CENTRE FOR EPIDEMIC RESPONSE & INNOVATION

STELLENBOSCH UNIVERSITY

Accelerating genomics-based surveillance for COVID-19 in South Africa

ENVIRONMENTAL AND SOCIAL MANAGEMENT PLAN

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1. INTRODUCTION

1.1. BACKGROUND

The COVID-19 pandemic is one of the greatest challenges that humankind has faced in generations and has cost millions of lives and caused trillions of dollars in economic loss. Despite advances in the development and rollout of vaccines as well as in the clinical management of patients with COVID-19 disease, 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. The COVID-19 pandemic emerged in South Africa against a backdrop of existing HIV and TB. Furthermore, over the past 3 decades, several emerging and re-emerging pathogens have occurred internationally, mostly due to zoonotic or vector-borne diseases, several of African origin or severely impacting Africa. Due to a lack of immunity in local populations, these epidemics spread rapidly resulting in a massive loss of life. Influenza pandemics typically occur every 20 years. In addition, over the past two decades, three coronaviruses and several viruses, bacteria and parasites that affect humans have emerged in new regions, suggesting that humanity will continue to face a future burden of pandemics.

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 sequence large numbers of SARS-CoV-2-positive cases quickly and cost-effectively. 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. Sequencing data has proven useful in responding to COVID-19 outbreaks.

This project will expand the capacity of South Africa and the region to produce more than 20,000 SARS-CoV-2 genomes in a three-year period. Improving genomic surveillance of SARS-CoV-2 capacities will prepare for, prevent and mitigate the impact of future epidemics on the South African and regional population. The project will also allow for the expansion of genomic surveillance in Africa.

The overall objective of this Environmental and Social Management Plan (ESMP) is to outline how Stellenbosch University will comply with the provisions of the Environmental & Social (E&S) documents required under the Environmental and Social Framework (ESF), throughout the implementation of the Accelerating genomics-based surveillance for disease-causing pathogens in South Africa Project. The ESMP outlines the ways in Stellenbosch University and its partners will implement labor management procedures (LMP), Occupational health and safety (OHS) measures, waste management, resource efficiency and pollution prevention and management, traffic and road safety and community health and safety.

1.2. PROJECT DESCRIPTION

This project will expand the capacity of South Africa and the region to produce more than 20,000 SARS-CoV-2 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.

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. 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 100 African scientists on the production, analysis and quality control of the genomic data.

The project will include four components:

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

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. 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 COVID-19 samples identified in South Africa and the African region. The project will also support ACEGID in Nigeria. We anticipate that most 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
The project will also be used to expand capacity building throughout Africa through:

- Providing training and capacity building to other researchers on genomic data generation for SARS-CoV-2 and other pathogens
- 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

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

- CERI and other laboratories of the NGS-SA to procure additional reagents, equipment and test essays 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 samples to be sent to the regional laboratories in South Africa. 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 train public health officials and scientists for genomic sequencing data analysis in near-real time

Sub-component 3.1: Strengthen data sharing and integration

Rapid sequencing of virus genomes is now achievable in varied settings, and analyses of genomic sequences have huge potential for informing public health efforts. 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 the patient's epidemiological, clinical and vaccination data (**Figure 1**).

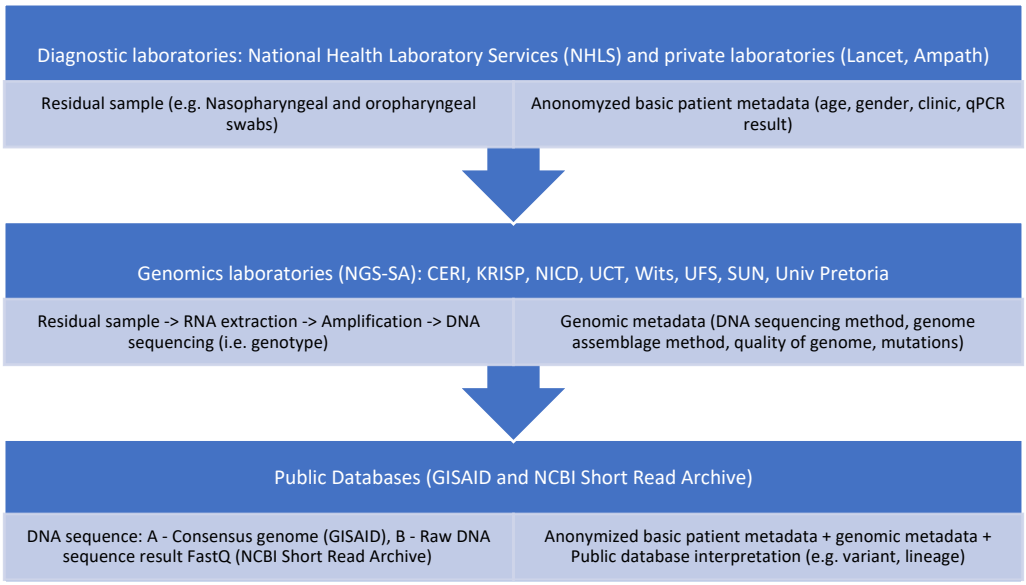


Figure 1 *Data flow from diagnostic laboratories to genomics laboratories to public database (GISAID)*

Sub-component 3.2: dashboard production

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 National Institute for Communicable Diseases (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 publicly available on a website. 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

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 in the analysis and quality control of the genomic data.

Component 4: Project management, monitoring and evaluation

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.

2. POLICY AND LEGAL FRAMEWORK

2.1. WORLD BANK ENVIRONMENTAL AND SOCIAL FRAMEWORK

The evaluation of the Project's risks and impacts was done in line with the World Bank's Environmental and Social Framework (ESF) which was subsequently classified as a low risk rating. Five (5) of the 10 World Bank Environmental and Social Standards (ESS) are applicable to the Project and guides this Environmental and Social Management Plan (ESMP):

- **ESS1 – Assessment and Management of Environmental and Social Risks and Impact:** ESS1 emphasizes the importance of identifying, assessing, and managing potential environmental and social risks and impacts throughout the project lifecycle. It includes requirements for environmental and social assessments, stakeholder engagement, and management plans to address identified risks.

- **ESS2 – Labor and Working Conditions:** ESS2 aims to guarantee fair and secure working conditions for workers and communities impacted by the project. It includes non-discrimination, labor rights, occupational health and safety, and grievance procedures.

- **ESS3 – Resource Efficiency and Pollution Prevention and Management:** ESS3 promotes efficient resource use and reduces pollution by encouraging sustainable practices during project implementation.

- **ESS4 – Community Health and Safety:** ESS4 addresses community health and safety concerns. It requires projects to assess and manage potential health and safety risks affecting communities and provide measures to ensure their well-being and security.

- **ESS10 – Stakeholder Engagement and Information Disclosure:** ESS10 stresses the significance of involving stakeholders throughout the project lifespan, including transparency, information sharing, and meaningful consultation with impacted communities and other stakeholders.

The project will also comply with the World Bank Environmental Health and Safety Guidelines that contain performance levels and specific parameters considered achievable in terms of processes, descriptions, and suggested good practices. The General Guidelines contain requirements and good practice on Environmental, Occupational Health and Safety, Community Health and Safety and other aspects of project implementation.

The ESMP, as the identified E&S risk management instrument, should examine the project's potential negative and positive environmental and social impacts and recommends any measures needed to prevent, minimize, mitigate, or compensate for adverse impacts.

2.2. LEGAL FRAMEWORK

CERI complies with all relevant and applicable South African laws and regulations for research. Investigators from South Africa are affiliated with Stellenbosch University (SU) and will utilize the established SU ethics committee structures (*http://www.sun.ac.za/english/research-innovation/Research-Development/integrity-ethics/health-ethics*). The Health Research Ethics Office (HREO) at the SU Faculty of Medicine and Health Sciences supports SU researchers towards compliance in the protection of human participant safety, rights and welfare in health research. Functions of this office include the administration of the two SU Health Research Ethics Committees (HREC), an animal REC; and the Biosafety and Environmental Ethics REC. These RECs provide general guidance on meeting local and international health research ethics requirements; and building institutional health research ethics capacity and approve the laboratory facilities. These ethics committees are registered with the South African Department of Health's National Health Research Ethics Council (NHREC) as well as with the US Office for Human Research Protections (OHRP) Federal-Wide Assurance: 00001372 and Institutional Review Board (IRB) Number: IRB0005239. The HREC complies with the South African Health Act No 61 (2003) as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46 as well as the SA GCP Guidelines 2006 2nd Ed. The general safety procedures that are in place in the CERI Laboratory are guided by the Occupational Health and Safety Act (1993) of the Republic of South Africa.

3. ENVIRONMENTAL AND SOCIAL MANAGEMENT PLAN

3.1. RISK AND IMPACT IDENTIFICATION

Key identified environmental and social risks and impacts relating to CERI's activities under this project include:

3.1.1. EXPOSURE TO INFECTIOUS PATHOGENS

Biosafety risks relate to exposure to infectious pathogens by laboratory personnel is the biggest risk identified. These exposures may result through working with samples prior to extraction or when extracting RNA from whole blood. Based on the activities that will be performed for this Project, the risk assessment gives a medium risk level with the likelihood of occurrence as being "might occur at some time" and the consequence of the risk as needing first aid treatment, on-site release immediately contained, medium financial loss. A risk assessment[1] will be carried out for all potential hazards identified and understood by all personnel working within the laboratory.

3.1.2. INFRASTRUCTURE AND EQUIPMENT DESIGN AND SAFETY

The project will be performed in existing CERI laboratories at SU in South Africa and the ACEGID Laboratories in Nigeria. No new infrastructure will be needed for this project and infrastructure and equipment design is not applicable for this project. The operational functionality of the existing equipment will be assessed during the risk assessment (**Annex 1**) process to ensure that all equipment is in good standing.

3.1.3. LABOUR AND WORKING CONDITIONS OF PERSONNEL

The anticipated risks and impacts associated with the project related to working conditions (including health and safety) are expected to be negligible. The current scope of engagement planned under the project includes CERI and ACEGID conducting genomics-based surveillance for disease-causing pathogens. Any personnel employed for this project will be on a fixed-term contract and will be employees of SU in South Africa. A full list of SU Human Resources Policies and Procedures are presented as **Annex 2**. SU/CERI will also sub-contract ACEGID in Nigeria to support technological transfer in South Africa to Nigeria. ACEGID will exercises control over the work, working conditions, and treatment of the project workers in Nigeria.

3.1.4. MANAGEMENT OF WASTE (INCLUDING HAZARDOUS WASTE)

To ensure that waste is managed appropriately, and environmental impacts are minimized, the Project will implement the existing SU and ACEGID Waste Management Policies and Procedures. These institutions perform their waste management operations in accordance with internationally recognized waste management hierarchy and in order of preference aim to:

- Eliminate waste;
- Reduce the amount of waste produced;
- Reuse materials where possible;
- Recycle wastes where feasible;
- Recover as much energy as possible from the remaining waste;
- Treat (mitigate the inherent hazard of the waste); and
- Dispose of residual wastes responsibly.

