RAMP Project Abstract: NEW YORK, US

Project Title: Evaluating the impact of expanded low risk behavior guidelines with PrEP use on recruitment of participants into HVTN Phase 1 studies

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

Proposed Project Dates: Flexible 8-10 weeks On-site between May 2022 – September 2022

Project Site: New York Blood Center, New York

Project Overview:
The goal of Project ACHIEVE/New York Blood Center Clinical Research Site based in New York City is to work on novel ways to prevent HIV and other infectious diseases, including the SARS-CoV-2 virus that causes COVID-19. As part of the research site, you will have the opportunity to work with a diverse team of clinical investigators, epidemiologists, social scientists, community engagement and recruitment staff, and more and be immersed in innovative clinical, socio-behavioral, and epidemiologic research.

As a RAMP scholar you will have the opportunity to work with Hong Van Tieu, MD, MS, Lab Head and Associate Member of the Laboratory of Infectious Disease Prevention/Project ACHIEVE at the New York Blood Center (NYBC), Jorge Soler, PhD, and the Project Achieve research team consisting of co-investigators, clinicians, counselors, recruiters, and community educators who are experienced in recruitment, community engagement, study implementation and conduct, and retention in research studies among general and at-risk populations.

While participating in this 8 to 10-week program, you will work with the team to conduct a two-phase research project, (1) to characterize the impact of the expanded low risk eligibility criteria on recruitment of participants into HVTN Phase 1 studies at the research site in New York City, and (2) to conduct an online survey-based study to examine the impact of the expanded low risk eligibility at U.S. sites (to include individuals who are taking pre-exposure prophylaxis (PrEP) and who may not meet the sexual behavior criteria in the original low risk behavior guidelines) on HVTN Phase 1 vaccine trial participation. You will be integrally involved in all aspects of the study including developing the surveys and recruitment materials, programming the surveys, recruiting, analyzing the data, and preparing the manuscript. You will also be required to complete online human subject trainings before joining the study team.

Project Summary:
The HVTN Phase 1 HIV vaccine studies aim to test the safety and tolerability of vaccine candidates in individuals aged 18-50 years who are generally healthy and considered at low risk for HIV infection. Previously, low risk behavior guidelines have aided site staff in determining eligibility based on various factors including number of sex partners in a given timeframe, condom use with anal and/or vaginal sex, substance use, and recent sexually transmitted infections. Pre-exposure prophylaxis (PrEP), such as tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC) (daily oral dose or intermittent, event-based or 2-1-1) and Descovy™ (TAF/FTC daily oral dose), is highly efficacious in preventing HIV and is approved by the U.S. FDA.

Based on recommendations from the HVTN PrEP Working Group, new HVTN Phase 1 studies, such as HVTN 137 and 302, have begun to incorporate the expanded low risk eligibility criteria at U.S sites to include individuals who are taking PrEP and who may not meet the sexual behavior criteria in the original low risk behavior guidelines. Specifically, individuals who report equal to or greater than six consecutive months of protective PrEP use, commit to maintaining protective PrEP use throughout trial, and report
equal to or greater than 70% when asked the following: “Thinking about the past 4 weeks, what percent of the time were you able to take all your PrEP medications?” are now considered low risk and are eligible to enroll into HVTN Phase 1 trials at U.S. sites.

We are proposing a two-phase study to:

**Aim 1:** Characterize the impact of the expanded low risk eligibility criteria on recruitment of participants into HVTN Phase 1 studies at the New York Blood Center Clinical Research Site (CRS) in New York City (endpoints: number of contact cards received during in-person outreach/online screening from 09/2021 to 08/2022, number of participants who screen in person, number of participants who enroll into studies, total N as well as N of those who meet low risk guidelines based on the expanded PrEP criteria)

**Aim 2:** Conduct an online survey-based study from a community-recruited sample of 250 men and transgender individuals who have sex with men and/or transgender individuals who are on PrEP to understand their awareness of HIV vaccine trials, especially in the context of Phase 1 trials and recently expanded eligibility criteria to enroll those on PrEP, factors that hinder and encourage participation in the trials (including restriction on HIV testing outside, PrEP adherence), and willingness to participate in Phase 1 HIV vaccine trials.

The insights from this study will help inform the success of the expanded PrEP criteria on recruiting and enrolling participants who are on PrEP into HVTN Phase 1 studies in the U.S.

**Regulatory requirements for the project and plans for completing them:** IRB approval will be obtained from the New York Blood Center Institutional Review Board before the start of this study. The RAMP Scholar and all members of the research team will complete CITI and required IRB training before they are allowed to participate in the study. Online informed consent will be obtained from all research participants before they are directed to the main survey study. Electronic data will be stored on password protected computers at the NYBC; hard copies will be stored locked filing cabinets accessible to members of the research team only.

**Expected Deliverables:**
- HVTN Full Group Meeting – presentation
- Abstract submission to a scientific conference
- Manuscript for submission to a peer-reviewed journal

**Project Contact Person(s):**
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