**Letter of Amendment: 11 March 2024**

**Study Title:** A Randomized Open Label Switch Study Comparing Darunavir/Ritonavir with Lopinavir/Ritonavir in HIV-Positive Participants  
**Protocol Number:** WRHI052  
**Protocol Version and Date:** Version 3.0 dated 26 October 2017  
**HREC Reference No:** 150705B

**Dear Members of the Wits HREC,**

We request an amendment to the above-mentioned protocol to permit the secondary use of data collected in the study within the HE2AT Center's project, which is focused on examining heat-health interactions in urban environments.

**Overall Rationale for the Amendment:**

This amendment seeks to expand the application of the study data to encompass broader research goals, particularly those about climate change and health, by allowing its secondary analysis within the HE2AT Center's project.

**Summary of Changes and Rationale:**

The invaluable data obtained from the study can significantly enhance our understanding of the intersection between health outcomes and environmental factors, such as urban heat. Currently, the protocol does not make provisions for secondary data use. Therefore, we propose to formally add a paragraph that outlines the conditions under which the data will be shared and used for secondary purposes.

**Professor Francois Venter's Approval:**

We have received approval from Professor Francois Venter for the secondary use of the study's data for the HE2AT Center's project, ensuring the proposed data use is consistent with our objectives and adheres to ethical standards.

**Implementation of the Protocol Modification:**

With your approval, the protocol amendment will be effected immediately. This modification will add clarity to the scope of secondary data use and ensure continued adherence to ethical standards and participant confidentiality.

**Specific Protocol Changes:**

We propose the following specific amendment to Section 9.0 "Data Management":

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| --- | --- | --- |
| Section | Original Text | Proposed Amendment |
| 9.0 Data Management | [No specific mention of secondary data use] | Add: "Data from this study may be utilized for secondary analysis within the HE2AT Center project, addressing broader research questions related to the impact of climate change on health. Data will be shared using secure methods, with stringent adherence to ethical guidelines and the original consent obtained from study participants." |

**Conclusion:**

The amendment will significantly elevate the value of the data by facilitating its application in addressing critical public health questions associated with climate change and urban heat exposure. We anticipate the committee's favorable response to this amendment.

Sincerely,

[Your Name]  
[Your Position]  
[Your Institution/Department]  
[Contact Information]