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**Stellenbosch University
Centre for Epidemic Response and Innovation
("CERI")**

**Accelerating Genomics-Based Surveillance for COVID-19 Response in South Africa
TF0B8412**

OPERATIONS MANUAL

Date: 20 March 2023
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Contents

TABLE OF ACRONYMS	3
A. INTRODUCTION	4
B. STRATEGIC CONTEXT	5
Country Context	5
C. SECTORIAL AND INSTITUTIONAL CONTEXT	7
Higher Level Objectives to which the Project Contributes	8
D. PROJECT DEVELOPMENT OBJECTIVES AND OUTCOME INDICATORS	9
E. PROJECT DESCRIPTION	9
F. INSTITUTIONAL AND IMPLEMENTATION ARRANGEMENTS	13
G. FINANCIAL MANAGEMENT ARRANGEMENTS	15
H. PROCUREMENT ARRANGEMENTS	20
I. ENVIRONMENTAL AND SOCIAL RISK MANAGEMENT COMPLIANCE	32
J. MONITORING AND EVALUATION (M&E)	39
ANNEX 1: TERMS OF REFERENCE FOR KEY PROJECT POSITIONS	41
ANNEX 2: RESULTS FRAMEWORK	45
ANNEX 3: PROCUREMENT PLAN	48

Table of Acronyms

ACEGID	African Centre of Excellence for Genomics of Infectious Disease
CERI	Centre for Epidemic Response and Innovation
COVID-19	Coronavirus Disease 2019
DoH	Department of Health
DSI	Department of Science & Innovation
ESCP	Environmental and Social Commitment Plan
ESF	Environmental and Social Framework
ESS	Environmental and Social Standards
FMHS	Faculty of Medicine and Health Sciences
FY	Financial Year
HEPR	Health Emergency Preparedness and Response
IBRD	International Bank for Reconstruction and Development
IFR	Interim Financial Report
IPF	Investment Project Financing
KRISP	KwaZulu-Natal Research Innovation and Sequencing Platform
LAC	Latin America and Caribbean
NDoH	National Department of Health
NGS-SA	Network for Genomic Surveillance in South Africa
NGO	Non-Governmental Organization
NICD	National Institute for Communicable Diseases
PAD	Project Appraisal Document
PDO	Project Development Objective
PIU	Project Implementation Unit
POM	Project Operations Manual
RGMO	Research Grant Management Office
SANBI	South African National Bioinformatics Institute
SA	South Africa
SAMRC	South African Medical Research Council
SARS-CoV-2	Severe Acute Respiratory Syndrome coronavirus 2
SDGs	Sustainable Development Goals
SU	Stellenbosch University
WBG	World Bank Group

A. Introduction

1. The “*Accelerating Genomics-Based Surveillance for COVID-19 Response in South Africa*” Project (the Project) is financed by a US\$5 million grant from the Health Emergency Preparedness and Response (HEPR) Multi-Donor Trust Fund administered by the World Bank (Grant TF0B8412). The Project was approved on 11 April 2022, and became effective on 20 Jun, 2022, with a project closing date of 31 March 2025. The project is being implemented by the Centre for Epidemic Response and Innovation (CERI), while logistics and administrative aspects are managed by Stellenbosch University.
2. This Project Operations Manual (POM) should be considered a ‘living’ document; as such the Manual will be reviewed continually to accommodate changes in Stellenbosch University/World Bank regulations as well as changes in the Higher Education Act of SA where these have significant consequences on the project’s Financial Management environment.
3. This Manual was developed by the core project implementation team at CERI in consultation with other departments, and the World Bank, and describes the management structures and processes related to the implementation of the Project. All users of this Manual are urged and encouraged to provide feedback and lessons learned from their ‘on-the-ground’ experiences with the Manual. All approved amendments will be referenced and filed in a Manual Amendment File and disseminated to all implementing parties. The revised version number of the Manual will be indicated, and a summary of the changes appropriately incorporated. **The core implementation unit at CERI will be responsible for ensuring periodic revisions and documentation of the amendments in the Manual.** For each amendment, the date and version number shall be indicated on the cover. If there are differences between this manual and the Grant Agreement, the text of the Grant Agreement will prevail.
4. The Operations Manual takes into consideration information from other project related documents including the Project Paper (PAD), Procurement, Financial Management, and safeguards documents.
5. The POM shall not be amended without prior written approval of Stellenbosch University and World Bank.

The objective/purpose of this manual is to:

- a. Detail the implementation arrangements and procedures to be followed (i) during implementation and coordination of the Project; (ii) in carrying out processes relating to financial management, procurement, environmental and social safeguards, monitoring, evaluation, reporting and communications to ensure consistency, timeliness and accuracy.
- b. Provide information and guidance to stakeholders on the scope, content, organization, implementation arrangements and activities of the Project.
- c. Indicate the performance criteria agreed to for the management and implementation of the Project and
- d. Ensure that the requirements for transparency, compliance and accountability are met.

The Points of contact

6. The key points of contacts at CERI for any questions related to this POM are:

Name: Mrs. Suzette Grobler
Title: Grants Manager
Email: groblers@sun.ac.za

B. Strategic Context

Country Context

7. South Africa (SA) is one of the largest economies in Africa and their population has been seriously affected by the COVID-19 pandemic. As of mid-December 2022, SA reported over 4 million cases of COVID-19 infections and more than 100,000 deaths. SA accounts for about 50 percent of the total confirmed cases of COVID-19 and 60 percent of deaths in sub-Saharan Africa. SA has gone through five waves of COVID-19 infections surges. The first two waves of the pandemic in SA were dominated by novel variants of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), Alpha (B.1) and Beta (B.1.351/501Y.V2), whereas the third wave was dominated by the Delta variant. The fourth and fifth waves were driven by the Omicron variant. These variants have also spread widely to neighbouring countries and may evolve further and affect diagnostics and vaccines effectiveness.
8. In June 2020, SA established the network for genomic surveillance (NGS-SA), funded by the Department of Science & Innovation (DSI) and the South African Medical Research Council (SAMRC), to monitor genetic changes that impact pathogenicity, diagnostics and therapeutics and vaccines. This network combines five of the largest laboratories in the country and their associated academic institutions in five major SA cities (Figure 1).

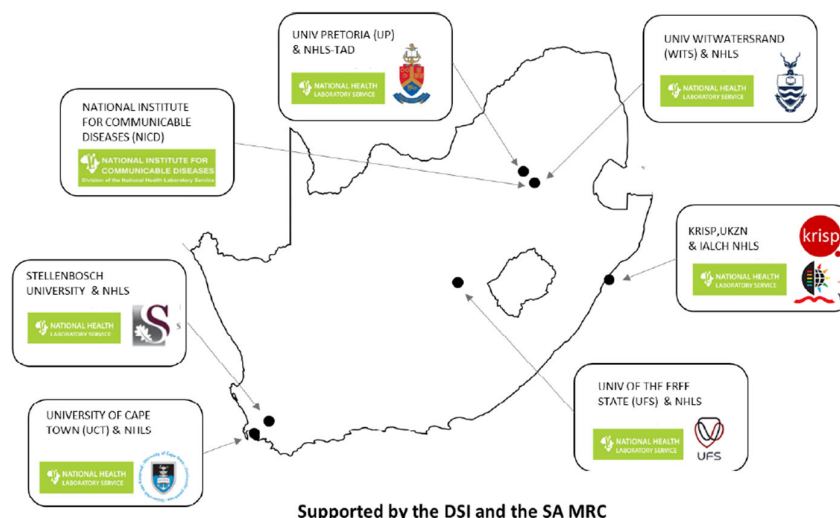


Figure 1 Laboratories and Universities constituting the NGS-SA

Since then, the network has expanded to also include private diagnostic laboratories and other academic institutions in and outside South Africa. At present, the NGS-SA produces a weekly report of genomic data in SA. These reports are sent to the minister of health and

made available at the National Institute for Communicable Diseases (NICD) and NGS-SA websites (Figure 2).

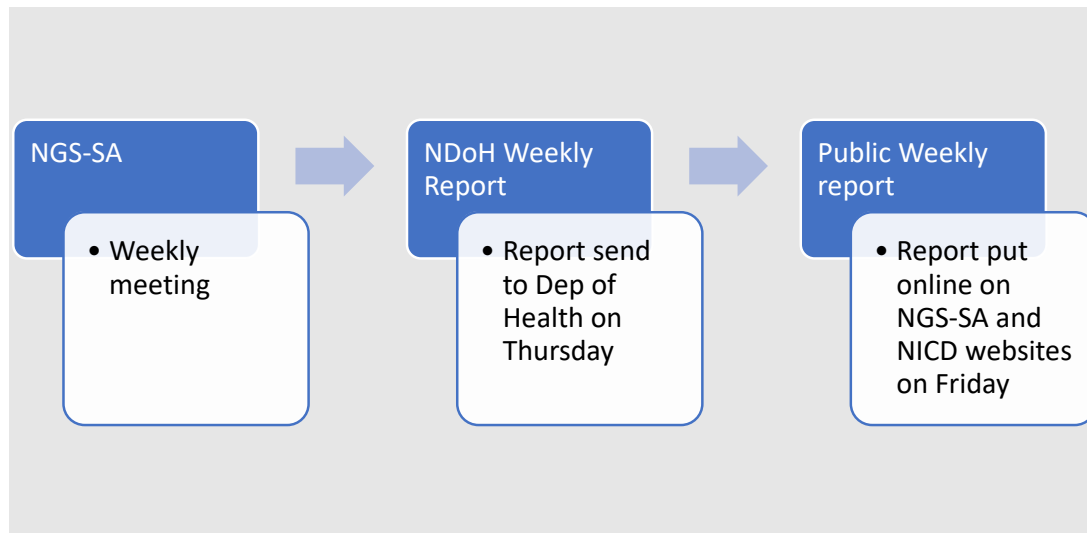


Figure 2 Weekly communication by NGS-SA to South African Department of Health

9. **The analysis from the NGS-SA has already been influencing public health policy and practice.** For example, their genomic analysis of the large nosocomial outbreak in KwaZulu-Natal helped understand the initial spread of the virus and was used to advise health care facilities across the country on how to strengthen infection prevention and control systems¹.
10. **In recognition, the WHO selected the South African National Bioinformatics Institute (SANBI) and Kwazulu-Natal Research Innovation and Sequencing Platform (KRISP) and the Centre for Epidemic Response and Innovation (CERI) as their reference laboratories for genomic sequencing.** Further, the CERI has been established at Stellenbosch University by the director of KRISP to expand the efforts of KRISP and allow data to be produced more effectively for South Africa and Africa. Another reference laboratory in Africa selected by the WHO is the African Center of Excellence for Genomics of Infectious Diseases (ACEGID), at Redeemer's University in Ede, Nigeria.
11. **CERI, together with the Department of Health (DoH) and the NGS-SA, announced the detection of a new Covid-19 virus variant (Omicron) in South Africa in late November 2021.** As a high-throughput genomics facility, CERI provides support to all other laboratories of the NGS-SA, the National DoH and other health ministries in the region.
12. **Since September 2020, SA has served as one of the few hubs for the entire Africa region to reinforce genome sequencing of the SARS-CoV-2.** By the end of 2020, SA had generated almost all of the 4,948 sequences completed in the region and identified 35 SARS-CoV-2 lineages. By the end of 2021, SA has produced approximately 30,000 genomes for the continent.
13. **However, there is a lack of funding to sustain the genomic sequencing process. The financial gap needs to be filled to support continued genomic data generation and**

¹Msomu N, Mlisana K, de Oliveira T; Network for Genomic Surveillance in South Africa writing group. A genomics network established to respond rapidly to public health threats in South Africa. *Lancet Microbe*. 2020;1(6):e229-e230. doi: 10.1016/S2666-5247(20)30116-6. Epub 2020 Aug 18. PMID: 32838349; PMCID: PMC7434425.

analysis. The NGS-SA has only received funding from the SA government to produce 15,000 genomes and all of the current funding has been exhausted. The NGS-SA needs additional funding if it is to continue producing genomic data in 2022 and beyond.

14. **Many LMICs do not have the strong health systems and genomic sequencing infrastructure (instruments and properly trained personnel) needed to underpin a good genomic surveillance system,** that could in turn report to regional/continental systems and/or global systems. Outside of the HICs (High Income Countries), sub-Saharan Africa and LAC (Latin America and Caribbean) regions seem to have better regionally coordinated sequencing and surveillance reporting systems. Despite this apparent success, gaps still exist in these and other regions.