Appropriate measures and actions will be implemented to avoid or control exposure, through the delivery, storage, transportation, and disposal of potential infectious pathogens and wastes. Implementation of CERI's Health and Safety Management Manual **(Annex 2: List of SUHR Policies**
) will ensure that any potential community exposure to infectious pathogens is minimised. The Waste Management Plan (WMP) (**Annex 9**) serve as a guideline for the project Management for the effective management of wastes.

3.1.5. EMERGENCY PREPAREDNESS AND RESPONSE

CERI will identify and implement measures to address potential emergencies such as fire, explosions, leaks, or spills, which may occur for a variety of different reasons, including failure to implement operating procedures that are designed to prevent their occurrence. The emergency measures are outlined in detail in the Health and Safety Management Manual (**Annex 2:** List of SU HR Policies).

3.1.6. SAFETY OF SERVICES

Appropriate quality management systems will be implemented to anticipate and minimize risks and impacts that genomic sequencing may have on community health and safety, including the safe disposal of waste from the laboratories. All waste disposal will be in compliance with applicable national and internationally recognized environmental, health, and safety standards. At a minimum, procedures and

responsibilities for hazard identification and assessment will be defined at the beginning of the project and processes for monitoring and managing risks will be put in place.

CERI's Health and Safety Management Manual (**Annex 2:** List of SU HR Policies), will guide the specific management plans to address key risks and impacts.

3.1.7. RESOURCE EFFICIENCY

While the project will not have a significant impact on water or raw materials during its operations, high energy consumption is anticipated within the labs operations. Reasons for high energy usage could include:

- **Specialized Equipment:** Specialized equipment such as sequencers, and centrifuges often require significant amounts of energy to operate efficiently.
- **Climate Control:** Temperature, humidity, and ventilation control to maintain optimal conditions for experiments and equipment lead to increased energy consumption for heating, cooling, and air circulation.
- **Safety Requirements**: Stringent safety requirements, including fume hoods, exhaust systems, and emergency power sources contribute to higher energy usage.

3.1.8. TRAFFIC AND ROAD SAFETY

CERI will identify, evaluate, and monitor the potential traffic and road safety risks to workers, affected communities, and road users throughout the project life cycle. The main road safety risk is potential spillage during transportation between sample collection sites and the laboratory. Essential traffic safety measures to consider when transporting samples in outlined in **Annex 10**. An accredited transport company will be used to ensure the safe transport of pathogens from sample collection points to the laboratories to prevent and mitigate potential road safety risks to road users and affected communities. For this project, BIOCAIR will be used for sample transport. According to road safety requirements, the company is certified by the International Air Transport Association (IATA). CERI will maintain documentation from the company to show their compliance includes IATA certification, standard operation procedure for sample transport and condition control (temperature), emergency action for spillages procedure and primary emergency response procedures.

3.1.9. ASSESSMENT OF KEY POTENTIAL COMMUNITY HEALTH AND SAFETY RISKS

The project will include genomics-based surveillance for disease-causing pathogens, and anticipated risks and impacts related to community health and safety are expected to be negligible. However, CERI will evaluate the risks and impacts of the project on the health and safety of the affected communities during the project life cycle, including those who, because of their particular circumstances, may be vulnerable. Mitigation measures will be proposed for any risks and impacts identified.

3.1.10. COMMUNITY EXPOSURE TO HEALTH ISSUES

The activities of this project will not increase the risk of exposure to waterborne, water-based, water-related, and vector-borne diseases, and communicable and non-communicable diseases.

3.1.11. STAKEHOLDER ENGAGEMENT

Effective communication, involvement of stakeholders, and engagement with the community are crucial for the success of projects, especially those with ethical, social, or environmental dimensions. However, there are certain risks associated with these aspects that can obstruct the progress of the project, cause misunderstandings, and lead to distrust or resistance.

Risk of Stakeholder Communication: Inadequate or unclear communication with stakeholders can lead to misunderstanding of project objectives, strategies, and outcomes, ultimately resulting in decreased support, missed opportunities for collaboration, and confusion among stakeholders.

Risk of Community Involvement: Insufficient engagement with local communities can lead to a lack of understanding of their concerns, needs, and perspectives. This can result in resistance, protests, or negative perceptions of the project's intentions.

Risk of Addressing Public Concerns: Failure to address public concerns, particularly those related to potential environmental or social impacts, can result in public opposition, negative media coverage, and legal challenges. Ignoring public concerns can also impede the project's ability to obtain necessary permits or approvals.

Table 1 below provides potential Environmental and Social Risks and Impacts associated with each of the components and activities of the Project:

Table 1: Potential E&S Risk and Impact for each Project Activity

Project Component:	Activity	Potential E&S Risk and Impacts
Component 1: Expanding the NGS-SA capacity and training		
Sub-Component 1.1:	Expand the capacity of the NGS-SA network through procurement of equipment, hiring of staff and purchase of reagents to sequence more genomes	1. **Resource Consumption:** Increased procurement of equipment, reagents, and resources may lead to higher consumption of materials, energy, and water, contributing to resource depletion and carbon emissions. 2. **Waste Generation:** The process of sequencing genomes involves the use of chemicals and reagents, which can result in the generation of hazardous waste if not managed properly. 3. **Energy Consumption:** The operation of additional equipment and laboratory facilities may result in higher energy consumption, increasing the environmental footprint. 4. **Occupational Health and Safety:** The hiring of staff and expansion of laboratory activities may expose workers to new risks if proper safety protocols are not in place. Handling reagents, chemicals, and biological samples can pose health hazards. Increased workload due to expanded activities may lead to burnout and stress among laboratory staff if adequate support and resources are not provided. 5. **Equity and Access:** The benefits of increased genome sequencing should be distributed equitably, with consideration for ensuring that underserved or vulnerable populations also benefit from the research outcomes.
Sub-component 1.2: Training staff and scientists for genomic sequencing data generation	The NGS-SA would serve as an integrated hub with sample collection taking place at multiple laboratories among the network member countries	1. **Resource Intensity:** The operation of multiple laboratories for sample collection and subsequent analysis could lead to increased consumption of resources, such as energy, water, and materials, contributing to environmental degradation. 2. **Waste Generation:** The process of sample collection and subsequent laboratory analysis can generate waste, such as consumables, chemicals, and hazardous materials, potentially leading to improper waste management if not adequately addressed. 3. **Transportation Impact:** Transporting samples between laboratories within and across countries may contribute to carbon emissions and other environmental impacts, especially if transportation is not optimized for efficiency. 4. **Equity and Access:** Ensuring equitable access to benefits and research outcomes for all member countries and communities, including those with limited resources, is essential to avoid potential social disparities. 5. **Inclusivity:** Ensuring that all member countries and communities are actively involved in decision-making, research design, and sharing of benefits can mitigate potential social exclusion. 6. **Traffic Safety:** The transportation of biological samples between laboratories involves potential risks related to proper packaging, regulatory compliance, security, training, and the need for emergency response plans to ensure the safety of both the samples and personnel. When samples are being transported between laboratories, it's important to establish strict transportation protocols.
	Organise 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	1. **Travel-Related Emissions:** Regular travel for meetings could lead to increased carbon emissions, especially if participants are flying or using vehicles. This contributes to climate change and environmental degradation. 2. **Resource Consumption:** Meetings involving multiple participants may lead to increased resource consumption, such as energy for facilities, paper for documentation, and catering services, unless sustainable practices are adopted. 3. **Equity and Inclusivity:** Frequent in-person meetings might inadvertently exclude individuals or laboratories that lack resources or face travel restrictions, potentially creating disparities in access to collaboration opportunities. 4. **Occupational Health and Safety:** Frequent meetings may place an additional burden on participants, affecting their work-life balance and potentially leading to burnout, travel-related risks, potential exposure to unfamiliar

Project Component:	Activity	Potential E&S Risk and Impacts
		environments, and adherence to health and safety protocols, necessitating precautions to safeguard the well-being of the participants. 5. **Traffic Safety:** The organization of monthly meetings between NGS-SA partners and laboratories generating genomic data in South Africa and the region may lead to increased road travel, potentially resulting in traffic safety risks such as congestion, accidents, and travel-related incidents for participants commuting to the meetings. 6. **Labor management and working conditions for trainers:** monthly meetings between NGS-SA partners and laboratories generating genomic data in South Africa and the region, potential labor management and working condition risks for trainers may include increased workload, travel-related fatigue, and the need for efficient scheduling to ensure the well-being and productivity of trainers involved in facilitating the meetings.
Component 2: Establishing an effective system to evaluate diagnostics and vaccine effectiveness against the variants in Africa		
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.	CERI and other laboratories of the NGS-SA to procure additional reagents, equipment and test essays 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	1. **Chemical and Waste Management:** The procurement of additional reagents and equipment for laboratory testing could lead to increased use of chemicals and production of hazardous waste. Inadequate management of chemicals and waste disposal could pose risks to environmental contamination. 2. **Energy Consumption:** Increased laboratory activities, especially if not optimized for energy efficiency, could contribute to higher energy consumption and associated carbon emissions. 3. **Occupational Health and Safety:** Hiring additional staff and conducting extensive analyses might increase the workload and potential exposure to hazardous materials for laboratory personnel, raising concerns about occupational health and safety. 4. **Occupational Health and Safety:** COVID-19 sample analysis poses health risks to lab staff without proper safety protocols. Procuring equipment, reagents, and test essays, hiring staff, and conducting genomic analysis for vaccine and diagnostic testing and identifying genomic changes require strict safety measures for handling infectious materials and ensuring lab personnel's health and safety under biohazard conditions. 5. **Ethical Considerations:** Analyzing and sharing genetic information from COVID-19 samples could raise ethical concerns related to privacy, informed consent, and data security, particularly if the data is not handled responsibly. 6. **Equity and Access:** The distribution and allocation of resources for testing and research should consider equity, ensuring that vulnerable or underserved populations have access to diagnostic testing and benefit from research outcomes. 7. **Sociopolitical Impact:** The findings of the research, especially if they indicate reduced vaccine effectiveness against specific variants, could have sociopolitical implications, influencing public health policies and public perceptions of the pandemic.
	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.	1. **Waste Generation:** Activities associated with meetings and capacity strengthening, such as documentation, handouts, and consumables, could lead to waste generation if not managed responsibly. 2. **Equity and Inclusivity:** Ensuring adequate representation from member countries may be challenging, and excluding certain countries due to logistical or financial constraints could perpetuate disparities and inequalities. 3. **Ethical Considerations:** Different member countries may have varying ethical and cultural norms, which could lead to ethical conflicts or challenges in achieving consensus on certain protocols.

