

RAMP Project Abstract: NEW YORK, US

Project Title: Enhancing engagement of cisgender women of color in Phase 1 HIV vaccine trials in New York City

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

Proposed Project Dates: Flexible 8 -10 weeks On-site between May 2023 – September 2023

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 Member of the Laboratory of Infectious Disease Prevention/Project ACHIEVE at the New York Blood Center (NYBC), Melonie Walcott, DrPH, MPH, Jorge Soler, PhD, MPH, 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.

The overall goal of this RAMP study is to identify strategies to develop sustainable partnerships with stakeholders and improve minority cisgender women's participation in clinical research studies. While participating in this 8 to 10-week program, you will work with the team to conduct a research project to enhance engagement of cisgender women of color in early phase HIV vaccine trials in New York City.

The specific aims of the project are to:

1. Identify strategies for building sustainable partnerships with stakeholders (agencies that provide services to cisgender women of color) and enhance the clinical research site's capacity to engage with these stakeholders and the population of cisgender women of color that they serve.
2. Examine stakeholders' perspectives of the barriers and facilitators to participation in HIV vaccine trials among cisgender women of color.
3. Identify measures that could be taken to improve community engagement, recruitment, and enrollment of cisgender women of color into HIV vaccine trials.

Project Summary:

The HVTN Phase 1 HIV vaccine studies aim to test the safety and tolerability of vaccine candidates in individuals aged 18-55 years who are generally healthy and considered at low risk for HIV infection.¹ Women represent one in five of all new HIV infections in the United States (U.S.).² Significant racial disparities persists.^{2,3} Black women are disproportionately affected, having the highest incidence, prevalence and deaths.^{2,3} In New York City (NYC), 90% of new HIV infections among women in 2018 were among Black (63%) and Hispanic (27%) women; and 56% of new cases occurred in high poverty areas.^{4,5}

Although Black and Latina women have markedly increased rates of infection, the rates of participation in HIV vaccine trials remains low within this population.⁶ Factors such as distrust of research and social cost of vaccine uptake,⁷ under representation of minority in the health and research; lack of access to care; lack of cultural humility in many clinical environments,⁶ HIV stigma⁸, have been documented as important barriers to participating in clinical studies among minority population. This problem is further compounded as traditionally research studies were primarily conducted among men. This approach has significantly undermined the progress of understanding gender differences in clinical decision-making, preferences and response to medications.⁹ Although women participation in clinical studies has increased over the years; given the disproportionate burden of the HIV epidemic among minority women concerted effort is warranted to increase representation of minority.

This research project seeks to enhance engagement of cisgender women of color in early phase HIV vaccine trials in New York City. The specific aims of the study are to:

1. Identify strategies for building sustainable partnerships with stakeholders (agencies that provide services to cisgender women of color) and enhance the clinical research site's capacity to engage with these stakeholders and the population of cisgender women of color that they serve.
2. Examine stakeholders' perspectives of the barriers and facilitators to participation in HIV vaccine trials among cisgender women of color.
3. Identify measures that could be taken to improve community engagement, recruitment, and enrollment of cisgender women of color into HIV vaccine trials.

To achieve this goal, we will conduct outreach to NYC-based agencies that service cisgender women of color, such as the St. Ann's Corner of Harm Reduction (SACHR), PurPLE Health and VOCES Latinas. SACHR is based in the Bronx and provides non-judgmental HIV prevention and support and harm reduction services to marginalized populations at their site and in the community via their mobile van). The PurPLE Health Foundation (Manhattan), provides services to women who experience gender-based violence, and VOCES Latinas is an agency that provides services to immigrant Latinos/Latinas in Queens. We will work in collaboration with these agencies to conduct approximately 6 focus group discussions involving 50 participants (stakeholders and minority cisgender women). The focus group discussions will be transcribed verbatim by a professional transcription service and will be coded and analyzed by the research team. Dedoose qualitative software will be used in the management and analysis of the qualitative data.

The findings from this study will be used to inform the development of new print and online materials to improve community engagement and recruitment of cisgender women of color into HIV vaccine trials. The insights from this study will help inform community engagement, recruitment, and enrollment of cisgender women of color into HVTN Phase 1 studies in the U.S. Importantly also, we hope this work will enhance our capacity to build sustainable partnerships with stakeholders which will enable us to conduct community based participatory research aimed at reducing inequity in HIV prevention and treatment among marginalized women.

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):

- Melonie Walcott, DrPH, MPH mwalcott@nybc.org
- Hong Van Tieu, MD, MS, htieu@nybc.org
- Jorge Soler, PhD, jsoler@nybc.org

References

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