C. Sectorial and Institutional Context

15. **The COVID-19 pandemic is one of the greatest challenges that humankind has faced in generations.** It has already cost more than five million lives globally, sickened nearly 300 million people around the world, upended countless livelihoods, and caused substantial economic loss. Despite advances in the development and rollout of vaccines as well as in the clinical management of patients with COVID-19, the end of the worst public-health crisis in a century is not yet in sight as new variants that decrease the effectiveness of the public health interventions and vaccines are emerging.
16. **The evolution of SARS-CoV-2 has generated viral variants that differ in their genetic sequence from the original strain detected in Wuhan in December 2019 and pose a great risk to public health.** Some of these variants are less sensitive to neutralization by convalescent sera or vaccine-induced neutralizing antibody responses, raising concerns about its negative impact on vaccine effectiveness. It is expected that SARS-CoV-2 will continue to mutate. There is a high risk not only for a vaccine and immune escape variant to emerge, but also for loss of sensitivity of molecular and antigen capture tests. Thus, continued generation, analysis and sharing of virus genomes in real-time will be important to monitor the expected efficacy and sensitivity of different vaccines and nucleic acid tests across the continent.
17. **The generation of near-real time genomic surveillance data and analyses has already proven useful in responding to COVID-19 outbreaks by producing actionable information for public health officials and policymakers.** Genomic surveillance integrates clinical, epidemiological, genomic, and phenotypic data to track changes in virus transmission, virulence, and effectiveness of medical countermeasures. Recent advances in next-generation sequencing make it possible to quickly and cost-effectively sequence many SARS-CoV-2-positive cases simultaneously. Parallel advances in bioinformatics, computational biology, and molecular virology make it possible to analyze the virus in context to assess risk in close to real-time. Near-real time open-source sharing of viral genome sequences has facilitated near real-time detection, comparison, and tracking of evolving SARS-CoV-2 variants that can inform public health efforts to control the pandemic.
18. **The rise of new SARS-CoV-2 variants has highlighted the need for partnerships at multiple levels and across institutions for detection and surveillance.** Building a strong and resilient global sequencing network can maximize the public health impact of sequencing, not only for SARS-CoV-2 but also for future emerging pathogens. Various pathogen-specific laboratory networks have invested in sequencing capacity as part of their surveillance activities. As the costs of sequencing are substantial and many parts of the sequencing

workstream can be used for various pathogens and sequencing objectives, national and regional collaborations are encouraged to ensure optimal use of existing capacity.

19. **The World Bank Group mounted the largest and fastest crisis response in its history when COVID-19 emerged as a global threat**, and has committed over US\$ 157 billion in grants and financing to help the countries mitigate the health, social, and economic impacts of COVID-19, boost countries' preparedness and ability to respond to the pandemic, deliver COVID-19 tools (vaccines, therapeutics, and diagnostics), protect the most vulnerable people from its critical shocks, and help countries strengthen health systems that are prepared for future disease outbreaks.
20. **Recognizing the global nature of health emergencies, in June 2020 the World Bank Board approved the creation of a new umbrella trust fund program, the Health Emergency Preparedness and Response (HEPR) Program.** The development objective of the Program is to support eligible countries and territories to improve their capacities to prepare for, prevent, respond and mitigate the impact of epidemics on populations. It was set up as a flexible mechanism to provide catalytic, upfront and rapid financing at times that other sources of funding are not available for health emergency preparedness and to fill specific gaps in terms of health emergency responses. Activities eligible for HEPR Program financing focus on two pillars: (a) preparedness for future health emergencies and (b) responses to emerging and current health emergencies. The HEPR Multi-donor Trust Fund (MDTF) is the anchor TF of the HEPR Program. South Africa has been allocated a HEPR MDTF grant to the value of \$5 million to improve genomic surveillance of SARS-CoV-2 capacities of South Africa and the African region, on condition that these TF resources are not used to purchase COVID-19 vaccines.
21. **The proposed project is aligned with World Bank Group (WBG) strategic priorities, particularly the WBG's support to achieving Universal Health Coverage and the Sustainable Development Goals (SDGs) by 2030**, as well as national plans and global commitments to strengthening pandemic preparedness. In addition, with its focus on health preparedness, it will directly complement other initiatives in promoting health security and building a resilient health system.

Higher Level Objectives to which the Project Contributes

22. **The proposed project is aligned with the WBG Country Partnership Framework for the period FY22 - FY26.** It will contribute to Cross-cutting Theme 3: Governance primarily through objective 3.3.6: Maintaining and Deepening the Knowledge Agenda.
23. **Specifically, this project will expand the capacity of South Africa and the region to produce more than 20,000 SARS-CoV-2 and other pathogen genomes in a three-year period (March 2022 and March 2025) by investing in CERi in South Africa** – one of the two most well-known sequencing groups in Africa. CERi will also support the other six laboratories of the NGS-SA by providing them with reagents, protocols, and training so that genomic data can be continually produced in South Africa. Genomics surveillance aims to transform public health interventions by monitoring genetic changes that impact pathogenicity, diagnostics, therapeutics and vaccines. It will facilitate knowledge exchange between academic institutions on the African continent and build capacity on genomic sequencing that will inform the health response to COVID-19 by governments.

D. Project Development Objectives and Outcome Indicators

24. **PDO Statement:** The project development objective (PDO) is to improve genomic surveillance of SARS-CoV-2 capacities of South Africa and the African region.
25. **Project Beneficiaries:** The primary beneficiaries will be the genomic laboratories that are based at CERI and NGS-SA and their staff. The laboratories will be able to produce more results from genomic sequencing and their capacity to provide reliable information to countries will be enhanced. In addition, the general population of South Africa and beyond will benefit in general, as a result of improved genomic sequencing capacity and more effective public health responses.
26. **PDO-Level Results Indicators are:**
 - a) This project is expected to yield the following main outcomes: (a) capacity of genomic sequencing in South Africa and the region is improved by upgrading CERI genomics laboratories and providing reagents and training to sequencing staff and scientists from other laboratories of NGS-SA; (b) establish an effective system to detect variants and evaluate diagnostics and vaccine effectiveness against SARS-CoV-2 variants in South Africa; and (c) strengthen the data system/ platform for sharing and analyzing sequencing data.
 - b) Key PDO indicators are: (a) number of sequences produced in Africa; and (b) number of staff and scientists who are able to produce genomic sequencing data; and (c) number of staff and scientists who are able to analyze genomic sequencing data.

E. Project Description

27. This project will expand the capacity of South Africa and the region to produce more than 20,000 SARS-CoV-2 and other pathogen genomes in a three-year period (March 2022 and March 2025) by investing in CERI and providing reagents and capacity building to other national and regional laboratories. Genomics surveillance aims to transform public health interventions by monitoring genetic changes that impact pathogenicity, diagnostics, therapeutics and vaccines. Therefore, this funding will not only help fight COVID-19, but also represent a unique opportunity to expand the genomics infrastructure that can be used for endemic diseases such as AIDS, tuberculosis, malaria, cholera, and other infectious diseases in South Africa and the continent. Furthermore, such genomics infrastructure could also be used to support Africa's preparedness for future epidemics and pandemic responses.
28. One of the concerns of the WHO is the time that it takes to produce sequence data to identify and control outbreaks. In the first year of the pandemic, Africa was the worst performing continent on the number and turn-around time to produce genomic data. In 2021, the data production improved from <10,000 genomes by the end of 2020 to > 50,000 in 2021. In addition, the turnaround time decreased from over 1 month to less than 15 days. In order to improve the turnaround time and quality of the genomic data produced, the project will evaluate bioinformatics software applications to assemblage and quality control of the data. In addition, the project will produce protocols for this process and train scientists in South African and African laboratories on how effectively to run these protocols. CERI and ACEGID are the two main training sites of the Africa CDC in Africa and together they have trained over 42 African countries on the production, quality control and analysis

of genomics data (see <https://www.genomics.africa>). The proposed project will train at least 50 African scientists on the production and 50 African scientists on the analysis and quality control of the genomic data.

Component 1: Expanding the NGS-SA capacity and training

Sub-Component 1.1: Expand capacity of the NGS-SA, including procurement of equipment, reagents and staff, monthly meetings to exchange and update

29. To detect an established local transmission cluster, whole genome sequencing is essential and should preferably be performed close to sample collection. The proposed project will enable viral genomes to be analyzed quickly with the application of standardized sequencing and bioinformatics pipelines. In order to do so, the project will support CERI and the other six laboratories of the NGS-SA to carry out sequencing of approximately 18,000 more COVID-19 and other pathogen samples identified in South Africa and the African region. The project will also support ACEGID in Nigeria. We anticipate that the majority of the sequences will be from South Africa as the country currently has the largest burden of SARS-CoV-2 infections. However, CERI currently supports 21 other African countries with genomic surveillance and will continue to do so as needed. Assuming a success rate of 60% of sequencing, this project will add 12,000 high-quality genomes produced in Africa to the public global database. This will allow researchers to understand how SARS-CoV-2 is currently spreading and evolving as vaccines are rolled out in Africa. Specifically, the project will help CERI:

- expand the capacity of the NGS-SA network through procurement of equipment, hiring of staff and purchase of reagents to sequence more genomes
- The NGS-SA would serve as an integrated hub with sample collection taking place at multiple laboratories among the network member countries.
- organize monthly meetings between the NGS-SA partners and the national, regional laboratories that are generating genomic data in South Africa, and the region. This will allow close collaboration between African scientists.

Sub-component 1.2: Training staff and scientists for genomic sequencing data generation

30. The project will also be used to expand capacity building throughout Africa through:

- Providing training and capacity building to other researchers on SARS-CoV-2 and other pathogen genomic data generation
- Sharing of expertise, data and resources
- Transferring technologies developed in South Africa with ACEGID in Nigeria so the two specialized genomics facilities in the continent (i.e., CERI/KRISP and ACEGID) can have efficient systems to support other African countries on the continent.

Component 2: Establishing an effective system to evaluate diagnostics and vaccine effectiveness against the variants in Africa

31. The proposed project will allow for surge support to the operationalization of national sequencing protocols/ plans to quickly identify and share data on COVID-19 variants. Specifically, the project will support:

- CERI and other laboratories of the NGS-SA to procure additional reagents, equipment and test assays and hire staff to conduct analysis aiming to assess changes in vaccine

effectiveness and diagnostic testing and identify genomic changes potentially impacting on therapeutic and vaccine effectiveness. For example, a fully vaccinated individual becoming sick and hospitalized with COVID-19 could be the first sign that variant viruses are becoming resistant to vaccine-induced immunity. CERI and the other six laboratories of the NGS-SA will sequence approximately 2,000 COVID-19 samples identified in South Africa and the African region for the evaluation of diagnostics and vaccine effectiveness against the variants in Africa.

- CERI and ACEGID to establish an operational protocol to ensure adequate representations from member countries within the region regarding ethical regulations, laboratory and data safety measures and capacity strengthening.
- Countries with limited laboratory and sequencing capacity to establish a mechanism for COVID-19 samples (both vaccinated and unvaccinated samples) to be sent to the regional laboratories in SA. A protocol must be in place to ensure rapid transportation of samples, ideally with a target of 48-hours from sample arrival to analysis.

Component 3: Strengthening the data systems to share and training public health officials and scientists for genomic sequencing data analysis in near-real time.

Sub-component 3.1: Strengthen data sharing and integration

32. Rapid sequencing of virus genomes is now achievable in varied settings, and analyses of SARS-CoV-2 genomic sequences have huge potential for informing public health efforts surrounding COVID-19. The rapid generation and global sharing of virus genomic sequences provides information that will contribute to the understanding of transmission and the design of clinical and epidemiological mitigation strategies. The rapid sharing of pathogen genome sequence data, together with the relevant anonymized epidemiological and clinical metadata will maximize the impact of genomic sequencing in the public health response. Specifically, this component will support:

- Rapid sharing of virus genomic data generated during an outbreak with the global community as rapidly as possible to ensure maximum usefulness in improving public health.
- Facilitation of data integration (e.g., methodology; governance) between different data platforms including diagnostic, genomic, epidemiological, clinical and vaccination data. Proper sequencing data tools must be used and should be linked to patient's epidemiological, clinical and vaccination data (Figure 3).