Project Component:	Activity	Potential E&S Risk and Impacts
	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 South Africa	1. **Transportation Emissions:** Transporting samples over long distances, especially by air, could lead to significant carbon emissions and contribute to climate change. 2. **Cold Chain Logistics:** Maintaining a proper cold chain for sample transportation may require energy-intensive refrigeration and transportation methods. 3. **Waste Generation:** Packaging materials, coolants, and other supplies used for sample transportation could lead to waste generation. 4. **Equity and Access:** Establishing a mechanism that involves sending samples to a centralized location might inadvertently create disparities in access to genomic sequencing and analysis resources, favouring countries with greater resources. 5. **Data Privacy and Security:** Sharing sensitive health data across borders raises concerns about data privacy, security, and potential misuse of information. 6. **Ethical Considerations:** Differences in ethical norms, consent procedures, and regulatory frameworks among countries could raise challenges in obtaining proper approvals for sample transportation.
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:	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	1. **Data Transmission and Storage:** Rapid data sharing could result in increased data transmission and storage requirements, leading to higher energy consumption and associated carbon emissions. 2. **Server Infrastructure:** Hosting and managing large datasets for global sharing may require energy-intensive server infrastructure and data centers. 3. **Equity and Access:** Rapid data sharing might inadvertently favour countries or organizations with greater resources and infrastructure, potentially exacerbating disparities in global public health responses. 4. **Intellectual Property and Benefits:** The sharing of genomic data could lead to questions about intellectual property rights and the equitable distribution of benefits derived from the data. 5. **Communication and Trust**: Rapid sharing of data without proper communication and community engagement could lead to mistrust and misunderstandings. 6. **Labor management and working conditions of operation staff:** Intense time pressures, long working hours, and the need for efficient scheduling to support the timely dissemination of critical data while ensuring the well-being and mental health of trainers and personnel involved in this high-stress, time-sensitive task
	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	1. **Data Storage and Processing:** Integrating and processing large volumes of data from multiple sources may require energy-intensive computing resources, contributing to increased energy consumption and carbon emissions. 2. **Infrastructure Expansion:** Scaling up infrastructure to accommodate data integration may lead to the creation of additional data centers and server facilities, which could have environmental impacts. 3. **Data Privacy and Security:** Integrating diverse datasets raises concerns about data privacy, security breaches, and the potential misuse of personal information, especially when linking patient-level data. 4. **Equity and Access:** Data integration efforts may unintentionally exclude regions or populations with limited access to technology and resources, exacerbating social disparities in health insights. 5. **Transparency and Accountability:** Lack of transparency in data integration and sharing processes could lead to mistrust among the public and stakeholders.

Project Component:	Activity	Potential E&S Risk and Impacts
		6. **Stakeholder Involvement:** Engaging relevant stakeholders, including patients, healthcare providers, and communities, in the data integration process is crucial to address social concerns and ethical considerations. 7. **Communication and Education:** Transparently communicate the purpose, benefits, and potential risks of data integration to the public to foster understanding and trust. 8. **Ethical Review:** Ensure that data integration efforts adhere to ethical guidelines and regulatory requirements, especially when dealing with sensitive patient information. 9. **Data Ownership and Consent:** Address questions of data ownership and consent when integrating data from different sources to ensure that patient rights are respected. 10. **Labor management and working conditions of operation staff:** Long hours, stress, maintaining data accuracy, ensuring data privacy, and potential burnout, given the high demand for precise data integration and linkage between various datasets to support public health efforts.
Sub-component 3.2: dashboard production	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 National Institute for Communicable Diseases (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	1. **Energy Consumption:** The operation of a real-time dashboard, especially if it involves continuous data updates and user interactions, could result in increased energy consumption due to server operations and user access. 2. **Digital Infrastructure:** Developing and maintaining the dashboard may require additional digital infrastructure, contributing to the energy footprint of data storage and processing. 3. **Equity and Access:** Public health response efforts relying on digital dashboards might inadvertently exclude populations without reliable internet access or digital literacy, exacerbating health inequalities. 4. **Data Interpretation:** Making real-time data available to public health officials and experts may require training and capacity building to ensure accurate interpretation and meaningful analysis. 5. **Stakeholder Engagement:** Involving stakeholders in the dashboard development and utilization process is crucial to ensure that it meets their needs and addresses their concerns. 6. **Data Ownership and Use:** Clarify data ownership and usage rights, particularly if the dashboard relies on data from multiple sources or organizations. 7. **Labor management and working conditions of consultants**
Sub-component 3.3: Training program	This component will support CERI to train experts in the network to be able to analyze genomic sequencing data. Genomic data	1. **Travel-Related Emissions:** Conducting training programs that involve travel could contribute to carbon emissions, especially if participants need to fly to training sites. 2. **Resource Consumption:** Training programs, including workshops and materials, could lead to increased

Project Component:	Activity	Potential E&S Risk and Impacts
	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 100 African scientists on the production, analysis and quality control of the genomic data.	resource consumption, such as energy for facilities, paper for handouts, and other supplies. 3. **Skills Gap:** Training programs may create expectations for participants to apply their newly acquired skills, potentially leading to disappointment if opportunities for practical application are limited. 4. **Cultural Sensitivity:** Diverse cultural norms and practices among participants may affect the effectiveness of training and the integration of new skills. 5. **Sustainability:** Training a large number of scientists requires ongoing support and resources to ensure that the skills learned are continuously applied and developed. 6. **Traffic safety:** increased road travel due to the need for trainers and trainees to commute to and from the training sites regularly, posing potential hazards related to congestion, accidents, and travel-related incidents, especially given the extensive training goal and the diverse geographic locations of trainees. 7. **Occupational Health and Safety of Trainers:** potential exposure to infectious materials while handling genomic data and samples, the need for stringent safety protocols to mitigate the risk of infection, and ensuring the health and safety of personnel involved in this training, particularly given the weekly analysis demands and the goal of training a significant number of scientists.
Component 4: Project management, monitoring and evaluation		
Sub-component 4.1: 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	1. **Labor management and working conditions:** challenges in consultant recruitment, maintaining rigorous procurement and financial standards, and managing operating expenses, all of which can be mitigated through the implementation of a comprehensive project support plan and monitoring and evaluation system.

3.2. MITIGATION MEASURES

Table 2 Proposed Mitigation measures and timing

Anticipated E&S Risks and Impacts	Proposed Risk Mitigation Measures	Impact Mitigation		Impact/Mitigation Monitoring		
		Timing/Frequency	Responsibility	Parameter to be monitored	Frequency	Responsibility
Energy consumption: The project entails various energy-related challenges, including energy-intensive data integration, transmission, and storage, digital infrastructure development, laboratory activities, and server operations, all of which contribute to elevated energy consumption and associated carbon emissions	1) Prioritize the procurement of energy-efficient laboratory equipment and technologies to minimize energy consumption.	At time of purchase	Lab Manager	List of equipment procured	Annual	Lab manager
	2) Use energy-efficient and sustainable data storage and transmission methods to minimize environmental impacts.	At project inception	Data manager	List of servers and location	Annual	Data manager
Resource Consumption: The project presents resource-related challenges encompassing higher material, energy, and water consumption due to expanded equipment procurement, meetings, training programmes, and laboratory activities, potentially contributing to resource depletion and environmental impact.	1) Conduct thorough capacity assessments to determine actual needs before procurement to avoid unnecessary resource use.	Quarterly	Lab Manager	Reagent and consumable stocks	6-monthly	Lab manager
	2) Develop robust data management protocols to ensure accurate record-keeping and traceability of resources.	Quarterly	Lab Manager / Sample clerk	Asset register and LIMS system	6-monthly	Lab manager / Sample clerk
Traffic and Transport: The project entails transportation challenges involving energy-intensive cold chain logistics, long-distance sample transport leading to carbon emissions, and travel-related activities for training and meetings contributing to environmental impact and climate change.	1) Develop comprehensive logistical plans to ensure safe and efficient transportation, including contingency measures for potential disruptions. Standardized protocols for sample collection, transportation, and data sharing to ensure consistency and quality across member laboratories.	Annually	Lab Manager	SOP on sample transport	Annually	Lab Manager
	2) If in-person meetings are necessary, adopt sustainable practices such as energy-efficient venues, waste reduction, and eco-friendly transportation options.	Quarterly	Project manager	Summary of meetings	Annually	Director

Anticipated E&S Risks and Impacts	Proposed Risk Mitigation Measures	Impact Mitigation		Impact/Mitigation Monitoring		
		Timing/Frequency	Responsibility	Parameter to be monitored	Frequency	Responsibility
	3) Ensure that all necessary ethical approvals are obtained from relevant authorities in each country before samples are transported.	Quarterly	Project manager	Copy of ethics approvals and import permits	Annually	Project manager
	4) Implement rigorous quality control measures to ensure sample integrity and prevent contamination during transportation.	Weekly	BioCare	Quality control measures	Quarterly	Contractor
Waste Management: The project poses challenges in chemical and waste management due to increased procurement of materials, inadequate disposal, and potential waste generation during various project activities, highlighting the need for responsible waste handling to prevent environmental contamination.	1) Implement proper waste management practices for chemicals, reagents, and consumables to minimize hazardous waste generation.	Quarterly	Lab manager	SOP on waste management	Annually	Lab manager
	2) Encourage member laboratories to adopt resource-efficient practices, including energy-efficient equipment and waste reduction measures.	Quarterly	ACEGID	SOP on waste management	Annually	ACEGID
	3) Use eco-friendly and reusable packaging materials to minimize waste generation during transportation.	Weekly	BioCare	Quality control measures	Quarterly	Contractor
Capacity Building: Capacity strengthening endeavors may unintentionally foster reliance on external resources instead of nurturing self-sustaining local proficiency, necessitating collaboration with local entities to align training initiatives with Project objectives and priorities	1) Provide training and professional development opportunities for local staff to enhance their skills and expertise.	As needed	Project leader	Training summary	Annually	Project leader
	2) Focus on building sustainable local capacity rather than creating dependency on external expertise. This could include training trainers and providing resources for ongoing learning.	As needed	Project leader	Training summary	Annually	Project leader
	3) Alongside sample transportation, invest in capacity building initiatives in countries with limited laboratory capacity to enhance local genomic sequencing capabilities.	As needed	Project leader	Training summary	Annually	Project leader
	4) Provide comprehensive training to public health officials, experts, and users to enable accurate interpretation and effective utilization of the dashboard.	As needed	Project leader	Training summary	Annually	Project leader

