KENYA MEDICAL RESEARCH INSTITUTE SCIENTIFIC & ETHICS REVIEW UNIT (SERU)

Title of Proposal: Single-dose HPV catch-up vaccination efficacy: A blinded, randomized study of single-dose HPV vaccination among adolescent girls and young women in Kenya

Short Title: KENya Single-dose HPV Vaccine-Efficacy (KEN SHE) Study

Principal Investigator(s):

Prof. Elizabeth Bukusi	Principal Investigator
Dr. Maricianah Onono	Co-principal Investigator
Dr. Ruanne Barnabas	Principal Investigator / Protocol Chair
Dr. Nelly R. Mugo	Co-Principal investigator / Protocol Chair
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Dr. Jared Baeten	Co-investigator
Rachel Winer	Co-investigator
Deborah Donnell	Co-investigator
Elizabeth Brown	Co-investigator
Connie Celum	Co-investigator
Denise Galloway	Co-investigator

Centre: Centre for Microbiology Research

SERU/NON-SERU/SSC/NON-SSC No.: 3741 (Kisumu Sites and 3745 (Thika and Nairobi Sites)
(Tick the appropriate identifier)

1) **Date of scientific and ethics (SERU/SSC/NON-SSC) approval:**
   1. **Kisumu Sites** September 26, 2018 latest Renewal dated August 28, 2020
   2. **Thika and Nairobi Sites** October 18, 2018 latest approval dated September 28, 2020
2. **Date the study stopped collecting data where applicable:** Data collection is ongoing
   - ✓ Date for the last participant was recruited (and enrolment) November 5, 2019
   - ✓ Date the last follow up was made. Follow up of participants is ongoing
3. **The copy the last continuing review approval or initial approval if this is the first request for renewal:** Kindly find a copy of the last continuing review approval letter dated dated August 28, 2020 for Kisumu site and September 28, 2020 for Thika and Nairobi Sites

4. **Project period covered:** January 9, 2020 – January 9, 2021

5. **Research objectives:**

Primary Objectives:

1. To test the efficacy of immediate single-dose bivalent or nonavalent HPV vaccination to prevent incident persistent HPV 16/18 infection compared to delayed nonavalent HPV vaccination for young women age 15-20 years.
2. To test the efficacy of immediate single-dose nonavalent HPV vaccination to prevent incident persistent HPV 16/18/31/33/45/52/58 infection compared to delayed nonavalent HPV vaccination for young women age 15-20 years.
3. To determine whether vaccine-type HPV antibody responses after single-dose bivalent or nonavalent vaccination are noninferior in 9-14-year-old girls versus 15-20-year-old young women.

Secondary objectives

1. To assess cost, cost-effectiveness, and budget impact of single-dose HPV vaccination to support implementation strategies for single-dose HPV vaccination following WHO recommendation in high cervical cancer burden settings.
2. To evaluate B-cell markers as a proxy for immune memory following single-dose bivalent and nonavalent vaccination.

6. **Research progress summary:**

	Kisumu	**Thika**	**Nairobi**
Total number Screened	1502	1132	474
Enrolled	1200	778	297
Screen-out	241	354	177
Withdrawn	0	0	0
Lost to follow up	2	29	10
Death	1	0	0

7. **Amendments:** No amendments were made during this reporting period.
8. **Adverse events –** Kindly find attached a summary of the adverse events

9. **Projects outputs:** There were no project outputs including publications abstracts, products or patent applications that were made during this period.
10. **Constraints:** None
11. **Plans for the next project year:** Project activities planned for the coming year include: retention, follow up, data collection, sample collection and concept and abstracts writing