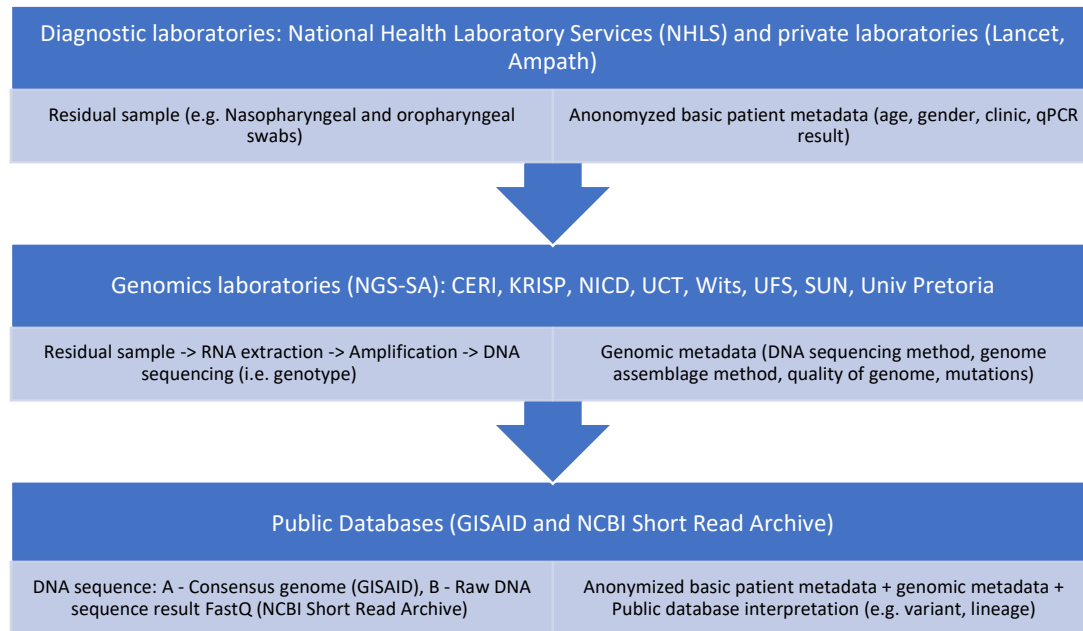


Figure 3 Data flow from diagnostic laboratories to genomics laboratories to public database (GISAID)

Sub-component 3.2: dashboard production

33. This sub-component will support the production of a dashboard to provide information in real-time to public health officials and to serve the purpose for public health response strategy development. At present, the NGS-SA produces weekly report of genomic data in South Africa. These reports are sent to the minister of health and made available at the NICD and NGS-SA websites. As part of this project, CERI will optimize the process and create a dashboard for South Africa and African data. This will allow data to be updated daily from public databases and experts and public health officials to perform the own variation of analysis on the data. The dashboard will be coded in Python and R-studio and will be available in CERI, NICD and NGS-SA websites. In addition, CERI will run training programs and focus group discussions with experts and public health officials to better adapt the dashboard to be used for public health response.

Sub-component 3.3: Training program

34. This component will support CERI to train experts in the network to be able to analyze genomic sequencing data. Genomic data collected at CERI and other laboratories should be analyzed, ideally weekly, focusing on: (a) local transmission versus imported cases; (b) chains of transmission; (c) rates of epidemic growth, including cases and deaths; (d) genetic changes. CERI and ACEGID are the two main training sites of the Africa CDC in Africa and together they have trained scientists from over 42 African countries on the production, quality control and analysis of genomics data (see <https://www.genomics.africa>). The proposed project will train at least 50 African scientists on the production, and 50 African scientists on the analysis and quality control of the genomic data.

Component 4: Project management, monitoring and evaluation

35. This component is designed to finance activities related to project management and monitoring, including project implementation support, project monitoring and evaluation.

Key activities include: (i) recruitment of environment and social consultant; (ii) support for procurement, financial management, environmental and social sustainability; (iii) operating expenses. A project implementation support plan and a monitoring and evaluation system will be set up at the start of the project.

Project Cost and Financing

Project Components	Project cost	Trust Funds
Component 1: Expanding the NGS-SA capacity and training staff	US\$2,504,690	US\$2,504,690
Sub-component 1.1: Expand capacity of the NGS-SA, including procurement of equipment, reagents and staff, monthly meetings to exchange and update	US\$1,860,365	US\$1,860,365
Sub-component 1.2: Training staff and scientists for genomic sequencing data generation	US\$ 644,326	US\$ 644,326
Component 2: Establishing an effective system to evaluate diagnostics and vaccine effectiveness against the variants in Africa	US\$1,195,293	US\$1,195,293
Component 3: Strengthening the data systems to share and training public health officials and scientists for genomic sequencing data analysis in near-real time	US\$ 914,903	US\$ 914,903
Sub-component 3.1: Strengthen data sharing and integration	US\$ 333,106	US\$ 333,106
Sub-component 3.2: dashboard production	US\$ 458,772	US\$ 458,772
Sub-component 3.3: Training program	US\$ 123,025	US\$ 123,025
Component 4: Project management, monitoring and evaluation	US\$ 385,115	US\$ 385,115
Total Costs	US\$5,000,000	US\$5,000,000
Total Project Costs	US\$5,000,000	
Total Financing Required	US\$5,000,000	

Notes: HEPR Program grant funding cannot be used for retroactive expenditure; HEPR Program grant cannot be used for purchasing vaccines.

F. Institutional and Implementation Arrangements

36. **The project will be implemented by CERI located at Stellenbosch University in Cape Town, South Africa.** The administration and logistics of the project will be managed by Stellenbosch University (SU). SU is a research-intensive university, which already manages over US\$ 1 billion of research funding per year and SU will have the relevant financial, institutional and fiduciary responsibility for the project.
37. **A core implementation team that will be established at SU will be led by Principal Investigators** and include: Infectious Disease Specialist; Senior Bioinformatician; Bioinformaticians; Laboratory Technician; Medical Scientist; Grant and Contract Manager;

Head of Scientific Support and Financial Manager. The Financial Manager will be responsible for the fiduciary management and CERI will employ an environmental and social safeguards expert who will be responsible for environmental and social (E&S) risk management of the proposed project.

38. **While CERI at Stellenbosch University will be the principal recipient, it will buy reagents for all of the other six laboratories of the NGS-SA** (i.e., University of Cape Town, NHLS-Virology in Tygerberg, University of the Free State, University of Witwatersrand, University of Pretoria and NICD). The way that this project will be managed by SU is the same that the NGS-SA was created and managed with funds from the SAMRC and the DSI. CERI at SU will procure bulk reagents from the genomics companies and distribute them to the other laboratories of the NGS-SA. This allows bulk discount orders to be approved, making genomics data generation more affordable and by decreasing the burden of procurement of the smaller laboratories of NGS-SA.
39. **CERI will also sub-contract ACEGID to support technological transfer in South Africa to Nigeria.** CERI will provide knowhow and support to ACEGID so ACEGID can analyze more samples and support the African continent together with CERI as the two specialized genomic facilities in Africa. However, the sub-contract to ACEGID will not exceed 10% of the total project costs and these costs will be allocated in the three main activities of the project.
40. **A project implementation support plan and a monitoring and evaluation system will be set up** at the start of the project. CERI will implement the monitoring and evaluation plan. A combination of tools will be used to monitor the implementation of the project. For example, the number of genomes submitted to the dashboard and to GISAID will be monitored weekly. Routine laboratory quality control procedures will also be in place to monitor the quality of the genome sequencing. Data will also come from routine project activity reports. The project results framework has eleven (11) indicators- three Project Development Objective (PDO) indicators and eight intermediate results indicators (IRI). One indicator will be reported monthly, and the rest semi-annually. The agreed indicators for monitoring and evaluating the overall performance of the project include:

Indicator Name	Baseline	End Target	Frequency
PDO 1. Number of sequences produced in South Africa and African region	0	20,000	Every six months
PDO 2. Number of staff and scientists who are able to produce genomic sequencing data	0	50	Every six months
PDO 3. Number of staff and scientists who are able to analyze genomic sequencing data	0	50	Every six months
Component 1: Expanding the NGS-SA capacity and training			
IRI 1. Number of meetings held	0	36	Monthly
IRI 2. Turnaround time of producing sequencing data	>15 days	<15 days	Every six months
IRI 3. Number of reagents to be procured for generating sequencing data	0	18,000	Every six months
Component 2: Establishing an effective system to evaluate diagnostics and vaccine effectiveness against the variants in Africa			

IRI 4. Operational protocol for rapid transportation of samples is developed	0	1	Every six months
IRI 5. Analytical protocol for evaluating the effectiveness of diagnostics and vaccines is developed	0	1	Every six months
IRI 6. Number of reagents to be procured for analysis of diagnostic and vaccine effectiveness	0	2,000	Every six months
Component 3: strengthening data systems to share and training public health officials and scientists for genomic sequencing data analysis			
IRI 7. A dashboard is produced to provide weekly update of genomic data and synthesis information on epidemiological and clinical and vaccination data	0	1	Every six months
IRI 8. Number of training sessions organized for capacity building of genomic sequencing data analysis	0	4	Every six months

41. **NGS-SA data generation follow strict biomedical ethics processes:** the genomic surveillance in South Africa was approved by the University of KwaZulu Natal Biomedical Research Ethics Committee (BREC/00001510/2020), the University of the Witwatersrand Human Research Ethics Committee (HREC) (M180832), Stellenbosch University HREC (N20/04/008_COVID-19), University of Cape Town HREC (383/2020), University of Pretoria HREC (H101/17) and the University of the Free State Health Sciences Research Ethics Committee (UFS HSD2020/1860/2710). The genomic sequencing in Botswana was conducted as part of the national vaccine roll-out plan and was approved by the Health Research and Development Committee (Health Research Ethics body, HRDC#00948 and HRDC#00904). Individual participant consent was not required for the genomic surveillance. This requirement was waived by the Research Ethics Committees. It's confirmed that all necessary patient/participant consent has been obtained and the appropriate institutional forms have been archived, and that any patient/participant/sample identifiers included were not known to anyone (e.g., hospital staff, patients or participants themselves) outside the research group so cannot be used to identify individuals.

G. Financial Management Arrangements

42. The Financial Management section of this manual is intended to act as a guidance and a reference document to CERI's core implementation team and the Research Grants Management Office on financial management arrangements in this project. This manual is also intended to ensure accountability, efficiency, flexibility, responsiveness, transparency, reliability, and resilience in achieving the project objectives. It should be read in conjunction with other project documents such as the Grant Agreement and the Disbursement and financial information letter (DFIL).
43. The overall responsibility for project financial management rests with Prof Tulio de Oliveira, the Principal Investigator on this project, supported by the Project Accountant based in the Research Grants Management Office of the University's Faculty of Medicine and Health Sciences (FMHS). The Project Accountant will provide the Principal Investigator with monthly financial reports. The Project Accountant will report to the Manager: Research Grants, Faculty of Medical and Health Sciences Grants Management Office. The Research Grants Management Office will:
- a. Prepare regular internal financial reports comparing budget vs actual expenses and discuss variances

- b. Projections to guide the Principal Investigator’s further decisions
- c. Invoice the World Bank/Draw down from the disbursement system as required and in line with the agreement documents
- d. Compile and submit financial reports as per contract to the World Bank within timelines noted in the agreement
- e. Process correcting journal entries as required
- f. Respond to other ad-hoc financial queries as required
- g. The finance department will ensure that expenses are in accordance with the Stellenbosch University’s financial policies and procedures

Project Costs and Budget

44. The total project estimated budget is US\$ 5 Million as indicated in the table below.

Table 1: Summary Project Budget

Project Components	Component Cost
Component 1: Expanding the NGS-SA Capacity and Training Staff for Genomic Sequencing Data Generation	US\$ 2,504,690
Component 2: Establishing an Effective System to Evaluate Diagnostics and Vaccine Effectiveness Against the Variants in Africa	US\$ 1,195,293
Component 3: Strengthening the Data Systems to Share and Training Public Health Officials and Scientists for Genomic Sequencing Data Analysis in Near-Real Time	US\$ 914,903
Component 4: Project Management, Monitoring and Evaluation	US\$ 385,114
Total	US\$ 5,000,000

Annual Work Plan and Budget

45. The annual budget will be prepared based on approved work plans which will be reviewed and approved by a technical team in the World Bank. Monitoring of the budget will be done through the review of the management reports and the interim unaudited financial reports (IFRs) which will be submitted to the World Bank on a quarterly basis. The project accounting system will be based on the University’s accounting system called “Tera Term”, until the scheduled change over in 2023 to “Oracle”.
46. The Recipient shall, **not later than November 30th of each year**, prepare and furnish to the Bank an annual work plan and budget (“Annual Work Plan and Budget”) for the Project for the subsequent year (1 April – 31 March), said Annual Work Plan and Budget of such scope and detail as the Bank shall have reasonably requested.
47. The Recipient shall afford the Bank a reasonable opportunity to review such Annual Work Plan and Budget, and thereafter, the Recipient shall carry out the Annual Work Plan and Budget as shall have been approved by the Bank. Only the activities included in the Annual Work Plan and Budget shall be eligible for financing.
48. The Annual Work Plan and Budget may be revised as required during Project implementation subject to obtaining the Bank’s prior written approval.