Anticipated E&S Risks and Impacts	Proposed Risk Mitigation Measures	Impact Mitigation		Impact/Mitigation Monitoring		
		Timing/Frequency	Responsibility	Parameter to be monitored	Frequency	Responsibility
Data Privacy and Security: Ensuring accurate interpretation and meaningful analysis of real-time data for public health officials may necessitate training, while addressing data ownership, consent, privacy, and security concerns, especially when integrating diverse datasets or sharing sensitive genetic and health information across borders, requires clear guidelines, collaboration, and transparent governance to navigate potential social concerns.	1) Develop robust data management protocols to ensure accurate record-keeping and traceability of resources[2].	Annually	Project manager	Various resources	Annually	Project manager
	2) Develop standardized protocols for sample collection, transportation, and data sharing to ensure consistency and quality across member laboratories.	At project inception	Lab manager	SOP on sample collection and transportation	Annually	Lab manager
Equity, Access and Inclusivity: Promoting equity and access involves avoiding unintentional exclusion, ensuring fair distribution of benefits, and considering potential disparities in technology, resources, and representation, with a focus on transparency and inclusivity to address challenges and build trust among stakeholders and populations.	1) Develop collaborative mechanisms that promote equitable access to data and benefits, ensuring that resources and information are shared globally.	Monthly	Bioinformaticians	Sequences uploaded to GISAID	Annually	Project Manager
	2) Provide resources and support to regions or populations with limited access to technology to ensure equitable participation and benefits.	Annually	Project manager	List of institutions that have received training	Annually	Project manager
	3) Implement a fair and transparent selection process to ensure equitable access to training opportunities.	Annually	Project manager	Scoring sheet for training applications	Annually	Project manager
Ethical Considerations: Addressing ethical considerations involves navigating potential privacy issues, informed consent challenges, varying regulatory frameworks, and cultural norms, emphasizing responsible data	1) Adhere to regulations for staff recruitment	At time of employment	SU HR	Interview reports	Annually	Project Manager
	2) Obtain proper ethical approvals for sample collection, sharing, and data analysis.	Annually	Project manager	Copy of ethics approval / recertification	Annually	Project manager

[2] "resources" encompass various types of items or data, including:
Physical Resources: These could include tangible assets such as raw materials, equipment, machinery, tools, and physical products or goods.
Human Resources: This may involve managing and tracking information related to employees, contractors, or personnel involved in a project or organization.
Financial Resources: Financial data, including budget allocations, expenses, revenue, and financial transactions, might need to be accurately recorded and traced.
Information or Data Resources: This could refer to digital or informational assets like databases, documents, records, reports, and any other data critical to the Project's operations.
Inventory or Stock Resources: Resources may pertain to the stock of products, materials, or goods.
Personnel Resources: This include tracking and managing information about staff availability, skills, and roles

Anticipated E&S Risks and Impacts	Proposed Risk Mitigation Measures	Impact Mitigation		Impact/Mitigation Monitoring		
		Timing/Frequency	Responsibility	Parameter to be monitored	Frequency	Responsibility
handling, proper approvals, and ethical guidelines to ensure the respectful and secure use of sensitive genetic information, particularly in cross-border contexts.	3) Seek ethical review and approval from relevant ethics committees before study start	Annually	Project manager	Copy of ethics approval / recertification	Annually	Project manager
Occupational Health and Safety: Expanding laboratory activities, including COVID-19 sample analysis and meetings, can impact occupational health and safety, potentially exposing staff to health risks and workload challenges if proper safety protocols and support measures are not in place.	1) Implement rigorous safety protocols, training, and proper use of personal protective equipment (PPE) to ensure the well-being of laboratory staff when handling hazardous materials and to minimize health risks.	Prior to working on the project and annually thereafter	Lab manger	SOPs on PPE / safety and training logs	Annually	Lab manager
	2) Hire an appropriate number of trained personnel to distribute workload effectively, preventing excessive exposure to hazardous materials and reducing occupational health risks.	At start of study	Lab manager	Number of laboratory staff employed	Annually	Lab manager
	3) Allocate resources for safety equipment, training, and facility upgrades to create a safe and conducive working environment that minimizes health risks for laboratory personnel.	Monthly	Lab manager	PPE stock	6-monthly	Lab manager / sample clerk
	4) Establish mechanisms for ongoing training, health monitoring, and support to ensure the long-term health and well-being of laboratory staff as genome sequencing activities expand.	Annually	Lab manager	Training logs / agenda	Annually	Lab manager
Sociopolitical Impact: The findings of the research, especially if they indicate reduced vaccine effectiveness against specific variants, could have sociopolitical implications, influencing public health policies and public perceptions of the pandemic.	1) Communicate research findings transparently and responsibly to public health authorities, policymakers, and the public to ensure accurate understanding and informed decision-making.	As needed	Project Director	Press release / e mails / publications	Annually	Project Director
	2) Uphold the highest standards of scientific integrity and peer review to ensure that research findings are robust and reliable before they are communicated to the public and policymakers.	Annually	Project Director	List of research findings published in peer-reviewed journals	Annually	Project Director
	3) Continuously monitor public perceptions, reactions, and policy responses to research findings, and be prepared to provide clarifications or updates if needed.	Annually	Media and Communications Officer	Summary of media coverage and overall sentiment	6-monthly	Media and Communications Officer

Anticipated E&S Risks and Impacts	Proposed Risk Mitigation Measures	Impact Mitigation		Impact/Mitigation Monitoring		
		Timing/Frequency	Responsibility	Parameter to be monitored	Frequency	Responsibility
	4) Collaborate with international partners and organizations to share findings, insights, and best practices, contributing to a global understanding of the sociopolitical implications of genomic research.	Annually	Project Director	List of international collaborators	Annually	Project Director
Stakeholder Engagement: Open and transparent communication, along with meaningful stakeholder engagement, are essential for building trust, addressing concerns, and ensuring the successful development and utilization of the data integration dashboard.	1) Identify and involve a diverse range of stakeholders, healthcare providers, local communities, policymakers, scientists, and advocacy groups, to ensure comprehensive engagement.	Throughout project	Project Director	List of individuals engaged	Annually	Project Director
	2) Provide regular updates and progress reports on the development and utilization of the data integration dashboard to keep stakeholders informed and engaged.	Annually	Project Director	Number of people accessing the dashboard	Annually	Project Director
Training and Skills Development: Maintaining high-quality, scalable training programs while addressing operational challenges, supporting equitable participation through scholarships, bridging skills gaps, and ensuring long-term sustainability are crucial considerations for successful capacity strengthening.	1) Provide training and professional development opportunities for local staff and other African scientists to enhance their skills and expertise.	As needed	Lab manager	Training logs and agenda	Annually	Lab manager
	2) Facilitate opportunities for participants from other African countries to apply their skills effectively within their local contexts, promoting sustainable skill development.	Annually	Lab manager	Number of individuals who were trained that request assistance for local sequencing	Annually	Lab manager
Labor Management and Working Conditions	1) Implementation of a transparent Grievance Redress Mechanism (GRM). The GRM provides a platform for any stakeholder (internal and external) who has a grievance or problem that has arisen from their involvement with the project the right and the opportunity to lodge their grievance. The GRM builds on the existing HR procedures for local staff and is	Weekly	Lab manager	Efficiency of the GRM, specific Key Performance Indicators (KPIs) should be identified, data on grievance submissions should be gathered and analyzed, and continuous improvement should be made based on monitoring data.	Weekly	Lab manager

Anticipated E&S Risks and Impacts	Proposed Risk Mitigation Measures	Impact Mitigation		Impact/Mitigation Monitoring		
		Timing/Frequency	Responsibility	Parameter to be monitored	Frequency	Responsibility
	2) Reporting: Share your monitoring results with relevant stakeholders, both internally and externally, to maintain transparency and accountability.	Weekly	Lab manager	Transparency and accountability of the mechanism	Weekly	Lab manager
	3) Training and Awareness: Ensure that employees responsible for managing grievances are adequately trained and aware of the grievance mechanism's procedures and standards.	Weekly	SU HR / ES Consultant	No of individuals trained Efficiency of awareness campaign	Weekly	SU HR / ES Consultant

CERI EHS Management Program

CERI's existing environmental, health and safety management program, collectively referred to as the Health and Safety Management Manual (HSMM **Annex 2:** List of SU HR Policies), includes documented specific management plans and inter-related standard operating procedures (SOPs) that address management of key risks and impacts, including a chemical hygiene plan (CHP), a biosafety and security plan with safety precautions integrated into the manual, a safety audit checklist, a post exposure plan, and biosafety objectives, among others.

The HSMM, compiled to match the sections according to the ISO 15189 standard, describes amongst others the management of hazardous materials and the storage and disposal of hazardous waste and biohazardous/medical waste. These specific management plans have been developed and implemented at CERI to manage key risks and impacts, which is annexed to the EMP.

Most of the Environmental and Social standard (ESSs) are covered in the HSMM, such as assessments and management of Environmental and Social risks and impacts, the labour and work conditions are mentioned under the Personnel section and further elaborated on in the University's Staff Health and Wellbeing Plan (SHWP*http://www.sun.ac.za/english/human-resources/Documents/Wellness/SU%20Staff%20Health%20and%20Wellbeing%20Plan%20Approved.pdf#search=shwp*).

CERI, via the University of Stellenbosch, adheres to resource efficiency and pollution prevention and management, as dictated by the City of Cape Town in their policy on *Integrated Pollution Control and Waste Management* (*http://www.sun.ac.za/afrikaans/policy/Policy%20Documents/Environmental%20Health%20and%20Safety%20legal%20register%20summary.pdf#search=preventing%20pollution)*. The solid waste and liquid generated during operational activities at CERI are collected, removed and disposed of in the correct manner by BCL Medical Waste Management (https://www.bclmedicalwaste.co.za) and Enviroserv Waste Management (www.enviroserv.co.za), respectively. The resource efficiency and pollution prevention management plan is provided in **Annex 11**.

SU contributes to the community by means of outreach programs *http://www.sun.ac.za/english/faculty/healthsciences/Community%20Health*, and it is envisioned that sportsmen and woman from the community sport clubs will make use of the Sport fields, in order to practise their sport in a safe environment.

There are no conflicts in terms of land acquisitions, restricted land use, nor involuntary re-settlement, since the land on which the University reside are dedicated to all matters concerning Health, regardless of the Field in which these professionals practice.

CERI/ SU adheres to the conservation of Biodiversity and the sustainable management of living resources. Biodiversity is ensured, implemented, and maintained by Terra+, a professional landscaping design company. The well-designed landscape not only ensures biodiversity, but also manages the living resources by utilizing water-wise plants since Cape Town is considered as a water-scarce area. In addition, the well-designed gardens also contribute to the mental health well-being of those traversing the premises.

There is no conflict with indigenous peoples or local underserved communities. The communities, not only in Cape Town, but those in the rest of South Africa as well, who benefits from the activities done by CERI since COVID-19 samples from all over the country are sent to CERI to detect new variants and/or outbreaks of a certain variant.

CERI advocates for cultural heritage, by employing/training people from various walks of life, cultures, and countries (e.g., Indians, Caucasians, Blacks, Mixed Race). CERI celebrates all cultures in South Africa by hosting a Cultural Heritage Day on the 24th of September, a public holiday in South Africa.

The Financial intermediaries, as per SU's policy and procedure on *Purchasing and Tender* *http://www.sun.ac.za/afrikaans/policy/Policy Documents/Purchasing and tender policy and procedures.pdf - search=purchasing%20and%20tender*) facilitates the monetary aspects of the projects.

Regular stakeholder meetings are to be held to both provide feedback and in turn implement any requests/suggestions made by the stakeholders after having provided feedback.

