PROJECT SUMMARY

Background: Cervical cancer is the most frequent malignancy in women in developing countries including Ethiopia. In Eastern Africa, about 35.8% of women in the general population are estimated to harbor cervical HPV infection at a given time. Ethiopia has a population of 27.19 million women 15 years and older who are at risk of developing cervical cancer. Current estimates indicate that every year 7095 women are diagnosed with cervical cancer and 4732 die from the disease. In spite of this, the cervical cancer screening coverage in Ethiopia is still very low (0.6% of all women aged of 21 and older). Examination of cervical cancer mainly depends on conventional Pap smear and Ethiopia has very few pathologists who serve a population of about 95 million which further aggravates the situation. HPV detection and typing is also affected by the anatomic site the sample is collected from as well as the method of specimen collection (clinic-based/self collected) vs clinic-based (physician collection). HPV genotyping is an important step in HPV management, assisting to identify patients with a higher risk of developing cervical cancer and also contributing to the epidemiological data as well as development of type-specific vaccines. It is known that specific intratype HPV genome variations may be related to virus infectivity, pathogenicity, progression to cervical cancer, viral particle assembly and host immune response.

Objective: To evaluate the clinical performance of VIA, VILI, copoloscopy, HPV DNA tests; cervical cancer specimen collection techniques; and to investigate urine based molecular epidemiology of HPV and explore the genetic variability of HPV in Adama town, Ethiopia.

Methodology: A cross-sectional probability sampling technique will be used. St.Aklesia Memorial Hospital (SAMH), Adama, Oromiya, Ethiopia. will serve as the study site. The study will recruit 390 participants whose age older than 21, presenting to the hospital for routine examination without documented history of cervical cancer (hysterectomy). The whole procedures are not involving any invasive steps rather simple and easy collection techniques. VIA, VILI and copoloscopy examination will be performed and cervical cancer sample and urine using ThinPre PreservCyt solution will be collected by trained nurse and gynecologist. All important clinical and demographic data will be collected using structured questionnaires. Laboratory method will include HPV DNA extraction, amplification and genotyping; and sequencing analysis. Statistical analysis will be performed using SPSS and genetic variability analysis will be done using MEGA software. The sensitivity, specificity, positive and negative predictive value of self and doctor result analysis will be done. Ethical clearance will be sought from Addis Ababa University, St. Aklesia Memorial Hospital, WAKA HPV Project and IPRH.

Estimated cost of budget: \$39, 360.83; Completion of project: within 4 years.