Internal Controls

49. **Internal Controls** – The project’s internal controls will be based on the Higher Education Act of South Africa and supplemented by the Operational Manual when the need arises. The RGMO under leadership of Mr Eugene Baugaard provided input in the preparation of this section of the Operations Manual.
50. **Internal Audit** – The value of the grant amount will require a single audit for the project specific activities for the life of the project. The audit report will be submitted to the Bank within 6 months after the close of the project. The audit report will disclose the information on activities financed by the grant. A detailed management letter containing the auditor’s assessment of the internal controls, accounting system and compliance with financial covenants in the Grant Agreement, suggestion for improvements, and management response to the letter will be submitted to the Bank together with the audited financial statements.
51. **Financial Reporting** - The Project Accountant will be responsible for producing on a regular basis the required financial reports to monitor and effectively manage the project. Cost centre financial reports will be produced on: (a) a monthly basis for internal review and reporting and (b) on a quarterly basis for submission **to the World Bank**. The quarterly **unaudited Interim Financial Reports (IFRs)** will be submitted to the World Bank through the Client Connection system, within 45 days after the end of each calendar quarter. The quarterly IFR will cover the entire project financial transactions within the quarter. The Project receipts and payments report for the quarter will be tailored to fit into the content and format agreed with the World Bank. A draft IFR will be shared with World Bank’s FM Specialist and Task Team Leader (TTL) for No-Objection before uploading in Client Connection.
52. **The Quarterly IFR report will be prepared in US Dollars and will be submitted not later than 45 days after the end of the financial quarter.** The contents of these reports should consist of:
- (i) Statement of Sources and Uses of Funds
 - (ii) Statement of Uses of Funds (Actual vs Budget for the quarter and cumulatively)
 - (iii) Designated Account Bank Statement
 - (iv) Designated Account Activity Statement (reconciled to cash balances)
 - (v) Designated Account Expenditure for Contracts not Subject to Prior Review
 - (vi) Financial forecast for the next six months
53. The university’s accounting system can produce quarterly reports. The reports will be submitted to the Principal Investigator with relevant supporting documentation within 30 days of the end of the reporting quarter. The reports are reviewed by the Principal Investigator. The final review is by the Manager of the Research Grants Unit at the Faculty of Medical and Health Sciences. Once approved the reports will be submitted to the World Bank, within 45 days of the end of the reporting period.
54. The World Bank FM Specialist gives clearance for the previous quarter’s expenditure report and the TTL gives no-objection for the next 6 months’ expenditure forecast.
55. The Research Grants Office of the university will produce annual project financial statements

on behalf of the project implementation unit, which will consist of:

- (i) A *Statement of Sources and Uses of Funds / Cash Receipts and Payments* that recognize all cash receipts, cash payments and cash balances controlled by the entity for this project and separately identifies payments by third parties on behalf of the agency.
- (ii) The *Accounting Policies Adopted and Explanatory Notes* should be presented in a systematic manner with items on Statement of Cash Receipts and Payments being cross referenced to any related information in the notes. Examples of this information include a summary of fixed assets by category of assets.
- (iii) A *Management Assertion* that the HEPR funds have been expended in accordance with the intended purposes as specified in the relevant World Bank Grant Agreement.

Funds Flow and Disbursement Arrangements

56. **Flow of Funds.** The agreed funds flow diagram is presented below and should be viewed in the context of the funds flow arrangements as well as disbursement arrangements described below.

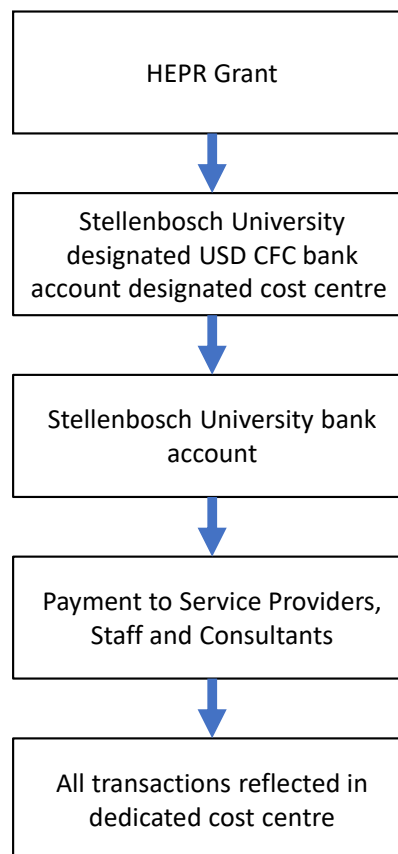


Figure 4: Flow of Funds

57. Upon the signing of the Grant Agreement, Stellenbosch University will open a segregated account in its books for World Bank Funds. Funds will flow from the World Bank into the USD Designated Customer Foreign Currency (CFC) Account at First National Bank. The designated cost centre will show expenditure in the local currency and will document all financial activities.

Banking Arrangements

58. **Designated Account:** A CFC account was opened at the First National Bank and denominated in USD. Disbursements from the World Bank Grant will be deposited in this account.

Disbursement Arrangements

59. Release of funds by the World Bank for project activities will be referred to as *disbursements*. The terms and conditions of disbursements are always specified in the Financing Agreement and the Disbursement and Financial Information Letter.
60. The project will use the Advance Disbursement Method whereby withdrawals from the grant account will be deposited in the Designated CFC Account. Disbursements from the CFC account will be based on quarterly IFR documentation to be prepared and submitted by RGM. Upon effectiveness of the grant agreement and submission of a withdrawal application, the World Bank will disburse an amount equivalent to six months expenditure into the Designated Account. Subsequent disbursements will be based on six-monthly estimated expenditure, considering the balance in the Designated Account at the end of the reporting period.
61. **External Audit** – The value of the grant amount will require a single audit for the project specific activities for the life of the project. The project financial statements will be audited by Ernst and Young, the contracted auditors of Stellenbosch University in accordance with the Higher Education Act requirements. The final project audit report will be submitted to the Bank within 6 months after the close of the project. The audit report will disclose the information on activities financed by the grant. A detailed management letter containing the auditor's assessment of the internal controls, accounting system and compliance with financial covenants in the Grant Agreement, suggestion for improvements, and management response to the letter will be submitted to the Bank together with the audited financial statements.
62. **Financial Governance and Accountability.** The project will have adequate financial management in place to ensure that funds are used for the purposes intended and to prevent material errors and fraud. The World Bank will review adequacy of project financial management during implementation review missions, and Stellenbosch University will ensure that adequate financial management is maintained through the implementation of the project.

H. Procurement Arrangements

63. The structure for procurement execution is as follows:

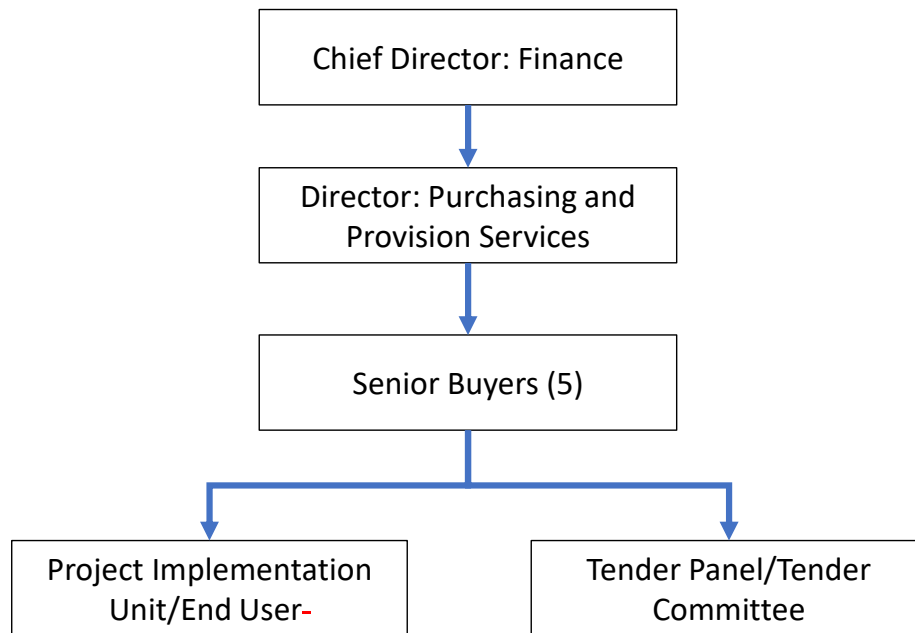


Figure 5: Procurement Process Flowchart

64. The roles/functions of the various committees/role players

- (i) **Tender Panel:** The tender panel is known as the Tender Committee of Stellenbosch University. The Tender Committee must see to it that the best possible conditions are negotiated for the University in the selection of all tenders that serve before the Tender Committee.
- (ii) The tender committee is determined by the department that is doing the purchase, in this case the CERI core implementation team. The tender committee must be approved by the Chief Director of Finance when purchasing products or services and for capital tenders in the terms of the Regulations regarding Delegation of powers and responsibilities.
- (iii) The Purchasing and Provision Services division fulfils a technical advisory and a compliance function regarding every tender committee, but no staff member of the Division Purchasing serves as a member of any tender committee.
- (iv) The Purchasing and Provision Division appoints a person to scrutinise tender specifications and to advise the Tender Committee on the tender process and risks involved in tenders.
- (v) The Tender Committee appoints a person as its secretary to take the minutes. The documents prepared as part of the minutes will include: (a) attendance register, (b) date of the meeting, (c) list of all matters considered, (d) the decision made for each matter, (e) the reasons for any rejections or clarifications, (f) a note on the basis for any evaluation made, (g) any conflicts of interest declared by members, (h) any dissenting opinions among members; and (i) such other records as may be necessary. The Tender Committee may invite independent advisers, and other technical staff, to explain submissions or provide technical advice, where required.

- (vi) The core implementation team staff roles include: (a) preparing the procurement plan and upload in the World Bank's Systematic Tracking of Exchanges in Procurement (STEP) system; (b) facilitate all procurement processes through the university's Central Procurement Unit; (c) draft specifications; (d) receive tender committee reports; (e) ensure that evaluation reports conform to World Bank policies and procedures; (f) coordinate contract negotiations with the support from the University's Central Procurement Unit and the University's Legal Services, (g) procurement record keeping; (h) coordinate contract management; (i) coordinate asset management with the university's asset management unit; (j) liaise with the World Bank Senior Procurement Specialist in relation to clarification or assistance during bidding processes; and (k) any other duties as dictated by the project activities.

Applicable Procurement Procedures

65. Procurement under the project will be carried out in accordance with the "World Bank Procurement Regulations for IPF Borrowers for Goods, Works, Non-Consulting and Consulting Services" dated November 2020 ("Procurement Regulations"). The procurement regulations are available on the World Bank website (www.worldbank.org). The project is subject to the World Bank's Anticorruption Guidelines, dated October 15, 2006, and revised in January 2011 and July 1, 2016. A comprehensive Project Procurement Strategy for Development (PPSD) has been prepared by the core implementation team. In accordance with paragraph 5.9 of the Procurement Regulations, the World Bank's STEP system will be used to prepare, clear and update Procurement Plans and monitor all procurement transactions of the Project.
66. The provisions in the "Regulations" shall precede the provisions in this manual, to the extent provided in the legal agreements and the procurement plan.
67. All project expenditure for procurement of goods, and services shall become eligible for reimbursement/disbursement by the World Bank only if they are procured as per laid down procedures of the World Bank in the aforementioned regulations and the approved Procurement Plan.
68. The World Bank may declare mis-procurement if goods & services are not procured as per agreed norms. If 'mis-procurement' is declared by the World Bank, this would result in non-reimbursement of the related expenditures by the World Bank and this may lead to deletion of the related amount from the Bank's grant amount for the Project. Therefore, officials associated with the procurement related activities shall be responsible and accountable for adhering to the World Bank's Regulations in procurement, as any lapse in procurement procedure will result in financial loss to the University.

Methods of Procurement and Related Thresholds and Prior Review Thresholds

69. **General Procurement:** As per the PPSD prepared by the core implementation team, the university will use the Open National Approach for Goods and Consulting Services, except for the purchase of reagents for which a Limited Market Approach will be used; with standard procurement documents for request for quotations (RfQ). The university will use the Direct National Approach for specialised goods and items for which the university has existing procurement contracts in place. The procurement documents of the university will be used. All items are subject to post review, and the procurement thresholds shall be as listed in the Procurement Plan, approved by the World Bank.