The following environment, health and safety SOPs and accompanying documentation have been developed and implemented by CERI:

- CF04: Risk Assessment Form (Annex 1)
- CHSM01: Health and Safety Management Manual (**Annex 2**)
- CF41: Orientation Form (**Annex 3:** Labour Management Procedures)
- CM01: Quality Manual (**Annex 5**)
- CSOP08: Health and Safety Standard Operating Procedures (**Annex 6**)
- CWI21: Ethical Code of Conduct
- CWI22: Risk Management

3.3. IMPLEMENTATION ARRANGEMENTS AND MONITORING

CERI's safety management program is managed by 5 executive members of SU's Health and Safety Team that meets quarterly and is responsible for training, recording and monitoring of incidents and revisions to specific management plans and SOPs. Each specific management plan and SOP includes procedures and responsibilities for surveillance, monitoring and reporting on performance related to the relevant risks and impacts for that plan or procedure. These documents are available on SU's website. In addition, CERI maintains an audit checklist (see the example in Table 1) to conduct quarterly checks of work areas and implementation of environment, health and safety measures, the main purpose being that of improvement. The assessment tool is intended to be used as a guide to assess compliance to quality system management recommendations for Next Generation Sequencing for Genomic Surveillance.

The assessment tool and action items for CERI's Facilities and Safety are organized and managed through an assessment tool/plan (Table 1) that is assessed quarterly and revised and updated regularly as needed. The tool also provides a longitudinal view of the progress made and where attention is needed should a certain area be flagged as such. A score is

given for each quality system essential, which is to be improved upon or maintained should all the parameters have been met.

An E&S Consultant has been appointed. He will report to Prof. Tulio de Oliveira and will work closely with the project staff to monitor the implementation of the project according to the metrics outlined in Table 2. The technical metrics of the project are evaluated monthly and reported to the World Bank each quarter in the quarterly report. The monitoring of the environmental, social, health and safety (ESHS) performance of the Project are monitored 6-monthly and reported to World Bank annually.

3.4. BUDGET ALLOCATION

The budget for E&S Risk Management activities includes the following:

- Development of the suite of E&S Risk Management documents ($2, 263)
    - ESMP
    - LMP
    - Waste Management
    - Resource Efficiency
    - Traffic Safety
- Monthly implementation & monitoring of E&S ($83, 859)
- Trip to Nigeria to assess E&S at the sub-awardee (ACEGID) ($4, 794)
- Total budget for E&S Risk Management = $90, 916

4. GRIEVANCE MECHANISM

4.1 Objective

The Accelerating Genomics-based Surveillance for COVID-19 Response in South Africa and the African Continent Project has a primary objective of enhancing the genomic surveillance capacity of SARS-CoV-2 in South Africa and the wider African region. To ensure transparency and accountability, the project is committed to following national laws and global requirements in establishing and implementing a Grievance Mechanism (GM). This GM serves as a trusted platform, providing stakeholders with an efficient, fair, transparent, and cost-effective means to voice their concerns or discontent in a friendly environment.

While the project anticipates minimal complaints from stakeholders, the general public, or the community due to its nature, it has taken proactive steps by establishing a Grievance Redress Mechanism (GRM) to address any issues that may arise. This GRM ensures that even in unlikely scenarios, there is a systematic and responsive approach in place for resolving concerns related to the project.

4.2 Purpose

The GRM provides a platform for any stakeholder who has a grievance or problem that has arisen from their involvement with the project the right and the opportunity to lodge their grievance and discuss it with an eye to resolving it, if possible, to mutual satisfaction. The purpose of standard operating procedure (SOP) is to outline the procedures to be followed in addressing any grievance.

4.3 Scope

Stellenbosch University has implemented robust grievance mechanisms for project participants, bolstered by an established ***Grievance Procedure policy*** (**Appendix 1**) that will remain in force throughout the project's duration. Moreover, the university extends its support to staff and students, offering channels to report a spectrum of issues, including cases of unfair discrimination, harassment, gender-based violence (GBV), bullying, and victimisation. Reporting avenues are available via email at *unfair@sun.ac.za* or through an accessible online platform at *https://ciims.sun.ac.za/ReportingPage/*.

The project's GM, as outlined in the SOP, details the responsibilities of CERI members and outlines the precise procedures CERI personnel are to follow when managing complaints received from stakeholders. This GM is specifically designed to handle grievances related to the project and provides a structured process for receiving, evaluating, and redressing program-related grievances originating from affected stakeholders, communities, and the public.

Under the GM, stakeholders have an accessible platform to lodge grievances and engage in constructive discussions with the aim of achieving a mutually satisfactory resolution. The SOP serves as a guiding document for CERI personnel, ensuring a systematic approach to grievance resolution.

CERI's GM is inclusive, encompassing all stakeholders, both internal (employees and contractors' employees) and external (the community, students, government agencies, etc). It welcomes a diverse range of complaints and grievances, even including anonymous submissions, related to CERI's activities and those of its contractors.

While the procedure addresses formal grievances comprehensively, it also underscores the importance of proactively addressing concerns through stakeholder engagement to prevent them from evolving into formal grievances, promoting a harmonious working relationship within the project's ecosystem.

4.3 Responsibility

To ensure the effectiveness and efficiency of the Project's GRM, the procedures for handling grievances will be administered by CERI. CERI shall maintain records where grievances and complaints, including minutes of discussions, recommendations and resolutions made, will be recorded and disclosed on the CERI website.

4.4 Grievance Categories

To plan effective, well-informed grievance investigations and to track the sources of grievances and complaints, CERI will categorise grievances. Typical categories of grievances include:

- **Employee:** Complaints relating to the hiring process or management of employees by CERI and/or its contractors (e.g.: alleged discrimination during hiring).
- **Social conduct:** Complaints relating to CERI and/or contractors' employees' conduct (on or off work hours) around CERI activities (e.g.: drunk and disorderly conduct around the lab while off work, harassment of fellow workers).
- **Environment and socio-environmental**: Complaints relating to the impact of the CERI's and/or contractors' activities on the environment and social receptors linked to environmental impacts (e.g.: claims of environmental pollution, improper waste disposal).

- **Safety and security:** Complaints relating to the CERI's and/or contractor drivers' conduct (e.g.: vehicles speeding above limits, road accidents, security workers at the lab)

Non-Project related grievances: Non-project related grievances refer to SUN activities or processes not related to the project.

CERI will make information about the grievance mechanism accessible to the project stakeholders and means of communication will be culturally appropriate and understandable to the local population in the area.

Awareness raising should include the following components:

- What the GM does and does not address
- How grievances and complaints can be lodged (channels) including supporting people to access the mechanism (filling in forms for disabled / elderly, etc.)
- What information is required when lodging a grievance.
- What to expect:
    - Procedures and time frames for initiating and concluding the grievance redress process
    - Boundaries and limits of the GM in handling grievances

When awareness will be raised:

- Awareness of the GM will be raised prior to the implementation of the Project. Awareness raising efforts should continue throughout the life of the Project.

How awareness will be raised:

- Display of posters in public places such as University notice boards, project offices, in and outside the laboratory.
- CERI and contractors' website (clearly indicated on the main page)

Channels for lodging a grievance include:

- CERI website to include a link to this grievance mechanism and the grievance form
- Telephone (form to be filled in by CERI staff member):
- Email: CERI@sun.ac.za
- Forms and drop box at CERI Project office (grievance forms and drop box must be visible and accessible to the public):
- Verbally to CERI staff (form to be offered and/or filled in by CERI staff member):
- Grievances received by any other channel are VALID and should be transferred to an official form, handled by the mechanism, and logged.

4.4 Steps for addressing and resolving a grievance

Information on the grievance mechanism is retrievable from CERI's website *www.ceri.org.za*

Stakeholders, the general public and the community can submit their complaints, grievances, or inquiries via telephone or email as summaries in **Table 2** below.

Table 2: Contact details for complaints, grievances, or inquiries and further feedback

Description	**Contact details**
Implementing agency:	Stellenbosch University
Main contact:	Professor Tulio de Oliveira

Address:	Tygerberg Medical School, Stellenbosch University, Francie van Zijl Drive, Tygerberg, 7505, Cape Town, South Africa
E-mail:	ceri@sun.ac.za
Website:	*https://ceri.org.za/contacts-3/*
Telephone:	+27 (0)82 962 4219

The key steps of the grievance redress procedure are summarized below:

Step	**Description of process**	**Timeframe***	**Responsibility**
1. Grievance uptake	Grievances can be submitted via the email or phone		Complainant
2. Sorting, processing	Any complaint received is forwarded to Cheryl Baxter and logged in a database.	Upon receipt of complaint	Cheryl Baxter or designee
3. Acknowledgement and follow-up	Receipt of the grievance is acknowledged to the complainant by Prof de Oliveira (or designee)	Within 2 days of receipt	Prof Tulio de Oliveira or designee
4. Verification, investigation, action	Investigation of the complaint is led by the Complaint Committee and a proposed resolution is formulated by the Committee and communicated to the complainant by Prof Tulio de Oliveira (or designee). If required, a meeting with the complaint will be held to better understand the complaint.	Within 10 working days	Complaint Committee composed of CERI management and, if external representation required, Prof Carolyn Williamson
5. Monitoring and evaluation	Data on complaints are collected in a database and reported to the World Bank every 6 months and disclosed on the CERI website	6-monthly	Prof Tulio de Oliveira
6. Provision of feedback	Feedback from complainants regarding their satisfaction with complaint resolution will be filed in the project files	Upon receipt	Prof Tulio de Oliveira

**All periods indicated are the maximum time allowed for the relevant step in the procedure for resolving grievances, unless a different arrangement has been made with the complainant.*

Step 1: Grievance uptake

The communication channels for stakeholders and the community to submit their grievances includes an email address, face-to-face communication (either in-person or virtually) or telephonically. Stakeholders can submit their grievances via the email (*ceri@sun.ac.za*) or phone (+27 (0)82 962 4219). The email address is monitored daily.

Any stakeholder who lodges a grievance will be asked to complete the **Grievance Form** to formally lodge the complaint in writing.

Step 2: Sorting and processing

Any complaint received will immediately be categorised and brought to the attention of Director and the grievance will be recorded in the Project Grievance database by the Head of Scientific Support. Should the grievance be categorized as a non-Project related grievance, the relevant department within SUN will be notified during the processing.

Step 3: Acknowledgement and follow-up

The complainant will be sent a notification to acknowledge receipt of the grievance within 2 business days. For non-Project related grievances, additional information will be provided regarding the relevant department responsible for dealing with the grievances.

Step 4: Verification, investigation, action

The Complaint Committee, comprised of the CERI Management, will investigate the complaint. If the complaint is about one of the members of the Complaint Committee, then other team members will be asked to investigate the complaint. A meeting will be held, either in-person or virtually, within 7 business days from grievance receipt to discuss the grievance and proposed resolution. The minutes of the meeting and a proposed resolution formulated by the Complaints Committee will be recorded on the Minutes of Complaints Committee Form. Should it be necessary, a meeting will be held with the Complainant to better understand the grievance. The outcome of the meeting and proposed resolution will be communicated to the Complainant by Prof Tulio de Oliveira (or designee) within 10 working days. Both parties will sign the minutes. If the process fails to produce a resolution, the complaint will be referred for arbitration to an impartial senior executive member from each respective organization who is not involved in the project.

