up. Will enhance smooth operation when there is temporary power offs.