

**Project Title:** Perceptions, experiences, and knowledge of current and previous participants involved in Infectious Disease Clinical trials research within Rustenburg Sub-district in Bojanala District, South Africa.

**Preferred Scholar On-Site Project Dates:** 8-10 weeks On-site between (May 2024 November 2024)

**Project Site:** Rustenburg, South Africa (The Aurum Institute Rustenburg)

**Project Overview:** The Aurum Institute Rustenburg research site conducts HIV Vaccine Trials and social behavioural and PrEP studies. The scholar will be working with the research team comprised of scientists, social behavioural and community engagement teams. This research project aims to explore the perceptions, experiences, and knowledge of individuals participating in clinical trial research within the Rustenburg Bojanala District of South Africa. As part of the project, the scholar will be understanding how participants perceive and experience their involvement in clinical research as is crucial to inform future studies, ensure ethical practices, and increase community engagement in clinical trials research. The scholar will be required for a period of 8 to 10 weeks.

### **Objectives:**

1. To explore and document the perceptions and attitudes of current and previous participants in infectious disease clinical trials within the Rustenburg Sub-district, towards their participation and the broader implications of their involvement.
2. To identify and analyse the challenges and benefits the participants within the Rustenburg Sub-district associate with their engagement in infectious disease clinical trials, with a focus on the local context.
3. To assess the level of knowledge among participants within the Rustenburg Sub-district regarding the infectious diseases being studied, the clinical trial procedures, potential risks, and their ethical rights and responsibilities as research subjects.
4. To contextualize the findings from this study within the broader body of literature on clinical trial participation, enabling a comparative analysis of participant perspectives between the Rustenburg Sub-district and other geographic regions.
5. To contribute insights that inform the design of effective recruitment strategies, participant engagement initiatives, and ethical considerations for future infectious disease clinical trials conducted within the Rustenburg Sub-district.
6. To provide recommendations for community engagement efforts that address local cultural and healthcare dynamics, aiming to enhance participant awareness, knowledge, and overall trial experience in the context of infectious disease clinical trials.

### **Project Summary:**

This qualitative descriptive study aims to explore the perspectives and experiences of previous clinical research participants in the Rustenburg Bojanala District, South Africa. Purposeful sampling will be used to select participants from a centralized database of individuals who consented to be contacted for future studies. 30 Individual in-depth interviews will be conducted separately for cisgender males and cisgender females, aged 18 years and above, Data will be collected through recorded interviews using an open-ended questionnaire and a demographic questionnaire.

Thematic content analysis will be employed to analyse the data, with Microsoft365 used for initial coding and grouping, and QSR NVIVO version 12 software utilized to develop a comprehensive codebook. Community engagement will be prioritized, collaborating with local healthcare providers, community leaders, and stakeholders to align the study with community needs and values. Ethical considerations will be strictly observed, ensuring informed consent, confidentiality, and protection of participants' rights.

The project aims to offer valuable insights into clinical trial participation in the region, enhancing the design and implementation of future HIV vaccine trials, addressing community concerns, and fostering greater participation and trust in medical research. By contributing to the global effort to combat HIV/AIDS, the research seeks to facilitate the development of an effective HIV vaccine. Findings will be disseminated through scientific publications, conferences, and community workshops, promoting awareness and involvement in ongoing HIV epidemic efforts.

### **Regulatory requirements for the project and plans for completing them:**

This research project will be submitted to the University of Witwatersrand Health Research Committee by January 6<sup>th</sup>, 2024. We anticipate approval by the end of February 2024. This process involves preparing a comprehensive research protocol. The protocol will outline the research objectives, methodology, participant recruitment strategies, informed consent process, and data handling procedures. Informed consent forms will be developed in multiple languages spoken in the Rustenburg Bojanala District, ensuring clear explanations of the research, potential benefits and risks, voluntary participation, and the right to withdraw at any time.

To protect participants' privacy, the team will employ secure data collection and storage systems, restricting access to authorized personnel only. Data will be anonymized to safeguard identities. Community engagement will be integral, collaborating with local healthcare providers, community leaders, and advocacy groups to address community concerns and garner support.

The research team will conduct regular compliance checks to ensure adherence to all relevant regulations and guidelines throughout the project. Data management will follow industry-standard practices, with secure storage on encrypted servers. Furthermore, all researchers and project staff will be required to disclose any potential conflicts of interest before their involvement in the study. These ethical considerations will ensure the project's integrity and its ability to contribute valuable insights to the field of research.

### **Expected Deliverables/Learning Objectives:**

- Throughout this journey, the scholar will gain hands-on experience in various aspects of qualitative research, including research design, data collection, analysis, interpretation, and dissemination. They will develop skills in interpersonal communication, ethical considerations, analytical thinking, and academic writing. This experience can greatly contribute to their growth as a researcher and equip them with valuable skills applicable to future academic pursuits, such as further research, postgraduate studies, or even careers in academia, public health, or social sciences. As well as having the opportunity to do clinical shadowing and enhance their skills while onsite daily learning different things done onsite.
- HVTN Full Group Meeting – poster and oral presentations

**Project Contact Person(s):** (Dr William Brumskine, [WBrumskine@auruminstitute.org](mailto:WBrumskine@auruminstitute.org))  
(Monica Pule, [MPule@auruminstitute.org](mailto:MPule@auruminstitute.org))  
(Kabelo Mabeleng, [KMabeleng@auruminstitute.org](mailto:KMabeleng@auruminstitute.org))  
(Tania Adonis, [Tadonis@auruminstitute.org](mailto:Tadonis@auruminstitute.org))