Step 5. Monitoring and evaluation

A summary of the complaints received will be collected in the Project Grievance database and reported to the World Bank every 6 months. The following information will be provided:

- 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.

Step 6: Provision of feedback

Any feedback from complainants regarding their satisfaction with complaint resolution will be filed in the project files.

Other mechanisms to submit complaints

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). 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.

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.

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.

4.5 Training

All employees[3] at CERI and its contractors shall be trained on the GM and how to handle stakeholders expressing grievances, complaints, and concerns. Training should be refreshed annually.

4.6 Reporting

CERI will report monthly on the implementation of the grievance mechanism.

The objective of reporting is to:

- Verify that the GM is being implemented as intended including:
  - Proper documentation of the process (log filled in; grievance files kept)
  - Proper communication with grievants (informed of investigation progress, escalation, solutions)
  - Timely implementation of grievance process and identification of sources of delay
- Identify trends in grievances and grievance management:
  - Open and closed, resolved and unresolved grievances per category, complaints per category
  - Changes in number of open and closed, resolved and unresolved grievances per category and complaints per category
  - Open and closed, resolved and unresolved grievances per level
  - Reasons for escalation
  - Changes in number of grievances that escalate
  - Changes in average time to resolution
  - % of resolutions accepted
  - Common sources of grievants (particular communities or contractors)
  - Grievant profile (age, gender, etc.)

The report will include the following sections:

- Summary of awareness raising activities undertaken during the period
- Grievance statistics (tables and charts); narrative explanation

[3] Employees that may be approached by a stakeholder regarding a grievance.

- Summary of open grievances (table format) including status, actions undertaken in the period, actions to be undertaken in the coming period, narrative explanation and observations
- Observations and recommendations for improving the GM, in particular the investigation process and communication with grievants; implementation of training

4.7 Grievance Management Team and Responsibilities

The grievance management team may include but is not limited to:

Role	Responsibilities
CERI GO CERI PI Project Manager	• Promote awareness and understanding of the existence and purpose of the grievance mechanism to communities, contractors, and stakeholders • Principle contact point for grievance receipt • Assesses grievances • Develops investigation plans • Manages investigation • Maintains grievance log and grievance files • Maintains interface with grievants
E&S consultant	• Provide input for the development of the GRM. Provide advice on the implementation of the GRM and evaluation and monitoring of the functioning of the grievance mechanism

ANNEX 1: RISK ASSESSMENT FORM TEMPLATE

Stellenbosch UNIVERSITY IYUNIVESITHI UNIVERSITEIT	Form number: CF04 Version: 1.0	Risk Assessment Form	CERI

Date:	
Activity / Process	

Description of hazard and associated risk:

Risk evaluation:

Hazard Category								**Risk**		**Severity**
Tick appropriate box								Multiply these scores		Use risk matrix
Biological	Chemical	Electrical	Environmental	Ergonomic	Fire / Explosion	Mechanical	Radiation	Consequence	Likelihood	Final Score

Risk level indicator	
Tick applicable Risk	
Low	
Medium	
High	

Measures to control risk / eliminate hazard
Engineering/
Mechanical Measures:

Target date to resolve:	**Actual date resolved:**
Assigned to:	Resolved by:

Comments / re-evaluation of risk / hazard

Name:	Signature:	Date:

Key to Scoring System:

Likelihood		
Score	**Description**	**Frequency**
5	Almost certain	Is expected to occur in most circumstances
4	Likely	Will probably occur in most circumstances
3	Possible	Might occur at some time
2	Unlikely	Could occur at some time
1	Rare	May occur in exceptional circumstances

Consequence		
Score	**Description**	**Severity**
1	Insignificant	No injuries, low financial loss
2	Minor	First aid treatment, on-site release immediately contained, medium financial loss
3	Moderate	Medical treatment required, onsite release contained with outside assistance, high financial loss
4	Major	Extensive injuries(disablement), loss of production capability, off-site release with no detrimental effects, major financial loss
5	Catastrophic	Death, toxic release off-site with detrimental effect, huge financial loss

Risk Matrix	**Risk level indicator = Likelihood x Consequence**				
Likelihood	**Consequence (Severity)**				
	Insignificant 1	Minor 2	Moderate 3	Major 4	Catastrophic 5
5	**5**	**10**	**15**	**20**	**25**
4	**4**	**8**	**12**	**16**	**20**
3	**3**	**6**	**9**	**12**	**15**
2	**2**	**4**	**6**	**8**	**10**
1	**1**	**3**	**3**	**4**	**5**

	Low risk
	Medium risk
	High risk

Definition of Risk levels	
Low	Acceptable risk. The activity/process can continue with the identified hazards, but these must be monitored to discover changes that could increase the risk level.
Medium	The risk can be acceptable for this activity/process, but necessary control measures have to be implemented within a reasonable timeframe.
High	Risk is not acceptable. Activity/process cannot continue before risk control measures have been implemented.
Risk Control Measures	
Avoid hazard	Can the hazard be avoided or altered to reduce the likely-hood or risk? Substitute or replace the hazard
Procedural controls	Can the procedure be altered to avoid or reduce the risk? Can the individual be removed or distanced from the risk? Can the activity be carried out at a time that would have a lesser impact on others?
Engineering/ mechanical	Can engineering or mechanical aids be utilized to avoid or reduce the risk?
Emergency procedures	Document procedures to follow in the event of things going wrong. Can training be used to reduce the risk?

ANNEX 2: LIST OF SU HR POLICIES

SENIOR APPOINTMENTS

- **AP0051** - *Framework for Senior Appointments - Grade 1 to Grade 4*
- **AP0052** - *Regulations for the appointment and reappointment of a Rector and Vice-Chancellor*
- **AP0053** - *Process Flow - Rector and Vice-Chancellor - Appointment*
- **AP0054** - *Process Flow - Rector and Vice-Chancellor - Reappointment*
- **AP0055** - *Regulations for the appointment and reappointment of a Vice-Rector*
- **AP0056** - *Process Flow - Vice-Rector - Appointment*
- **AP0057** - *Process Flow - Vice-Rector - Reappointment*
- **AP0058** - *Regulations for the appointment and reappointment of a Chief Operating Officer (COO)*
- **AP0059** - *Process Flow - COO - Appointment*
- **AP0060** - *Process Flow - COO - Reappointment*
- **AP0061** - *Regulations for the appointment and reappointment of a Registrar*
- **AP0062** - *Process Flow - Registrar - Appointment*
- **AP0063** - *Process Flow - Registrar - Reappointment*
- **AP0064** - *Regulations for the appointment and reappointment of a Chief Director*
- **AP0065** - *Process Flow - Chief Director - Appointment*
- **AP0066** - *Process Flow - Chief Director - Reappointment*
- **AP0067** - *Regulations for the Appointment a Senior Director*
- **AP0068** - *Process Flow - Senior Director - Appointment*
- **AP0069** - *Regulations for the appointment and reappointment of a Faculty Dean*
- **AP0070** - *Process Flow - Faculty Dean - Appointment*
- **AP0071** - *Process Flow - Faculty Dean - Reappointment*

APPOINTMENTS

- **AP0027** - *Procedure for Academic Appointments and Promotions*
- **AP0028** - *Policy on limited appointments for academic staff*
- **AP0029** - *Policy regarding special chairs with a specific research focus and dependent on external funding*
- **AP0030** - *Rules on the appointment of Adjunct Lecturers*
- **AP0031** - *Rules on the appointment of Vice-Deans and Acting Deans*
- **AP0033** - *Procedure for the appointment and reappointment of Distinguished Professors*
- **AP0034** - *Rules and procedures for conferment of Emeritus Professorships and Emeritus Associate Professorships*
- **AP0040** - *Rules for the appointment of Acting Departmental Chairs*
- **AP0041** - *Rules for the appointment of Departmental Chairs*
- **AP0042** - *Rules of procedure regarding extraordinary appointments/appointment of Honorary Professors and appointment of Research Fellows*
- **AP0043** - *Rules for the appointment of Divisional Heads: Faculty of Medicine and Health Sciences (FMHS)*
- **AP0044** - *Rules for the appointment of Executive Heads*
- **AP0045** - *Guidelines for appointment and promotion of lecturers*
- **AP0046** - *Guidelines for the appointment, promotion and recognition of academic staff in disciplines leading to professional qualifications*
- **AP0072** - *Guidelines for Joint Internal Appointments*
- **AP0050** - *Code for employment equity and diversity*

CONDITIONS OF SERVICE

- **CS0051** - *Conditions of service of research and support service staff*
- **CS0052** - *Conditions of service for Temporary staff*

- **CS0053** - *Conditions of service for lecturing staff*
- **CS0054** - *Regulation for appointment* and or continuation of service after the age of 65
- **CS0055** - *Template for annual reporting on the IOC*

REMUNERATION POLICY

- **RM0081** - *Remuneration policy*
- **RM0082** - *Guidelines for the payment of substitute remuneration*

HEMIS

- *HEMIS Personnel Categories*
- *HEMIS Program Classification Structure Summary*

AWARDS

- **TK0101** - *Rules of procedure for Chancellor's awards*

GENERAL

- **GN0130** - *Regulation regarding exemption from combined tuition fees at Stellenbosch University*
- **GN0132** - *Procedure for injury on duty (IOD) Stellenbosch Campus*
- **GN0133** - *Procedure for injury on duty (IOD) Tygerberg Campus*
- **GN0134** - *Job description: Faculty Dean*
- **GN0136** - *Guidelines for Managing Working Hours*
- **GN0137** - *Policy for cellphone and data card policy*
- **GN0138** - *Policy on conflict of interest*
- **GN0139** - *Workplace Breastfeeding Guideline - Faculty Medicine and Health Sciences*
- **GN0140** - *Request for Disbursement of Allowance*

EMPLOYEE RELATIONS

- **IR0151** - *Policy for the prevention of nepotism*
- **IR0152** - *Disciplinary code*
- **IR0153** - *Grievance Procedure*
- **IR0156** - Unfair Discrimination and Harassment Policy

JOB EVALUATION

- **JE0201** - *Policy and procedures with regard to job evaluation*

PRIVATE WORK

- **BW0276** - *General procedure for private work by lecturing staff*
- **BW0277** - *General procedure for private work by support service staff*
- **BW0278** - *General Procedure for Private Work by Lecturing Staff at the Faculty of Medicine and Health Sciences*

PERFORMANCE MANAGEMENT

- **PM0301** - Performance management policy and strategy
- **PM0302** - *Check list for performance management*
- **PM0303** - SU Framework to manage the performance in relation to COVID19