Table 2. Procurement Mechanisms to be used

Item to Procure	Procurement Mechanism	Evaluation Options
Verti Thermal cycler	Direct Selection	Direct-National
Laboratory Maintenance, Warranties & Licences	Direct Selection	Direct National
Chemagic 360 automated extraction system	Direct Selection	Direct National
Agilent Technology 2100 bioanalyzer	Direct Selection	Direct National
Nextseq 2000 Sequencer	Direct Selection	Direct National
Hamilton NGS STAR96	Direct Selection	Direct National
CAPTAIRBIO 320 PCR workstation	RfQ	Direct National
Laptops	RfQ	Direct National
High Performance Computing Server	RfQ	Direct National
Thermomixer C	RfQ	Open National
Printer	RfQ	Open National
Beckmann Coulter Ultra Centrifuge	RfQ	Open National
Class 2 Biosafety Cabinet	RfQ	Open National
Lab Multichannel Pipettes	RfQ	Open National
Lab Pipettes	RfQ	Open National
Reagents	RfQ	Limited
EIS Consultant	Individual Consultant	Open National

Procurement Methods

70. The methods of procurement to be used under this Project are described below. Threshold contract values for the use of each method are shown below.

71. **Conflict of Interest:** The World Bank requires that firms or individuals involved in the procurement under this project shall not have a conflict of interest. *More information on the Conflict of Interest can be found in the World Bank's Procurement Regulations for IPF Borrowers for Goods, Non-Consulting and Consulting Services dated November 1, 2020, par 3.14 – 3.17*

Description of Procurement Process for Consulting Services

Table 3. Methods for Consulting Services

Methods for Firms	
QCBS	Consultants Quality- and Cost-Based Selection
CQS	Consultant's Qualifications Based Selection
QBS	Consultants Quality-Based Selection
FBS	Fixed Budget Based Selection
LCS	Least-Cost-Based Selection
DS	Direct Selection
Methods for Individuals	
IC	Selection of Individual Consultants

72. The one consulting service contract (Environmental & Safety Consultant) for the project will be procured by the project using the Individual Consultant method below:

73. Consultant's Quality- and Cost-Based Selection (QCBS):

This is the method where the selection is based on the quality of the proposals and cost of services to be provided. This method is appropriate when the scope of work of the assignment is precisely defined and the TOR is well specified and clear; further an estimate for the staff time as well as the other inputs and cost required of the Consultants can be assessed with reasonable precision. QCBS is a competitive process among Shortlisted consulting firms under which the selection of the successful firm takes into account the quality of the Proposal and the cost of the services. Among the Proposals that are responsive to the requirements of the request for proposals document and are technically qualified, the Proposal with the highest combined (quality and cost) score is considered the Most Advantageous Proposal.

74. Direct Selection (DS) involves asking a specific consultant to prepare technical and financial proposals, which are then negotiated. Since there is no competition, this method is acceptable only in exceptional cases and made on the basis of strong and convincing justification where it offers clear advantages over the competition. Some circumstances can be:

- (i) The assignment represents a natural or direct continuation of a previous one awarded competitively, and performance of the incumbent consultant has been satisfactory.
- (ii) A quick selection of consultant is essential to address an emergency operation and crisis;
- (iii) Only one consulting organization has the qualification or experience of exceptional worth to carry out the assignment.

75. Selection of Individual Consultant: For hiring of individuals, it is necessary to finalize the job description, qualification, experience required, and terms of engagement. Thereafter an advertisement (if the assignment is complex) may be put into the newspapers indicating the above details. The applications received shall be scrutinized and a ranking shall be prepared. Thereafter the top-ranked individuals (number depending on how many applicants met the minimum requirements specified in the advertisement) shall be invited for interviews/discussions and would be offered the assignment.

76. The steps to be followed in the Selection of Individual Consultants:

- (i) Establish the need for the assignment and outsourcing the services vs employing an incumbent;
- (ii) Finalize the job description, qualification and experience required and terms of engagement or the preparation of the Terms of Reference (TOR);
- (iii) Preparation of cost estimate and the budget provision;
- (iv) Advertising (if the assignment is complex) or place a notice on the notice board of website disclosing your estimated cost;
- (v) Receipt of CVs (Minimum Three CVs are required) among those who have expressed interest in the assignment or have been approached directly by the Procuring Entity;
- (vi) Evaluate, scrutinize and rank CVs;
- (vii) Top-ranked individual/s shall be invited for negotiations and award of the contract to the selected consultant/applicant.

77. Preparation of the TOR: A well-defined TOR should be prepared specifying the services to be provided via the following: (i) Background information, (ii) A precise Statement of objectives, (iii) An outline of the tasks to be carried out, (iv) A time schedule for completion

of tasks, (v) The support / inputs provided by the Procuring Entity, (vi) Composition of Review Committee to monitor consultants work (vii) List of key personnel whose CV and experience would be evaluated; (ix) duration of the contract.

78. TORs will be approved by the Bank for all consultancy assignments covered under prior or post review.
79. **Preparation of cost estimate and budget:** based on assessment of the resources needed to carry out the assignment, staff time, logistical support, and physical inputs. Costs shall be divided into three broad categories: (i) fee or remuneration, (ii) reimbursable, and (iii) miscellaneous expenses. While preparing cost estimates, the scope of work indicated in the TOR shall be considered.
80. **Deciding the contracting** strategy viz. going for lump-sum or time-based contract, individual vs firm, advertising vs internal short listing, terms of payment etc. Depending on the decision made, one of the selection methods above will be chosen.
81. **Advertising** i.e. should the estimated value of the consultancy exceed or be equal to USD 300, 000, the Expression of Interest to be published in newspapers having wide circulation, one national & one regional newspaper and on the official website of the Project and the World Bank.
82. **Short listing of consultants** i.e. the expressions of interest received shall be evaluated based on the relevant qualifications and experience specified in the advertisement, to arrive at a shortlist of the consultants. The preparation of a shortlist of firms to provide Consulting Services is required for all selection methods except CQS and Direct Selection. The Borrower prepares the shortlist of firms that have expressed interest and have the relevant experience and managerial and organizational capabilities for the assignment. The shortlist shall include not fewer than five (5) and more than eight (8) firms. The Bank may agree to shortlist comprising a smaller number of firms when not enough qualified firms have expressed interest in the assignment, not enough qualified firms could be identified, or the size of the contract or the nature of the assignment does not justify wider competition. The following is not normally included in the same shortlist with private sector firms: a) UN Agencies; or b) SOEs or institutions and not-for-profit organizations (such as NGOs and universities), unless they operate as commercial entities that meet the requirements of Paragraph 3.23 b. of the World Bank Procurement Regulations. If such entities are included in the list, the selection should normally be made using QBS or CQS. The shortlist shall not include individual Consultants.
83. **Evaluation:** A Tender Committee consisting of a minimum of 3 members shall be formed, and this committee will evaluate the proposals received. The evaluation of the proposals shall look at both quality and the cost. The Tender Committee members shall evaluate the proposals individually and submit the report in the prescribed format, clearly indicating strengths and weaknesses of each proposal. The evaluation will be carried out in compliance to the terms and conditions outlined in the RfQ document and non-responsive proposals, if any, shall be kept outside the evaluation with clearly documenting the reasons.
84. **Combined Evaluation:** The combined evaluation of successful bids would be done by assigning 75 or 80 % weight to the technical score and 25 or 20% to the financial (application of weight for commercial offer will depend on the method used). The consultant scoring the

highest marks will be recommended by the Evaluation Committee for selection and invited for negotiations as per the terms and conditions of the RfQ document.

85. Negotiations and Award: Table 4 below presents a summary selection of consultants. It may be necessary to conduct negotiations with the selected consultant on the TOR, the methodology, staffing, and special conditions of the contract. The firm obtaining the highest total score should be invited for negotiations and discussions. These discussions shall not substantially alter the original TOR or the terms of the contract, lest the quality of the final product, its cost, and the relevance of the initial evaluation be affected. In methods where price is a factor of the selection (QCBS, FBS and LCS), no negotiations can be held on unit rates. Based on the final negotiated TOR and contract, an award is made to be selected Consultant.

Table 4: Summary of Process Steps, Roles and Timelines for Selection of Consulting Services under QCBS

Request for Quotations	Action by	Documents to be filled	Timelines
TORs	End user/CERI Principal Investigator or his representative/Procurement Unit	TORs approved by World Bank	14 days
Invitation to Identified Consultants to provide quotation	Procurement Unit	Email (showing names of consultants/companies) inviting consultants to provide quotations	5 days
Receive Quotations	Procurement Unit/End user/CERI Principal Investigator	Summary list of quotations received	21 days from Invitation
Shortlist Quotations	Procurement Unit, End User, CERI Principal Investigator or his representative	List of shortlisted consultants	4 days
Draft Negotiated Contract	End User/Legal Services	Draft Contract	14 days
Notice of Award issued	End user/CERI Principal Investigator or his representative/Procurement Unit	Letter to Consultant, informing of intention to award. Letters to unsuccessful candidates informing them of the outcome, and of who the successful candidate was.	1 day
Contract signed	End user/Legal services	Signed Contract	14 days
Contract Implementation and Management	End user/CERI Principal Investigator or his representative	Implementation Documents/Monthly or Quarterly reports/Invoices	Dependent on duration of contract
Payment of Consultants	Consultant, End user, Procurement Unit (issue of PO), Debtors	Signed Invoice approved by Principal Investigator/Purchase Order	30 days from date of invoice
Contract Close Out	End user/ CERI Principal Investigator or his	Close Out Report.	7 days

	representative/Legal Services		
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86. **Rejection of All Proposals and Re-Invitation:** Rejection of all proposals and re-inviting new proposals, shall be referred to the CERI core implementation team at the project level and shall be subject to the Bank’s No Objection.

Table 5: Thresholds for Prior Review, Procurement Approaches and Methods

A. Goods, Works and Non-Consulting Services: Moderate Risk Project				
Category	Prior Review (USD millions)	Procurement Approaches and Methods (USD millions)		
		Open International	Open National	Request for Quotation (RfQ)
Works	≥ 10	≥ 20.0	< 20	≤ 0.2
Goods, IT, and non-consulting services	≥2	≥5.0	<5.0	≤ 0.1
B. Consulting Services				
Category	Prior Review (USD millions)	Short List of National Consultants (USD million)		
		Consulting Services		Engineering and Construction Supervision
Consultants (Firms)	≥ 1	≤ 0.3		≤ 0.3
Individual Consultants (IC)	≥ 0.3	NA.		NA.

87. Any Direct Selection contract shall be agreed for inclusion in the procurement plan. Where the cost falls under the prior review thresholds, they shall not be subject to prior review.

88. The technical aspects of procurement documents including technical specifications and non-legal TORs are reviewed and cleared by the university’s procurement unit. Bank procurement clears all Terms of Reference and the proposed selection of consultants for project-related procurement, financial and for the project coordinator activities, or any other positions included in the conditions of the Grant Agreement.

Description of Methods of Procurement for Goods and Non-Consulting Services

89. **Open National Approach** (Section V of Regulations): An Open National approach is the competitive bidding procedure normally used for national level public procurement and may be the most appropriate method of procurement of goods, works and non-consulting services which, by their nature or scope, are unlikely to attract foreign competition. Under this approach, the university’s own procurement documents may be used. However, such documents must be reviewed and found to be consistent with the Bank’s core procurement principles, anti-corruption guidelines, sanction framework and contractual remedies. Open National Approach is the most appropriate method of procurement where foreign bidders are not expected to be interested because:

- a. Of the size and value of the contract,
- b. the goods, works and non-consulting services are available locally at prices below the international market, and
- c. works are labour intensive, and scattered geographically or spread over time

90. However, foreign bidders are not to be precluded from participation if they wish to bid and are agreeable to accept Open National terms and conditions as applicable to local bidders. The following conditions apply to the Open National approach:

- a. Only the Standard Procurement Document agreed with the World Bank (and as amended from time to time), shall be used for bidding;
- b. Request to bid shall be advertised in at least one widely circulated national daily newspaper (or on a widely used website or electronic portal with free national and international access along with an abridged version of the said advertisement published in a widely circulated national daily inter-alia giving the website/electronic portal details from which the details of the invitation to bid can be downloaded), at least 30 business days prior to the deadline for submission of the bids;
- c. No special preferences will be accorded to any bidder either for price or for other terms and conditions when competing with foreign bidders, state owned enterprises, small scale enterprises or enterprises from any given state;
- d. Extension of bid validity shall not be allowed with reference to Contracts subject to Bank's prior review without the prior concurrence of the Bank (i) for the first request for extension if it is longer than four weeks; and (ii) for all sequent requests for extension irrespective of the period (such concurrence will be considered by Bank only in cases of Force Majeure and circumstances beyond the control of the Purchaser/Employer).
- e. Re-bidding shall not be carried out with reference to Contracts subject to Bank prior review without the prior concurrence of the Bank. The system of rejecting bids outside a pre-determined margin of prices shall not be used in this project;
- f. Negotiations are not to be conducted even with the lowest evaluated responsive bidders (other than for consultancy services).
- g. No pre-qualifications will be conducted for goods and works.

