RAMP Project Abstract:

**Project Title:** The Role of the Microbiome in Rectal and Pharyngeal Sexually Transmitted Infections Amongst Men Who Have Sex with Men in a Comprehensive HIV Prevention Program

**Project Type:** Long-term project (12 months)

**Proposed Project Dates:** May 2022 – May 2023

**Project Site:** Columbia Clinical Research Unit, New York

**Project Overview:**

The goal of the Columbia Clinical Research Unit is to work on novel ways to prevent and treat sexually transmitted infections and HIV infection. As part of the research unit, you will have the opportunity to work with clinical investigators, epidemiologists, social scientists, data analysts and more. For this project, you will be working with an interdisciplinary team with the overall goal of understanding if the pharyngeal and rectal microbiome can predict incident STI infections. As part of this project, you will spend time learning how to recruit, consent, and enroll sexual and gender minority participants into an HIV prevention study. You will also have the opportunity to gain experience collecting and processing study samples and go to the lab for RNA extraction and 16s sequencing. Ideally, the candidate will work onsite in New York City. If circumstances due to COVID-19 preclude this from happening, the project can be done remotely with secured access to electronic health records and other media for communication. In addition to learning how to enroll participants, collect and process samples you will work with our clinical investigators, epidemiologist, and data analyst to analyze data and complete a manuscript.

**Project Summary:**

Sexually Transmitted Infections (STIs), including extra-genital infections, are a major public health issue, with 2019 representing the sixth consecutive year of increased STIs in the United States (US). High rates of bacterial sexually transmitted infections (STI) have been reported in men who have sex with men (MSM) receiving pre-exposure prophylaxis (PrEP). Three commonly discussed strategies for STI reduction include behavioral counseling, routine testing and treatment, and STI pre or post-exposure prophylaxis. These methods are all resource intensive and identifying individuals at highest risk of STI acquisition is critical. The microbiome holds potential to identify those at highest STI risk. Currently whether specific rectal or pharyngeal microbiome features are associated with risk STI acquisition is unknown. However, in women the vaginal microbiome has been linked to acquisition of gonorrhea and chlamydia. Furthermore, both the rectal and pharyngeal microbiome are potentially modifiable holding the potential to protect against sexually transmitted infections. Here we propose to utilize a longitudinal observational cohort (Stick2PrEP3.0) to study the contribution of the impact of the pharyngeal and rectal microbiome on risk of sexually transmitted infections.

**Hypothesis 1:** Changes in the rectal microbiome change susceptibility to gonorrhea or chlamydia rectal infection

- **Aim 1A:** Determine whether the rectal microbiome can predict incident rectal gonorrhea infection.
- **Aim 1B:** Determine whether the rectal microbiome can predict incident rectal chlamydia infection.
Hypothesis 2: Changes in the pharyngeal microbiome change susceptibility to gonorrhea pharyngeal infection

- Aim 2: Determine whether the pharyngeal microbiome can predict incident pharyngeal gonorrhea infection

Hypothesis 3: Changes in the rectal microbiome change susceptibility to Mycoplasma Genitalium colonization

- Aim 3: Determine whether the rectal microbiome can predict incident rectal Mycoplasma Genitalium colonization and/or infection.

Regulatory requirements for the project and plans for completing them: This project will be approved by the Columbia University Irving Medical Center Institutional Review Board prior to the scholar starting. Participants will need to complete CITI and required IRB training to be added to the IRB. We will assist in completing all the necessary modules, and IRB modifications to add personnel are approved quickly.

Expected Deliverables:
1. HVTN – presentation
2. Manuscript for submission

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