RAMP Project Abstract:

Project Title: Characterizing undiagnosed and incident STIs in an HIV vaccine trial cohort in South Africa (HVTN 702).

Project Type: Short-term project 8-10 weeks

Proposed Project Dates: Flexible 8-10 weeks on-site between (June 2022-Sept 2022)

Project Site: Seattle Vaccine Trials Unit (Fred Hutch)

Project Overview:

At the Seattle Vaccine Trials Unit, we conduct clinical trials, immunologic, and epidemiologic research to understand the mechanisms of vaccines to prevent HIV and other infections, and to research the immunology of HIV and other viral infections in order to design better vaccine candidates. We are working towards a goal of preventing HIV with a vaccine. We recognize that HIV affects individuals and entire communities, so work closely with our community partners to provide education about HIV, COVID-19, and participation in research, as well as access to clinical trials and inclusive research. As part of the research unit, you will have the opportunity to work with clinical investigators, epidemiologists, immunologists, community engagement specialists, and more. For this project, you will be working with an interdisciplinary team on two continents to understand two components of HIV vaccine research: 1) the contribution of undiagnosed sexually transmitted infections to a population of vaccine trial participants in South Africa (epidemiology/data analysis project); and 2) gain experience in the outreach, recruitment, and screening of participants into multiple HIV vaccine clinical trials in the Seattle area, and understand participants’ barriers and facilitators to participating in research.

For this project, you will spend 8-10 weeks on site at the Seattle Vaccine Trials Unit, learning and participating in the recruitment and screening of participants for participation in HIV vaccine trials, learning about the conduct of vaccine clinical trials, and conducting a mentored independent research project through analysis of data from a recently completed Phase 2/3 HIV vaccine trial in South Africa in collaboration with South African investigators.

As part of this project, you will also have the opportunity to participate in the University of Washington Principles of HIV/STI Research and Public Health Practice course, a 2-week intensive training program that will provide additional exposure to topic content and research methods to support your research project.

Ideally, the candidate will work onsite in Seattle. If circumstances due to COVID-19 preclude this from happening, the data analysis and HIV/STI training components of the project can be done remotely with secured access to data and the HIV/STI course attended remotely. You will work with our clinical investigators, epidemiologists, and consultant biostatisticians in Seattle and South Africa to understand the dynamics of non-HIV STIs in a vaccine trial cohort.

Project Summary:

This project aims to understand the prevalence, incidence, and predictors of non-HIV STIs in healthy South African adults (women and heterosexual men) participating in an HIV vaccine clinical trial. Undiagnosed STIs are a significant cause of morbidity, increased HIV risk, and infertility throughout the world. People at risk for HIV who participate in HIV vaccine trials are also at risk for STIs. In many parts of the world, access to high-quality diagnosis and treatment for STIs is limited. In the recently completed
HVTN 702 vaccine trial, study participants were routinely screened with high-quality diagnostics at study entry and periodically during the study for non-HIV STIs including syphilis, gonorrhea, chlamydia, and trichomonas. The aims of this project are to conduct a secondary analysis of the vaccine trial data to characterize:

1. The prevalence of non-HIV STIs in a cohort of sexually active South African adults (women and heterosexual men)
2. The incidence of non-HIV STIs in a cohort of sexually active South African adults (women and heterosexual men), *conditional on availability of data
3. Epidemiologic predictors of non-HIV STIs in women and heterosexual men.

With the goal of providing evidence to inform screening practices, frequency, and public health guidance for this population.

The project will be best suited for a scholar with some experience with data analysis, but support will be provided to conduct the research.

**Regulatory requirements for the project and plans for completing them:**
This is a secondary analysis of data from a completed HVTN protocol, which has already been approved by the IRB. The RAMP Scholar will need to be added to the parent IRB to conduct this analysis, so will need to complete online CITI/Human Subjects Protections training and required IRB training as required by the HVTN.

**Expected Deliverables:**
Abstract/Presentation to HVTN  
Manuscript for publication

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