**Study Title:** Collection of Comparison Neurocognitive Data in Resource-Limited Settings (A5271)

**Sponsor:** The National Institute of Allergy and Infectious Diseases (NIAID) and The National Institute of Mental Health (NIMH)

**Protocol Chair:** Kevin Robertson, Ph.D.

**Study Design:** This is a two-step prospective observational multinational study aimed at collecting comparative neurocognitive data in neurologically healthy HIV-seronegative individuals from resource-limited settings. The study involves a baseline neuropsychological assessment and a subset of participants returning for a second visit after 6 months.

**South African Sites:** Johannesburg (n=240) and Durban (n=240)

**Study Objectives:**

* Primary Objective: To collect comparative neuropsychological data in healthy controls to aid in the interpretation of neuropsychological tests in resource-limited settings.
* Secondary Objectives: To describe the distribution of neuropsychological scores in neurologically healthy HIV-seronegative individuals in resource-limited settings and estimate practice/learning effects associated with repeated neuropsychological assessments.

**Study Population:** The study aims to enroll 2400 men and women aged ≥ 18 years who are neurologically healthy and HIV-seronegative. The South African sites will contribute to this total enrollment, with participants stratified by age, sex, and education level.

**Study Assessments:** Participants will undergo a comprehensive neuropsychological assessment covering domains such as motor skills, speed of information processing, verbal learning, and memory. Assessments also include a medical history review, Karnofsky performance score evaluation, and measurements of body mass index (BMI).

**Study Duration:** Participants will be involved in the study for one day if they do not enter Step 2; those who enter Step 2 will have a follow-up period of 6 months.

Please let me know if you need further details or any specific information to be included in the synopsis.

[International Neurocognitive Normative Study: Neurocognitive Comparison Data in Diverse Resource Limited Settings: AIDS Clinical Trials Group A5271 - PMC (nih.gov)](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4981921/)