RAMP Project Abstract: HARARE, ZIMBABWE

Proposed Project Title: An investigation on the implications of VISP post HIV Vaccine Efficacy Trial participation in Zimbabwe.

Project Type: Short-term Project 8-10 weeks On-site

Proposed Project Dates: Flexible 8 -10 weeks On-site between (June 2023 – August 2023)

Project Site: Seke South, Chitungwiza, Zimbabwe

Project Overview:

Seke South CRS is an HVTN affiliated clinical research site with the primary purpose of conducting clinical trials in the quest to find safe and effective HIV prevention strategies involving HIV vaccines, monoclonal antibodies, long acting injectables and PrEP. The Clinical Trials Unit has over two decades' experience in conducting phase I-III trials in the advancement of HIV prevention. As part of the RAMP scholar's research team, they will have the opportunity to work with clinical investigators, epidemiologists, social scientists and researchers from other disciplines. For this project, the scholar will learn qualitative data collection methods and Vaccine Induced Sero-Positivity (VISP) implications amongst investigation vaccine recipients of the HVTN 705 trial. Through this project, the scholar will acquire skills to consent and facilitate qualitative interviews with the help of the site Social Behavioral Scientist. They will also get an opportunity to interact with health care providers in our communities and gain insight on how the health care systems in Zimbabwe work. Ideally the RAMP scholar will work onsite for 8-10 weeks. If the scholar cannot travel to the site due to COVID-19 restrictions, the project can be done remotely with secured access to participants records. After data collection is complete, the scholar with the help of the mentor will make a data analysis plan and analyze the data. The scholar will be provided guidance on manuscript writing by the mentor. The scholar will also be expected to prepare an oral or poster presentation for the HVTN 2023 annual meeting.

The purpose of this study is to outline the experiences of research participants who were in the active arm of the HVTN 705 trial in accessing health care services outside of the clinical research site during and after study participation. The study also seeks to understand the social impact that VISP has on the vaccine recipients. Findings from this study will be in the future to anticipate and prepare for any VISP related challenges which come with conducting HIV vaccine efficacy trials in a similar setting.

Project Summary:
Vaccine Induced Seropositivity (VISP) is the detection of vaccine induced antibodies to HIV whose production is triggered after receiving an experimental HIV vaccine[1]. In Zimbabwe, a few HIV vaccine trials have been conducted but the HVTN 705 trial was the first and largest HIV vaccine trial in the country. As such, the concept of HIV related VISP is still new and possibly not well appreciated by both the community and health service providers. This study seeks to understand and outline the implications of VISP post participation in an HIV vaccine trial through these objectives.

1. To understand social impact on HIV vaccine recipients because of VISP.
2. To determine effects of potentially having or having VISP on access to health services.
3. To understand health service providers handling of participants who potentially have or have VISP.

Regulatory requirements for the project and plans for completing them:

The proposal will be submitted to the Medical Research Council of Zimbabwe (MRCZ) and the Joint Research Ethics Committee for University of Zimbabwe Faculty of Medicine and Parirenyatwa Group Hospitals (JREC) in February 2023. We expect response from our IRBs within 2 months, thus approval will be obtained before the project starts in May 2023. The scholar will be required to complete GCP and HSP training, online courses are available. We will assist the scholar in completing the required trainings.

Expected Deliverables:

8-10 weeks onsite completing trainings and developing and conducting the qualitative study [this can be done virtually with the help of the site Behavioural Scientists, ensuring participants' confidentiality]. 6 months off site analysing data and preparing the poster or oral presentation at the HVTN full group meeting in May 2023 in Washington DC. Preparing a manuscript for submission for publication.

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