Table 6: Summary of Process Steps, Roles and Timelines for Procurement of Goods, Non-Consulting Services - Request for Quotation

RfQ documents (Goods)	Action by	Documents to be filled	Timelines
Specifications	End user/CERI Principal Investigator or his representative/Procurement Specialist and Procurement Unit	Specification Form	5 days
Prepare and publish short list and RfQ	Principal Investigator or his representative/Procurement Specialist and Procurement Unit	RfQ	5 days
Receive Quotations	Procurement Unit	Received quotations	30 days
Evaluation of Quotations	End user/CERI Principal Investigator or his representative/Procurement Unit (3 – 5 officers)	Signed evaluation report by evaluation team	5 days
Award Notification	Principal Investigator, Procurement Specialist/Procurement Unit	Signed award letter by Principal Investigator	1 day
Issue of Award Letter and Contract	End user/Legal services	Signed Contract	14 days
Contract Implementation & Management	End user/CERI Principal Investigator or his representative	Implementation Documents/Monthly or Quarterly reports/Invoices	Dependent on duration of contract
Payment of Suppliers	Contractors, End user, Procurement Unit (issue of PO), Debtors	Delivery Note and Signed Invoice approved by Principal Investigator and Purchase Order	30 days from date of invoice
Contract Close Out	End user/ CERI Principal Investigator or his representative/Legal Services	Close out report with supplier performance contract	7 days

Direct Selection

Table 7: Summary of Process Steps, Roles and Timelines for Procurement of Goods, Works, NCS and CS under Direct Selection

TENDER, RFQ Documents (Goods, Works)	Action by	Documents to be filled	Timelines
Specifications, Bill of Quantities/Schedule of works, TORS	End user dept, Principal Investigator, Procurement Specialist and Procurement Unit	Cleared Specifications, BOQs/Schedule of Works and TORs by World Bank	5 days
Prepare and Submit Justification for Direct Selection	Principal Investigator, Procurement Specialist and Procurement Unit	Cleared Justification by World Bank	5 days

Invitation for Bid, Quotation, Proposal	Procurement Unit	Request for bid, quotations, proposal	1 day
Receive Bids, Quotations, Proposal	Procurement Unit	Received Bids, Quotations, Proposal	21 days
Evaluation of bids, Quotations, Proposal	Procurement Unit, Procurement Specialist, End User Department & Technical Officer (3 to 5 officers)	Signed evaluation report by evaluation team	5 days
Award Notification	Principal Investigator or his representative, Procurement Specialist/Procurement Unit	Signed award letter by Principal Investigator	1 day
Contract Negotiation	Procurement Unit, Procurement Specialist, End User & Technical officer (3 – 5 officers)	Signed minutes of negotiations and contract	5 days
Issue of Award Letter and Contract	Principal Investigator or his representative, Procurement Specialist, Procurement Unit	Signed Contract by University's authorised representative	14 days
Contract Implementation & Management	End user/CERI Principal Investigator or his representative	Implementation Documents/Monthly or Quarterly reports/Invoices	Dependent on duration of contract
Payment of Suppliers, Contractor, Consultant	Supplier, Contractor, Consultant, End user, Procurement Unit (issue of PO), Debtors	Delivery Note, Signed Invoice approved by Principal Investigator and Purchase Order	30 days from date of invoice
Contract Close Out	Contractor, End user, CERI Principal Investigator or his representative, Legal Services	Close out report with supplier/contractor/consultant performance contract	7 days

General requirements for Procurement related complaints

91. A complaint may challenge:
- a. The University's selection documents, including prequalification, initial selection, request for bids, requests for proposals documents;
 - b. The University's decision to exclude an Applicant/Bidder/Proposer/Consultant from a procurement process prior to award;
92. Complaints shall be submitted in writing to the University in a timely manner and shall identify the name, contact details, and address of the complainant. In addition, the Complaint shall:
- a. Generally, identify the complainant's interest in procurement;
 - b. Identify the specific project, the procurement reference number, the current stage of the procurement process, and any other relevant information;
 - c. Specify any previous communication between the complainant and the University on the matters addressed in the complaint;
 - d. Specify the nature of complaint, and the perceived adverse impact on them; and

- e. State the alleged inconsistency with or violation of the applicable procurement rules.
93. The Procurement Official will refer the appeal to the University's Legal Services Department, in copy to the Tender Committee for further advice and action.
94. The University shall give prompt and fair consideration to each complaint that meets the requirements of the above provisions of and is submitted within the timelines set forth.
95. Complaints that do not meet the requirements should be addressed within a reasonable time. If such complaints relate to contracts subject to prior review by the Bank, they shall be shared by the University with the Bank in order to determine an appropriate course of action.

Timeline and process for review and resolution of complaints

96. Complaints challenging the terms of prequalification/initial selection documents: request for proposals documents, and any other University documents requesting Bids, Proposals or Applications should be submitted to the University at least ten (10) business days prior to the deadline for submission of Applications/Bids/Proposals, or within five (5) business days after the issuing of any amended terms, whichever is later. The University shall acknowledge in writing the receipt of the complaint within (3) business days and shall review the complaint and respond to the complainant not later than seven (7) businesses days from the date of receipt of the complaint. If as a result of the University's review of the complaint, the University decides to modify the prequalification/initial selection, request for bids/request for proposals, or other documents, the University shall issue an addendum, and if necessary, extend the application/Bid/Proposal submission deadline.
97. Complaints challenging the exclusion from a procurement process prior to contract award should be submitted to the University within ten (10) business days following the University's transmission to the interested party of notice of such exclusion. The University shall acknowledge in writing the receipt of the complaint within (3) business days and shall review the complaint and respond to the complainant not later than seven (7) business days from the date of receipt of complaint. If as a result of the University's review of a complaint, the University changes the results of the earlier stage/phase of the procurement process the University shall promptly transmit a revised notification of evaluation results to all relevant parties advising on the next steps.

Roles and Responsibilities of the University in complaints

98. The roles and responsibilities of the University are the following:
- a. Provide timely and sufficient information to Bidders/Proposers/Consultants;
 - b. Promptly acknowledge complaints received;
 - c. Resolve complaints promptly and fairly;
 - d. Preserve the confidentiality and proprietary information of applicants/bidders/proposers/consultants;
 - e. Maintain complete records of all debriefings and complaints and their resolution;
 - f. For contracts subject to prior review, inform the Bank promptly of any complaint submitted and provide the Bank a copy of all relevant documents and information; and
 - g. For contracts subject to prior review, consult with the Bank promptly and forthrightly throughout the complaint review and resolution process.

Table 8: Summary of Process Steps, Roles and Timelines for Resolution of Complaints

Type of Complaint	Complainant		University	
	Roles	Timelines	Roles	Timelines
Challenging the terms of prequalification/initial selection documents	Submission of complaint	10/5 days depending on type of complaint	Acknowledge and respond after review	3 days for acknowledgement and 7 days after review
Challenging the exclusion from a procurement process prior to contract award	Submission of complaint	10/5 days depending on type of complaint	Acknowledgement and response after review	3 days for acknowledgement and 7 days after review

99. **Record Keeping.** The CERI Grants Office shall record all processes involved during implementation of the procurement process, from the request for services until the contract completion. All records shall be maintained electronically and must be easily retrievable when the need arise during contract implementation and audits. The procurement file should include as a minimum the following documentation:

- a. Final bidding document (RfQ/RfB/RfP)
- b. Clarification correspondence with the bidders, if any
- c. Amendments to the bidding documents, if any
- d. Bids submission register (where applicable)
- e. Minutes of bids opening session
- f. Signed Conflict of Interest declaration forms
- g. Approved evaluation report
- h. Signed letter of award
- i. Copy of signed contract
- j. Copies of variation orders
- k. Delivery Notes
- l. Goods Received Note
- m. Payment invoices
- n. Copy of proof of payment
- o. Any pertinent documents and correspondence until contract closure

100. All this documentation shall also be in STEP.

101. Procurement subject to post review. Procurement documents, including solicitations of price quotations, evaluation sheets and contract awards will be kept by the Grants Management unit of CERI for periodic review by the World Bank supervision missions. The procurement post review audits to review the correctness of the procurement activities will be carried out during the first supervision mission after the procurement activities are completed. However, the World Bank reserve the right to conduct its procurement audit at any time during the program implementation. This review will determine the need for modifications and improvements of the procurement arrangements. The procurement files will be maintained for review by the World Bank's supervision mission and independent auditing, including consolidating procurement activities into Bi-annual and Annual Progress Reports.

102. **Procurement Reporting.** The CERI Grants Manager, with input from the RGMO, shall prepare bi-annual and annual procurement reports detailing procurement progress against the procurement plan. The report shall cover: a) The status of each package in the

procurement plan; b) Procurements in Process which include all procurements initiated by contracts not yet signed, signed contracts or cancelled Procurements and; c) All contracts that were signed during the quarter and procurements that were cancelled after initiation; d) Completed contracts which show all contracts that were completed during the quarter and; e) All payments and securities released. The report shall be submitted to the Principal Investigator for endorsement and record keeping.

I. Environmental and Social Risk Management Compliance

103. The environmental and social risk management instruments to manage and mitigate the potential project impacts and risks that have been prepared and publicly disclosed include the Environmental and Social Management Plan (ESMP). Other tools/instruments include the Labour Management Procedures (LMP) as part of the ESMP, the Stakeholder Engagement Plan (SEP) ([Stakeholders Engagement Plan \(SEP\) SU 20220203TdO \(krisp.org.za\)](#)), and the Environmental and Social and Commitment Plan (ESCP). Stellenbosch University will ensure compliance with the World Bank Environmental and Social Standards (ESSs). To that effect, the ESCP for the project sets out a summary of the material measures and actions that will be taken during project implementation as well as the timing for each of these measures and actions.
104. The SEP required in-depth site-specific consultations and was updated, adopted and implemented within ninety (90) days after project effectiveness. It will be promptly re-disclosed by Stellenbosch University once updated and within 90 days of project effectiveness. Thereafter, it will be implemented throughout the Project and updates as required. Stellenbosch University are accountable and responsible for ensuring that the SEP is incorporated into the project's management system, and that adequate staffing and budget is allocated to implementing the SEP. The SEP is to be updated throughout the life cycle of the project and re-disclosed when significant changes are made, for example a change in stakeholders or project scope.
105. The environmental and social risk management instruments are living documents to be updated from time to time during Project implementation, to reflect adaptive management of Project changes and unforeseen circumstances or in response to assessment of Project performance. Revised instruments will promptly be redisclosed.
106. Implementation of the material measures and actions set out in the ESCP will be monitored and reported to the Bank by Stellenbosch University as required by the ESCP and the conditions of the legal agreement, and the Bank will monitor and assess progress and completion of the material measures and actions throughout implementation of the Project.
107. Where Project changes, unforeseen circumstances, or Project performance result in changes to the risks and impacts during Project implementation, Stellenbosch University shall provide additional funds, if needed, to implement actions and measures to address such risks and impacts, which may include environmental, health, and safety risks and impacts.

Relevant Environmental and Social Standards

108. To address any potential negative environmental and social impacts and risks of this health systems strengthening for human capital development project the following standards are relevant: ESS1 (Assessment and Management of Environmental and Social Risks and Impacts), ESS2 (Labor and Working Conditions), ESS3 (Resource Efficiency and Pollution

Prevention and Management), ESS4 (Community Health and Safety), and ESS10 (Stakeholder Engagement and Information Disclosure). The applicability of the E&S standards is detailed below:

ESS 1 – Assessment and Management of Environmental and Social Risks and Impact

The Project could potentially have a significant adverse effect on the environment, the affected communities, the public or workers. During implementation, the main risks could include, for example, chemical spills within the laboratory; exposure of staff to hazardous substances; breach of security of databases containing results of sequencing; loss of samples in transit between countries.

The ESMP will set out principles, rules and guidelines and procedures to assess and manage expected environmental and social risks and impacts during project implementation.

ESS10 – Stakeholder Engagement and Information Disclosure

109. Stakeholder engagement is a principal tool for environmental and social risk management and successful implementation of the project. An inclusive draft SEP is required (including a Grievance Redress Mechanism [GRM]). The SEP shall identify all key existing and potential stakeholders, and will describe, among others, their level of interest, influence and support to the project and in its planning and implementation.