STAFF DEVELOPMENT

- **PD0326** - *Policy on staff development*
- **PD0327** - *Rules on the skills development of support staff within the framework of the policy on staff development*
- **PD0328** - *Guidelines for internships at SU*
- **PD0329** - *SU Training Forum Terms of Reference*

BENEFITS

- **DV0403** - *Benefits applicable to Pensioners*
- **DV0406** - *Benefits for Permanent Employees*
- **DV0430** - *Benefits for Fixed Term Employees - year and longer with benefits*
- **DV0435** - *Benefits for Fixed Term Employees - year and longer without benefits*
- **DV0440** - *Benefits for Fixed Term Employees shorter than one year*
- *Long-service Recognition Policy - 25 years*
- *Spouse- and child pension cancelation form*
- *Funeral cover additional dependants option form*
- *Group life insurance additional cover option form*
- *Government Notices - Code of practice: Managing exposure to SARS-COV-2 in the workplace, 15 February 2022*

FIXED-TERM APPOINTMENTS

- **TP0426** - *Guidelines regulating fixed-term appointments exceeding 3 (three) months*
- Fixed-term contract form (Old HEMIS form)

MEDICAL INCAPACITY

- *Guidelines for Incapacity processes*

ANNEX 2: HEALTH AND SAFETY MANUAL

CERI	Document number: CHSM01 Version: 1	Health and Safety Manual	Stellenbosch UNIVERSITY IYUNIVESITHI UNIVERSITEIT

Centre for Epidemic Response and Innovation

Health and Safety Management Manual

Number	CHSM01	**Written by**	Marinus Barnard
Version	1	**Reviewed by**	Yeshnee Naidoo
Version Date	04 October 2022	**Approved by**	Tulio de Oliveira
Next Review Date	03 October 2023	**Reviewed Date**	04 October 2022

Revisions/Reviews (changes from previous version highlighted)	
Date	**Action**

	DATE	SIGNATURE
IN USE MASTER		
IN USE COPY		
RECALLED		
OBSOLETE		

DEFINITIONS[1]

The term "**containment**" is used in describing methods for managing parasites, infectious agents and infected or potentially infected animals, tissues or other materials in the laboratory environment where they are handled or maintained. The purpose of containment is to reduce exposure of laboratory workers, other persons and the outside environment to potentially hazardous agents.

Primary containment, the protection of personnel and the immediate laboratory environment from exposure to parasitic or infectious agents is provided by good microbiological technique and the use of appropriate safety equipment.

Secondary containment, the protection of the external laboratory environment from exposure to parasites or infectious materials, is provided by a combination of facility design and operational practices. In some instances, primary containment is of less importance than secondary containment e.g where work is done with agents which are not hazardous to humans, but which are of significance should they escape to the environment.

Bio-Safety Level 2 (BSL2) Practices

BSL2 practices, safety equipment and facilities are those which are applicable to clinical, diagnostic, teaching and other facilities working with the broad spectrum of indigenous moderate-risk agents present in the community and associated with human disease of varying severity.

The BSL2 laboratory consist of combinations of laboratory practices and techniques, safety equipment and laboratory facilities which are commensurate with the intended function of the laboratory and the nature of the infectious agents to be handled or maintained therein. Specific infectious agents are assigned to one or more of five biosafety levels on the basis of the potential hazard which they constitute and of the intended laboratory procedure to which they will be subjected.

The CERI laboratory is a BSL2 laboratory. In addition to the practises required in a BSL1 laboratory, the BSL2 facility (defined as a containment laboratory) ensure the use of PPE, when conducting procedures with infectious agents, decontamination of all infectious waste, and is access controlled.

Activities with low aerosol generating potential with these agents can be conducted on the open bench using good microbiological techniques. The hepatitis agents (hepatitis A, hepatitis B, hepatitis C), and the salmonellae are representative of microorganisms assigned to BSL2. Primary hazards to personnel working with these agents relate to accidental auto-inoculation or ingestion of infectious materials. Procedures with high aerosol potential may predictably and significantly increase the risk of exposure of personnel to infectious aerosols and must be conducted in primary containment equipment or devices.

PURPOSE

This document defines the various safety procedures followed in the CERI laboratory to avoid/mitigate adverse impacts on personnel, on all operational and material requirements in the CERI laboratory as well as shared spaces with others.

In addition to the aforementioned, the document also describes all the activities and procedures associated with Good Laboratory Practice (GLP) for work performed in the presence of non-viable Class II Hazardous Biological Agents (as classified by the Occupational Health and Safety Act (OSH), Act no 85 of 1993 Regulations for Hazardous Biological Agents of South Africa)), the biosafety level required for analyses done by the CERI laboratory, the management of hazardous materials and the storage and disposal of thereof, as well as the management of Data-based waste.

All samples received are considered as being potentially infectious as they are pathogenic for humans. The risk of becoming infected is low for those who work in laboratories where samples containing non-viable SARS-COV-2 viruses are processed. All samples, however, are processed in an environment where specific engineering controls, administrative procedures and appropriate personal work practices ensure containment of the organism and protection of workers. When these controls and procedures are implemented and protective measures are followed, laboratory personnel can substantially reduce their risk of becoming infected.

The procedures in this document focus on the environment, health and safety of personnel working with non-viable SARS COV-2 samples in the BSL2 laboratory. All personnel working with non-viable samples or material which potentially contains biohazards, are trained to work in the BSL2 laboratory. Training involves undergoing a medical examination, a practical demonstration of the general activities in the BSL2 laboratory, as well as working under supervision before a person is considered competent to work independently.

PRINCIPLE

The CERI Laboratory is committed to the safety of its employees and the safety of others working in the environment. It is the responsibility of both the employer and employee to ensure safe practices and working conditions. Policies in this manual are in accordance with the Occupational Health and Safety Act and the University of Stellenbosch Safety Guidelines.

The Health Safety Manual is intended to address universal safety measures for ensuring a safe and healthy working environment. It describes good laboratory practice that must be understood and applied by all individuals working in the CERI Laboratory. It describes control measures which are essential to protect all laboratory workers from potential biological, chemical, and physical hazards. These controls consist of, but are not limited to, policies, guidelines, training requirements, standard operating procedures, personal protective equipment, laboratory inspections, and hazard evaluations.

For hazards and safety precautions not addressed in this manual, specific standard operating procedures must be developed where necessary by the Laboratory Manager or Principal Investigator, together with the Safety Officer.

PERSONNEL

Employees are provided with information and training when they start working at the laboratory to ensure that they are acquainted with the hazards of chemicals/pathogens present in their working environment and the steps that should be taken to protect themselves from these hazards. This training includes individual instructions and group meetings. Specific hazards in the work area are accentuated. Employees also receive periodic refresher training and information. Information will include all safety regulations, evacuation plans and /biological chemical hazard identification.

Training includes methods to identify possible chemical leakages and other dangers, measures that employees can take to reduce chemical and physical health hazards, applicable sections of the chemical hygiene plan and awareness of the chemical hygiene plan will be documented.

Staff are responsible for planning and conducting all operations in accordance with the biological/ chemical hygiene procedures and SOPs by developing good personal biological/chemical hygiene habits. This is achieved by using laboratory equipment for their intended purposes only, by being aware of potential unsafe conditions and the reporting of these conditions as soon as possible so that corrective and preventative actions can be taken to mitigate the situation/condition.

Protection of Personnel

Any person working in the BSL2 laboratory, or in BSL1 laboratories for molecular work, which might be exposed to HBAs must obey the rules and regulations put in place by the BMRI. These include practical aspects such as wearing of personal protective equipment (e.g., laboratory coats, gloves, masks, etc.), instructions regarding safe and health practices, personal hygiene, and good housekeeping as well as disposal and decontamination procedures with regards to waste. The basic concept of working in a laboratory is that workers must conduct themselves in a safe manner so that they do not place themselves or others at risk. It is everyone’s responsibility to ensure safety and if a worker in the laboratory feels that another individual is working in an unsafe manner, they are obliged to bring this to the attention of the person involved and to laboratory management. All personnel working in the BSL2 and/or BSL1 laboratory must attend the quarterly meetings which are arranged by the Laboratory manager. If an individual is unable to attend, they must give written notification which will be kept on record. All present at the meeting must sign an attendance list. Minutes must be kept of these meetings.

In the event of hazards presenting themselves, medical attention will be provided to employees in the case of them developing symptoms associated with exposure to a hazardous chemical or in the case of spillage or leak of a chemical hazard, or an explosion.

Operational Considerations

Keyboards and telephones in non-processing areas are designated as clean and should not be accessible to individuals handling samples or engaged in laboratory work. If a worker needs to use the keyboard or telephone, they must remove their gloves, wash their hands, and put on a new pair of gloves before doing so. Telephones

may only be used in the clean area of the laboratory, after hands have been washed and clean gloves have been put on. Individuals using clean keyboards must wear a new pair of gloves before doing so. Wash hands thoroughly before leaving the laboratory.

Medical Surveillance

Personnel will only be allowed to enter the BSL2 laboratory and other molecular laboratories, once a medical examination has been completed. An initial medical examination serves as a baseline against which future tests can be compared and evaluated, should the need arise.

Prior to performing any work in the BSL2 laboratory, personnel must undergo a medical examination comprising of a Hepatitis B antibody titre measurement and must have proof of vaccination against COVID-19. Based on the results from the initial medical examination, further vaccinations or tests might be requested by the Medical Officer. An annual health surveillance will be conducted in the form of a health assessment questionnaire to assist in screening. Visitors, such as training fellows, who are required to work in the BSL2 laboratory will also undergo medical testing before being allowed to work in the facility. Pregnant personnel may work in the BSL2 laboratory up to the point (based on ergonomic comfort) where they feel uncomfortable to do so towards the final trimester of their pregnancy if so desired by them.

All staff records are treated as confidential, and no information is used or supplied.

First Aid and work-related incidents

An incident or accident can be described as any personal injury, illness or condition sustained by an employee because of work-related trauma, inhalation or contamination. This section will apply should any staff member require medical assistance.

Minor Injuries

1. Report all injuries to the laboratory manager in writing. The injury will be reported by the laboratory manager to the Principal investigator.
2. Contact Human Resources so that an Employer's Report can be completed.
3. The injured person should go to the doctor of his/her choice with the completed report.

Serious Injuries

1. These are injuries in urgent need of a doctor or hospitalization.
2. Contact the laboratory manager immediately.
3. Immediately transport the injured person to a doctor or hospital and state that it was an INJURY ON DUTY.
4. Inform Human Resources within 24 hours.

The Incident/Adverse Event Register must be completed if any person receives first aid at the workplace. This register can be obtained from the safety officer, room F409. Tel: 0219389402

For minor cuts and illnesses, a first aid box is available in the laboratory and Room 412.

ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

General

Keyboards and telephones in non-processing areas are designated as clean and should not be accessible to individuals handling samples or engaged in laboratory work. Telephones may only be used in the clean area of the laboratory, after hands have been washed and clean gloves have been put on. Individuals using clean keyboards must wear a new pair of gloves before doing so. All staff is to wash their hands thoroughly with the appropriate disinfectant/antibacterial soap before leaving the laboratory.

