

Protocol Title: Global Genetic Genealogy Study

Principal Investigator	Hermínio Cossa, BSc, MSc, PhD; (Centro de Investigação em Saúde de Manhiça, Maputo, Moçambique)
Study Device(s):	DNA Saliva Collection Kit
Number of Sites:	Two (Manhica and Magude District)
Study Duration:	10 months (June 2024 to Mar 2025)
Primary Study Objective:	To determine how individuals and populations are genetically related; specifically, this research project aims to: <ul style="list-style-type: none"> • To understand human origins, • To determine human migrations • To explore population structure
Secondary Study Objective:	The current protocol seeks to expand the genetic diversity, and therefore utility, of the sponsor's genetic reference panel database by proactively recruiting underrepresented participants who may have no customer relationship with the sponsor. The aims of this biobanking protocol are to i) Enhance the sponsor's current genome reference panel database, with saliva/DNA samples from currently underrepresented global populations, for the purpose of increasing its utility and accuracy; ii) Enhance the sponsor's data and sample repository for current and future product and service development and; iii) Enhance the sponsor's data and sample repository for possible future original research.
Study Enrollment Total:	500 Individuals
Eligibility Criteria:	<ul style="list-style-type: none"> • Participants must be 18 years of age or older • Participant must be born in, or self-reported tracing back to one geographic region of interest or indigenous population • Participants must be willing to answer demographic and family history questions • Participants must be able to provide Informed Consent
General Study Design:	<p>Given the diverse populations sought for inclusion, this protocol involves different methods and strategies for subject recruitment depending on the type and location of the community being recruited.</p> <p>A saliva sample and family history will be collected from each voluntary participant. DNA will be extracted from each saliva sample using standard extraction methods appropriate to the study. The data will be saved and added to the reference panel if the inclusion criteria are met. Individual genetic results will not be communicated back to the individual participants, but data may be shared with third party-partner collaborators for the purpose of conducting this research as described in the protocol.</p> <p>The sponsor will partner with a local contact in the area of interest to engage the region's community stakeholders and decision-makers regarding the research study. The protocol and the Information and Informed Consent form will be revised to capture any community-specific requirements and submitted to a local IRB/REC by the partner for review. Physical copies of family history records and aggregated genetic results may be provided to participating communities if desired.</p>
General Statistical Plan:	Consent and collection of saliva samples and family history information will be obtained by an external collaborator that has received IRB approval from their local IRB. Saliva/DNA and family history information will be shared with the sponsor. The sponsor will run the saliva/DNA samples through a partner lab for genotyping. The sponsor will research the genetic information obtained for use in understanding human

	<p>origins, migrations, and population structure. Select samples will also undergo whole genome or exome sequencing for purposes of research and discovery, to improve our understanding of genetic variation among world populations and to help determine which SNPs to include in future arrays for specific populations. All genetic data generated from genotyping in this research study will be securely transferred over an encrypted transfer protocol to a secure sponsor's cloud server.</p>
Sponsor	<p>iProcess Global Research 1135 Kinwest Parkway, Suite 150 Irving, TX 75063</p> 