ESS2 – Labor and Working Conditions

110. The majority of the project's labor footprint will comprise the existing laboratories and laboratory personnel and University employees with the exception of a skilled Environmental and Social Impact Consultant. Labor camps are not anticipated as the project is likely to involve no civil works and the workers are expected to be residing in their homes at the relevant project location. A Labor Management Procedure (LMP), which illustrates types of workers to be engaged and their management in line with ESS2 and national labour laws and regulations, has been developed as part of this ESMP. Labour influx is not anticipated and social risks such as Gender Based Violence (GBV), sexual exploitation and abuse (SEA) within the project workforce are not envisaged as a possibility.

ESS3 – Resource Efficiency and Pollution Prevention and Management

111. The ESMP includes guidance with regards to waste management and resource efficiency and pollution prevention and management. A waste management plan and standard operating procedures will be prepared to address the disposal of general, biohazard and liquid waste, and recommend how these will be applied and monitored. In addition, the design of the CERI Laboratory will be prepared in a way to contribute to climate co-benefits, including use of energy efficient and sustainable technologies (e.g., solar panels, insulation, refrigeration system, LED lighting, etc.).

ESS4 – Community Health and Safety

112. While the implementation of the Project will have a small footprint, the incremental risks to the public health and safety and potential exposure to operational accidents will be considered. Traffic safety measures will be covered under the ESMP. As there are no construction works, labor influx is not anticipated; however, the ESMP will include clauses to avoid, minimize, manage and mitigate any SEA and GBV risks.

Responsible entities for implementation of E&S risk management

113. The environment and social requirements will be implemented by Stellenbosch University with support of an Environmental and Social Impact Consultant. The Environmental and Social Impact Consultant will report to the Principal Investigator (PI). CERI core implementation team will coordinate effective implementation of the project and serve as the vehicle for capacity building and skills transfer to other Stellenbosch University staff in the areas of FM, Procurement, E&S Risk Management, and M&E. An Environmental and Social Impact Consultant will be recruited to provide support in the implementation and monitoring of E&S requirements in the project. Stellenbosch University will play a principal role in the coordination, monitoring and supervision of E&S risk management activities.

Development of E&S Instruments

114. As an initial step, Stellenbosch University has prepared an ESCP which commits Stellenbosch University to environmental and social responsibility in as far as the project is concerned. The ESCP takes into account the findings of the Bank's environmental and social due diligence and the results of engagement with stakeholders, and it forms part of the legal agreement between the Bank and Stellenbosch University. An ESMP for the project will be developed to guide the development of management plans, procedures and/or guidelines needed for effective management of environmental and social impacts and risks assessed. The ESMP will be prepared to include Labour Management Procedure for managing labour related issues, training and capacity building plan, Community Health and Safety Plan and reference to the waste management component of the Infection Control and Waste Management Plan under the Project. A SEP has been prepared and will be updated and finalized for continual engagement with key stakeholders under the project.

Consultations and Disclosure

115. Stakeholder engagement is a principal tool for environmental and social risk management and successful implementation of the project. Consultation with project affected people, subject-matter experts and NGOs during the preparation and implementation of the ESMP is critical for projects with Substantial Risks. The SEP developed under the project guides all consultation under the project. It provides the principles, objectives, stakeholder groups, engagement methodologies, tools, findings, grievance redress, disclosure requirements and engagement plan under the project. This is an E&S requirement under the World Bank E&S Standards.

Monitoring and Reviews

116. Monitoring and review of E&S risk management will be aligned to the project monitoring and evaluation plan. Continuous environmental and social monitoring will be done by the Environmental and Social Impact Consultant to be engaged by Stellenbosch University. This will be done as per ESS 1 and associated plans and monitoring schedules. Contractors will be required to engage health and safety personnel to ensure compliance to environmental and social management requirements. The World Bank Environmental and Social Team will provide remote support and through missions visit the project and sites for periodic monitoring and review purposes. Stellenbosch University will also monitor the project through the review of project compliance reports and site visits.

Training and capacity building to address environmental and social risk management issues

117. The following training/ awareness and capacity building programs will be conducted with the implementing team and repeated throughout the lifecycle of the project:

- i. Orientation on Project plan, objectives, processes and expected outcomes to improve buy-in and support;
- ii. Training on project plans i.e., Environmental and Social Commitment Plan, Stakeholder Engagement, Communication plans and Grievance Redress Mechanism, Labor Management, Waste and Pollution Management, Community Health and Safety plans;
- iii. Specific training on related legislation including Occupational Safety and Health and Workmen's Compensation Act will be facilitated for the implementing team.
- iv. Specific training on Waste Management Methods, Waste Segregation and Waste Minimization will be done for laboratory personnel.

Grievance Redress

118. In compliance with the World Bank's ESS 10, a project-specific GRM is being set up by Stellenbosch University to handle concerns, complaints, suggestions and questions raised by stakeholders, the general public or the community. Any labor related grievances will be addressed in accordance with the LMP and the established Stellenbosch University Grievance Procedure policy. Stellenbosch University is responsible for ensuring the project workers GRM is functional and consistent with ESS 2 of the World Bank's ESF. The overall project GRM is not simply limited to receiving complaints and should receive any project related feedback and comments from project workers and stakeholders.

119. In the case of a complaint, the complainant always retains the right to take the matter to the appropriate legal or judicial authority as per the laws of South Africa at any point in time. The overall objectives of Project's GRM are to:
 - Provide a transparent process for timely identification and resolution of issues affecting the stakeholders; and
 - Strengthen accountability to beneficiaries, including project affected people.

120. **Scope of the Project GRM:** Stakeholders and other interested parties may raise questions, comments, suggestions and/or complaints, or provide any feedback on all activities funded by the project. The complaints or suggestions may be in relation to several factors relating to the environmental and social impacts and/opportunities presented by the project, including and not limited to:
 - Health and safety risks;
 - Negative impacts on the environment; and
 - Unacceptable behavior by staff or employees.

121. **Set up and Management of Project GRM:** The Project's GRM should be operational on project effectiveness and maintained throughout project implementation.

122. The GRM will be proportionate to the potential risks and impacts of the project and will be accessible and inclusive. The issues related to Health services touch everyone in South Africa even though only the priority health facilities will be the focus of this project. However other services including services to do with supply chains, referral systems, training of staff at various levels, etc., will face a lot of scrutiny by both the public and other agencies. Therefore, the project GRM will be set up and managed by the implementing team, with its day-to-day functions being managed by the Principal Investigator. The PI will appoint a dedicated staff to manage the GRM. The roles and responsibilities related to the GRM staff will be reflected in the updated SEP.

123. **Process of Receiving and Resolving Complaints:** The GRM is the primary and sole mechanism through which all project related grievances must be managed. The CERI website will include information on how feedback, questions, comments, concerns and grievances can be submitted by any stakeholder. It will also provide information on the way grievances will be handled, both in terms of process and deadlines.
124. **How to file a complaint:** The implementing team will provide the channels where stakeholders can make a complaint by phone, email, or in person to the Principal Investigator or other staff assigned to work on the GRM. The project will ensure the availability of all channels and accessibility to the complainant contact.
125. **Receiving and recording complaints:** On receiving a complaint, the responsible Project staff will acknowledge receipt to the complainant and record the complaint within 2 business days. The person receiving complaints will fill out the complaint form (example of a complaint form provided in the SEP and CERI Grievance Redress Mechanism Standard Operating Procedure) ([Microsoft Word - SOP CERI Grievance Procedures V1.0 20 September 2022.docx \(krisp.org.za\)](#)). In cases where the complainant prefers to remain anonymous, acknowledgment is not required, and the complaint will be recorded and automatically referred to the Principal Investigator who will determine how to proceed. The manner of how anonymous complaints are resolved is reported in the public progress implementation report to demonstrate that the grievance has been heard and treated despite the fact that it was anonymous. Upon registration of non-anonymous complaints, the GRM staff will investigate the issue themselves or refer the issue for resolution or mediation.
126. **Confidentiality and conflict of interest:** Complaints can be made anonymously. Confidentiality is a fundamental aspect of the project and ensuring confidentiality, accountability and anonymity is particularly critical in the case of GBV/SEA/SH complaints. The Principal Investigator must ensure there is no conflict of interest in the case of staff involved in investigating and resolving disputes. With respect to GBV/SEA/SH type complaints, the established procedures at Stellenbosch University will be followed.
127. The aim is to resolve all grievances within two (2) weeks. Any grievance which is not resolved within that timeframe will be reported in detail in the monthly Project Unit report and flagged in quarterly reports to the World Bank. All grievances will be aggregated to track trends for managerial response and be included in quarterly reports to the World Bank.
128. **Review complaints or/and questions:** Complaints must be followed up on within ten (10) working days with the objective of resolving all grievances within two (2) weeks. The person who oversees investigating complaints will gather the facts to understand the nature of the complaint, determine if it is project related, establish its legitimacy and seek to identify possible resolution strategies.
129. Investigation/follow-up can include site visits, document review, and meetings with parties who can solve the problem. The results of the investigation and response will be submitted for consideration to the Principal Investigator, who will decide what action to take. After a decision is made, and the complainant receives the information, the responsible staff will explain the action to be taken in the complaint form as well as details of the investigation and findings.

130. **Response to complaints:** The complainant will receive notification of receipt of complaint by e-mail. Responses are made in answer to a question based on the materials of the investigation and, if appropriate, will refer to national law. If more time is needed to investigate / resolve the complaint, the deadline of investigating complaints can be extended up to 30 business days by the Principal Investigator, and the complainant must be informed whether:
- a) Additional consultation is needed to respond to a complaint; and
 - b) Complaints need to be answered by complex information and need to learn additional materials to respond.
131. If the matter remains unresolved, or complainant is not satisfied with the outcome at the project level, the complaint will be referred for arbitration to an impartial senior executive member from each respective organization who is not involved in the project. Project Affected Parties (PAPs) / stakeholders also have the option to take their respective case/s directly to the established legal system as provided by South African law.
132. **Awareness raising:** Information about the GRM will be provided in an accessible format. It will be made available on the website and will be included in communication with stakeholders.
133. **Staff roles and responsibilities:** The Principal Investigator will assign roles and responsibilities to implementation team and GRM staff. Key responsibilities are listed below. Detailed guidance on the GRM is set up in the SEP.
- Management of the entire GRM system
 - Development and maintenance of the improvement of awareness
 - Collection of the complaints
 - Recording the complaints
 - Notification to complainants about receipts and deadlines for reviewing complaints
 - Sorting / categorizing complaints
 - Decision making based on the observation
 - Processing appeals or ongoing communication to complainants with the aim of resolving the issue peacefully
 - Publishing the responses to a complaint (need to be confirmed by the complainant)
 - Organizing and applying information delivery and awareness raising campaigns
 - Reporting and handling GRM results.
134. **Capacity building:** All parties involved in the SEP will attend a workshop that will orient everyone about the Project and appraise all individuals of responsibilities and reporting structures before project activities begin. A specific training will also be held for persons involved in the GRM and a manual will be developed for these users setting out how to classify complaints, where to escalate different categories of grievances received etc. Further, within the first year and continuing throughout the project duration, Stellenbosch University will design and implement targeted training for the implementation team and other entities responsible for Project implementation, focused on the Environmental and Social Framework (ESF) including but not limited to:
- World Bank procurement provisions for environment and social aspects of the ESF;
 - ESS 1 including specific aspects of environmental and social assessment;

- ESS 3 including health care waste management;
- ESS 4 including Emergency preparedness and response; and
- ESS 10 including stakeholder mapping and engagement;
- Other relevant contents that are deemed important for training purposes related to the Project Scope of work.

Transparency, Monitoring, and Reporting:

135. **Transparency:** Regular policies, procedures, and updates on the GRM system, complaints made and resolved, will be available on the CERI website. This component will be updated every mid-year.
136. **Routine internal monitoring and reporting:** The Principal Investigator will assess the GRM function on a quarterly basis to:
- Make summaries of GRM results on a monthly & quarterly basis, including suggestions and questions, to the project team and management.
 - Review the status of complaints that have not been resolved and suggest corrective actions as needed.
 - On the quarterly meeting, there will be a discussion and review of the effectiveness and use of GRM and collect suggestions on how to improve it.
137. **Submitting the midterm and annual progress report to the World Bank:** In the midterm (semester) and annual implementation reports that are submitted to the Bank, Stellenbosch University will include GRM results, which provide the latest information as follows:
- Status of GRM formation (procedures, staffing, awareness raising, etc.);
 - Number of complaints received and their status – whether resolved, pending or otherwise;
 - Types of complaint and resolutions given, unresolved problems and reasons;
 - The time needed to resolve complaints;
 - Any special problems solved by procedures/staffing;
 - Factors that can influence the use of the GRM / beneficiary feedback system; and
 - All corrective actions used.

World Bank Grievance Redress System:

138. Communities and individuals who believe that they are adversely affected by a project supported by the World Bank may also send complaints directly to the Bank through the Bank's Grievance Redress Service (GRS).
139. A complaint can be submitted to the Bank GRS through the following channels:
- Email: grievances@worldbank.org
 Fax: +1.202.614.7313
 Mail: The World Bank, Grievance Redress Service, MSN MC10-1018, 1818 H Street, Northwest, Washington, DC 20433, USA.
140. Complaints should be supported by available documentation and correspondence to the extent possible. The complainant may also indicate the desired outcome of the complaint. Finally, the complaint should identify the complainant(s) or assigned representative/s and provide contact details. Complaints submitted via the GRS are promptly reviewed to allow quick attention to project-related concerns.

141. In addition, project-affected communities and individuals may submit complaints to the World Bank's independent Inspection Panel, which will then determine whether harm occurred, or could occur, as a result of the World Bank's non-compliance with its policies and procedures. Complaints may be submitted to the Inspection Panel at any time after concerns have been brought directly to the World Bank's attention, and after Bank Management has been given an opportunity to respond. Information on how to submit complaints to the World Bank Inspection Panel may be found at www.inspectionpanel.org.

Monitoring Arrangement for Effective Environmental and Social Management

142. To ensure that the proposed mitigation measures have the intended results and complies with the World Bank requirements, an environmental and social performance monitoring program will be carried out. This can be achieved through daily and more sequenced monitoring by the Environmental and Social Impact Consultant and Stellenbosch University.
143. **Operation Phase Monitoring** - It is envisaged that operations phase of the proposed project and may present certain measures of environmental and social risks and impacts. Monitoring during the operational phase will be carried out more frequently especially during the first year of operation to ensure that any complaints about the project are readily captured and resolved.

J. Monitoring and Evaluation (M&E)

Routine monitoring of project results and progress towards the PDO and Intermediate indicator targets will be supported by the Results Framework (see annex 2). CERI, will monitor, verify and report on the achievement of results, with the necessary protocols for each indicator, in a timely and comprehensive manner. A member of the CERI core implementation team will be responsible for ensuring effective monitoring of project activities and support the reporting function of CERI. The project will use data from the CERI project management database, which tracks all samples processed in the laboratory, the public genome repository (GISAID), CERI training database and meeting minutes.

144. A baseline assessment of all the project indicators as defined in the RF will be conducted by the CERI within six (6) months of project effectiveness. CERI's Head of Research Support will ensure that a detailed indicator protocol is developed for all RF indicators to specify counting procedures and specific elements in data sources from where data will be collected. The indicator protocol shall be used to update the project M&E plan as an addendum and shall guide baseline data assessment and all subsequent reporting on RF indicators for the duration of the project. For indicators that require revision of data sources and/or development of new data sources, CERI will ensure that this is identified early, and necessary consultations made with relevant Stellenbosch University programs before effecting the changes. Any proposed changes to the project results must be discussed and agreed with the WB technical team as a formal restructuring process may be required.
145. To measure the extent to which project outcomes are being met, CERI shall conduct mid-term evaluations in line with World Bank procedures mid-way and an end-term evaluation as required at the end of implementation. The results of both evaluations shall be shared with World Bank accordingly in formats agreed between the CERI and the World Bank.

The Borrower shall furnish to the Bank each Project Report not later than forty-five (45) days after the end of each calendar quarter, covering the calendar quarter.

Annex 1: Terms of Reference for key project positions

Infectious Disease Specialist	
Purpose of the Job	Develop strategies to inform public health efforts in fighting epidemics/pandemics.
Primary Duties and Responsibilities	<ul style="list-style-type: none"> • Form the linkage between clinicians at the bedside and researchers at CERI • Use the data gained through these linkages in the team approach to develop a fast scientific approach to newly emerged clinical questions • Work with Bioinformaticians and Epidemiologists to facilitate data integration, including clinical and vaccination data. • Set up new collaborations and strengthen existing collaborations • Gain an understanding of transmission and use this in a team approach to design clinical and epidemiological mitigation strategies. • Bring this knowledge and strategies together to develop the best format in which to inform public health efforts.

Bioinformatician(Postdoc)	
Purpose of the Job	The Bioinformatician will work in a team to provide support for sequence assembly and genomic data analyses. The Bioinformatician will also be involved in training activities, both in-house and externally, and contribute to the development of bioinformatic software and pipelines.
Primary Duties and Responsibilities	<ul style="list-style-type: none"> • Perform routine sequence assemblies of sequence runs, including de novo and reference based assemblies and variant calling. • Educate other scientists on bioinformatic methods and applications of bioinformatics technology. • Experience in using programmes like R, MATLAB or SQL for data analysis. • Contribute to the working group's publications, including taking the lead in author role for some projects. • Develop libraries and implement best coding practices to build and continually improve computational capabilities and workflows.

	<ul style="list-style-type: none"> • Apply computer tools to transform genomic data into outputs that will contribute to health outcomes. • Contribute to report writing for various grant funded projects. • Responsible for reporting back results to CERI collaborators.
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Laboratory Technician	
Purpose of the Job	Provide support to Prof De Oliveira’s laboratory with conducting research and diagnostic tests to meet project deadlines and within allocated turnaround times.
Primary Duties and Responsibilities	<ul style="list-style-type: none"> • Undertake sample processing of various pathogens • Freezing and cataloguing of cells • Preparation of reagents • Participate in departmental academic activities (laboratory meetings, research updates, quality improvement meetings and audit, etc.) • General laboratory housekeeping

Sample Clerk	
Purpose of the Job	Provide support to the Centre for Epidemic Response and Innovation (CERI) team at Tygerberg Campus. This will include tracking samples and inventory control of reagents and laboratory consumables through the Laboratory Information Management System (LIMS).
Primary Duties and Responsibilities	<ul style="list-style-type: none"> • First point of contact for visitors to the CERI laboratory • Receive Samples at the CERI laboratory • Manage Laboratory Information Management System (LIMS): <ol style="list-style-type: none"> 1. Configure LIMS according to operational needs of laboratory 2. Perform daily database back-ups 3. Generate reports on LIMS 4. Create LIMS usernames and passwords for new staff members 5. Train end-users in using LIMS • Log and track samples through the LIMS system: <ol style="list-style-type: none"> 1. Log samples 2. Generate plate layout reports

	<ul style="list-style-type: none"> 3. Print labels 4. Execute SQL queries as needed to retrieve data • Track the number of sequences generated. • Update stock records of reagents and laboratory consumables on LIMS • Check and log samples into the BioRepository • Request samples from the BioRepository
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Senior Research Support Officer	
Purpose of the Job	Provide administrative support to CERI Management.
Primary Duties and Responsibilities	<ul style="list-style-type: none"> • First point of contact to the Director's office • Deal with correspondence in the Director's office: <ul style="list-style-type: none"> ➤ Manage Director's diary and remind him of important tasks, deadlines and meetings ➤ Compose and edit letters, documents and emails ➤ Minute taking • Organise meetings and appointments, including board meetings and scientific steering committee meetings: <ul style="list-style-type: none"> ➤ Invitations ➤ Drafting agendas ➤ Collate and distribute information packs ➤ Organizing the venue and refreshments • Collate and process expense claims for Director • Assist CERI team with organizing events and conferences • Provide support to the Head of Scientific Support and the Grants Manager: <ul style="list-style-type: none"> ➤ Literature review searches ➤ Prepare biosketches for grant applications ➤ Provide updated information on research outputs to Scientific Support team for reporting purposes. • Update the following webpages: <ul style="list-style-type: none"> ➤ CERI webpage and any other webpages that might be created as part of CERI. • Update CERI's Researcher's profiles on: <ul style="list-style-type: none"> ➤ SCOPUS ➤ Web of Science (WoS) ➤ Google Scholar ➤ NIH PubMed site ➤ University's productivity output system (RIG) • Miscellaneous tasks to support the Director

Medical Scientist

Purpose of the Job	Provide direct support to the Principal Investigator on this project to ensure objectives are achieved.
Primary Duties and Responsibilities	<ul style="list-style-type: none">• Share responsibility for committee and department assignments• Perform administrative, supervisory, mentoring and other related functions.• Establish new and strengthen existing collaborations within the University and beyond. The specific focus will be on collaborations within the government's health sector.

Annex 2: Results Framework

**Centre for Epidemic Response and Innovation
Stellenbosch University
Accelerating Genomics-Based Surveillance for COVID-19 Response in South Africa
Result Framework and Monitoring**

Project Development Objective (PDO): Improve genomic surveillance capacity of SARS-CoV-2 of South Africa and the African region

Indicator Name	Unit of Measure	Baseline	End Target	Frequency	Data Source/Methodology	Responsibility for Data Collection
Number of sequences produced in South Africa	Number	0.00	20,000.00	Every six months	NGS-SA website	CERI
Number of staff and scientists who are able to produce genomic sequencing data	Number	0.00	50.00	Every six months	Project activity reports	CERI
Number of staff and scientists who are able to analyze genomic sequencing data	Number	0.00	50.00	Every six months	Project activity reports	CERI

Intermediate Results Indicators

Indicator Name	Unit of Measure	Baseline	End Target	Frequency	Data Source/Methodology	Responsibility for Data Collection
Component 1: expanding the NGS-SA capacity to continue producing SARS-CoV-2 genomes and training staff and scientists for genomic sequencing data generation						
Number of meetings held	Number	0	36	Monthly	Meeting minutes / presentations	CERI
Turnaround time of producing sequencing data	Number days	>15 days	<15 days	Every six months	Project activity reports	CERI
Number of reagents to be procured	Number	0	18,000	Every six months	Project activity reports	CERI
Number of training sessions organized for capacity building of genomic	Number	0	4	Every six months	Project activity reports	CERI

sequencing data generation						
Component 2: Establishing an effective system to evaluate diagnostics and vaccine effectiveness against the variants in Africa						
Operational protocol for rapid transportation of samples is developed	Number	0.00	1.00	Every six months	Project activity reports	CERI
Analytical protocol for evaluating the effectiveness of diagnostics and vaccines is developed	Number	0.00	1.00	Every six months	Project activity reports	CERI
Number of reagents to be procured	Number	0	2,000	Every six months	Project activity reports	CERI
Component 3: strengthening data systems to share and training public health officials and scientists for genomic sequencing data analysis						
A dashboard is produced to provide weekly update of genomic data and synthesis information on epidemiological and clinical and vaccination data	Number	0.00	1.00	Every six months	Project activity reports	CERI

Target values

PDO

Indicator Name	End Target
Number of sequences produced in South Africa and African region	20,000
Number of staff and scientists who are able to produce genomic sequencing data	50
Number of staff and scientists who are able to analyze genomic sequencing data	50

Intermediate Results Indicators

Indicator Name	End Target
Component 1	
Number of meetings held	36
Number of training sessions organized for capacity building of genomic sequencing data generation	4
Turnaround time of producing sequencing data	<15 days
Number of reagents to be procured	18,000

Component 2	
Operational protocol for rapid transportation of samples is developed	1
Analytical protocol for evaluating the effectiveness of diagnostics and vaccines is developed	1
Number of reagents to be procured for analysis of diagnostic and vaccine effectiveness	2,000
Component 3	
A dashboard is produced to provide weekly update of genomic data and synthesis information on epidemiological and clinical and vaccination data	1

Annex 3: Procurement Plan

Procurement Plan Thresholds for Prior Review, Procurement Approaches and Methods

A. Goods, Works and Non-Consulting Services: Moderate Risk Project				
Category	Prior Review (USD millions)	Procurement Approaches and Methods (USD millions)		
		Open International	Open National	Request for Quotation (RfQ)
Works	≥ 10	≥ 20.0	< 20	≤ 0.2
Goods, IT, and non-consulting services	≥ 2	≥ 5.0	< 5.0	≤ 0.1
B. Consulting Services				
Category	Prior Review (USD millions)	Short List of National Consultants (USD million)		
		Consulting Services	Engineering and Construction Supervision	
Consultants (Firms)	≥ 1	≤ 0.3		≤ 0.3
Individual Consultants (IC)	≥ 0.3	NA.		NA.

Procurement Risk Analysis

Taking into account that the fiduciary functions is delegated to Stellenbosch University the procurement/contract administration risks on the stage of project preparation stage are “Moderate”.

Please indicate in the table any potential risks and mitigation measures

Risk Description	Description of Mitigation	Risk Owner
Lack of familiarity with the Bank's procurement regulations	Provide training on Bank procedures & STEP	WB
Global delay in obtaining reagents from Illumina (sole supplier)	Open line of communication with supplier and managing stock levels	Stellenbosch/Principal Investigator