BSL1 / BSL2 Laboratory

As owner of the BSL1 / BSL2 laboratory, the Biomedical Research Institute (BMRI) of the University of Stellenbosch, is responsible for the safe operation of the laboratory. This is done by putting structures and systems in place which will ensure compliance to section 43 of the Occupational Health and Safety Act, dealing with regulations for Hazardous Biological Agents (HBAs), with special attention to the handling of airborne transmitted HBAs such as SARS-COV-2. It is the responsibility of the BMRI to have at least one BSL1 / BSL2 meeting every quarter of the year. As these meetings are deemed important and considered part of refresher training. These meetings serve as a platform for both CERI laboratory management and staff to discuss issues such as safety, general operations and to introduce new procedures.

Ventilation

Proper ventilation ensures a safe and comfortable environment. The environmental conditions inside the laboratory must be monitored to ensure that results are not negatively influenced and to protect personnel working in the laboratory. Ventilation disruptions must be avoided as far as possible, and airflow must not disperse potentially infectious agents.

The air conditioning in the laboratory is designed primarily for temperature control and air movement to give a minimum of 12 air changes per hour. The ventilation system includes vents, biological safety cabinets and fume hoods, whilst the BSL2 laboratory is kept under negative pressure. This means that air is sucked into the room and leaves through ventilation ducts and filters in the ceiling. This is to prevent the release of hazardous agents. Biological safety cabinet class I are designed to protect the environment and personnel. Class II cabinets also protect the product from external contamination. Centrifuges must not be operated inside a BSC as this may disrupt the airflow by producing strong air currents. Biological safety cabinets are serviced once every six months. Biological safety cabinets are negatively affected by open doors or windows nearby, room air currents and movement close to the fume hood opening. Fume hoods should be inspected annually and requires routine maintenance on exhaust fans.

EMERGENCY PROCEDURES

Spillage

In the case of spillage/breakage in the laboratory the responsible staff member must make a strong verbal alarm to warn personnel that an accident has occurred. All personnel present in the laboratory must respond immediately and appropriately. Personnel not involved in the spillage or clean-up thereof must proceed to the exit immediately by avoiding the contaminated area. Personnel should try to limit air-intake and must try to breathe minimally to avoid inhalation of potential aerosols generated by the spill during the short evacuation period. All laboratory gowns/overcoats and gloves must be removed immediately and left on the floor, and the facemask is to be removed prior to exiting the laboratory. No running is allowed at any time.

The staff member who accidentally caused the spill is to clean it up with the appropriate disinfectants and dispose thereof in the correct manner. It is also the responsibility of this staff member to report the incident to the Platform Manager for the completion of the necessary forms and procedures to be taken.

If ones' eyes suffer harm from splashes, eye wash stations are available to mitigate the harm until further medical attention is required if need be. If a person's clothing has been contaminated by the spillage, or if major skin contact has occurred, even if PPE as worn, the person should strip off the contaminated/spoiled clothing inside the laboratory and proceed to the nearest emergency shower to completely rinse of the contaminant. Wash the whole body with water and the appropriate disinfectant soap.

In the case of a needle stick injury in the laboratory, the injured is to leave the laboratory immediately, report the accident to the Platform Manager and then consult the medical officer affiliated to the laboratory immediately. If needed, all personnel who were present during an accident are subjected to medical surveillance post-accident event to ensure their safety.

Fire

The Fire Safety Plan will help staff to utilize the fire-fighting equipment safely within the laboratory and ensure an orderly evacuation in the case of an emergency. The below table classifies fire into four classes, showing examples of each as well as the appropriate extinguisher for the respective class of fire.

Classification of Fire	**Example**	**Extinguisher**
Class A	Ordinary combustibles, such as wood, paper, cloth, etc.	Pressurised water and dry powder
Class B	Flammable liquids – gases, paint, grease, etc.	Dry powder and carbon dioxide
Class C	Electrical - instruments and computers	Carbon dioxide

Class D	Combustible metal fire	Chemical powder

This section provides information on emergency procedures and actions to be taken in the event of fire, or a simulated fire drill.

Stay calm, shout out “FIRE” and raise the fire-alarm immediately. Make sure that everyone in the laboratory is aware of the fire and notify Campus Security on EXT: 9507. Contact the Fire Brigade (Parow Fire Brigade 021 938 8222) or the Fire and Rescue Service of Cape Town (021 590 1900). Basic fire containment rules (such as closing of doors and windows) are to be applied if conditions allow for such and if it is safe enough to do so. If a bomb-scare is raised, windows and doors must be left open so as is mitigate the pressure in the laboratory/room. Ensure that the appropriate fire extinguisher, matched to the class of fire is used.

The below table describes the procedure for using the respective fire extinguishers, all which are inspected annually by the external service provider:

Extinguisher	**Procedure**	**Discharge range**	**Discharge time**
Water	1. Pull the pin 2. Aim the nozzle 3. Squeeze the handle 4. Sweep the extinguisher	9 – 12m	60 seconds
Carbon Dioxide	1. Pull the pin 2. Aim the nozzle at base of fire 3. Squeeze the handle	1 – 3m	30 seconds
Dry powder	1. Pull the pin 2. Aim the nozzle at base of fire 3. Squeeze the handle	2 – 6m	30 seconds

In the interest of time and safety, all staff that are not involved in handling the fire is to evacuate the area immediately. Timely evacuation is crucial should the operator not be able to extinguish the primary fire with the respective fire extinguisher. If time allows and personal safety is not affected, switch off all electrical equipment, safeguard important documents and hard drives, as well as personal belongings.

Remain calm and do not run during the evacuation of the building. The emergency staircase is to be used and under no circumstances shall the lifts/elevators be used. Evacuate the building via the nearest escape route using the signage provided and to be followed during emergency evacuation procedures. If any of the escape routes are filled with smoke, follow an alternative route. If the escape route is filled with smoke, place a wet cloth over the mouth and nose to prevent smoke inhalation and exit the building by crouching or crawling on the floor. All staff is to gather at the designated assembly point situated on the outside of the building to not obstruct the Fire Brigade.

Electrical Safety

Knowledge of electrical safety is essential to avoid unnecessary accidents in the laboratory. New, modified, or repaired equipment must be checked for safe operation before being placed

into service. Make sure that your hands, and working surfaces, are dry before touching electrical equipment or connecting cords. Examine electrical wiring, plugs, and extension cords routinely for any signs of deterioration or exposed wires and replace when necessary. All critical equipment used by CERI is connected to emergency power outlets, recognizable by their red/blue wall mountings.

All electrical outlets are inspected annually, and there are sufficient electrical outlets (emergency power, uninterrupted power) to avoid multiplug adaptor use. In the event of an electric shock, or emission of smoke or burning smell, immediately take the piece of equipment out of operation, label it clearly and have it serviced. Do not override fuses or interlock switches. Never pull on a cord to remove the plug from an electrical outlet, grasp the plug firmly and pull it out of the socket. Extension cords are not to be used.

EQUIPMENT

All equipment related documents stipulates the safety aspects associated with any piece of equipment. This document reiterates the most important equipment related procedures to ensure biosafety, personnel protection, protection to the environment and the like.

General

The proper use of equipment will prevent unnecessary mistakes thereby avoiding the risk of harm/injury. The equipment must be cleaned and disinfected weekly, or as soon as the equipment becomes contaminated. No centrifuges are to be used in biological safety cabinets since the motor may produce strong air currents which may disrupt the air flow. Use centrifuges with safety buckets when working with biological samples and disinfect after each run.

Clean and disinfect pipetting devices with appropriate disinfectant before and after each use thereof, or if it becomes contaminated during use. If the pipette is contaminated internally, the entire unit must be disassembled, decontaminated, sent for servicing and re-calibration, and once returned to the laboratory, subjected to a post-service functionality test via validation of the pipette.

Prior to service-provided maintenance all equipment is to be decontaminated with the appropriate disinfectant. A decontamination certificate is handed to the service provider as proof that the equipment is safe for maintenance/service to be done, thereby ensuring that the service provider is not exposed to hazardous material.

Biological Safety Cabinets
CERI uses Class II vertical laminar-flow biological cabinets, which is an open- fronted, ventilated cabinet with an average inward face velocity at the work opening of at least 23 metres per minute. This cabinet provides a high efficiency particulate air-filtered (HEPA), recirculated mass airflow within the workspace. The exhaust air from the cabinet is also filtered by high efficiency particulate air(HEPA) filters. Personnel protection provided by Class II cabinets is dependent on the inward airflow and they generally provide an equivalent level of personnel protection. The use of these cabinets alone, however, is not appropriate for containment of highest-risk infectious agents because aerosols may accidentally escape through the open front. The use of a Class II cabinet in the laboratory offers the additional capability and advantage of protecting materials contained within it from extraneous airborne contaminants; this capability is provided by the high efficiency particulate air filtered (HEPA) recirculated mass airflow within the workspace.

REAGENTS AND CONSUMABLES

Hazardous Chemicals
According to the Occupational Safety and Health Administration (OSHA) a hazardous chemical is defined as any element, chemical compound, or mixture of elements and/or compounds which is a physical or health hazard. A chemical is a physical hazard if there is scientifically valid evidence that it is a combustible liquid, a compressed gas, explosive, flammable, organic peroxide, an oxidizer, pyrophoric, unstable or water-reactive.

A chemical is a health hazard if there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees. Included are:

- Biohazards
- Carcinogens
- Irritants
- Reproductive toxins
- Corrosives
- Sensitizers
- Radioactive material
- Neurotoxins (nerve)
- Hepatotoxins (liver)
- Nephrotoxins (kidney)
- Agents that act on the hematopoietic system (blood)
- Agents that damage the lungs, skin, eyes, or mucous membranes

Material Safety and Data Sheets (MSDS)
All staff must know the location of this MSDS manual in the event of accidents or incidents involving chemicals or hazardous substances. Knowledge of MSDS ensures that all employees are able to react correctly in a potentially hazardous or harmful situation. All staff must familiarize themselves with the contents of the MSDS folders.

If a new reagent is ordered, and the current MSDS is not in the folder, the respective MSDS is added to the folder. Hard copies of the MSDS will be available in the areas where chemicals or hazardous substances are used.

Handling of Chemicals[2]

Knowledge on how to handle chemicals will ensure a safe and healthy workplace. The various chemical classes and identification labels are listed below.

Class A Chemicals – Compressed Gas

Compressed gases include all products, materials and substances contained under pressure greater than atmospheric pressure. Many hazards are associated with compressed gas, i.e., it can be toxic, flammable, corrosive, or cause frostbite in the case of cryogenic gases. Compressed gas cylinders must be handled correctly to avoid serious physical injuries. Dropped or damaged cylinders may become missiles if ruptured, or if valves are broken off.

1. Identification of contents

    - The contents of compressed gas cylinders must be identified clearly and labelled accordingly with durable labels that cannot be removed.
    - Delivery of unidentified compressed gas cylinders must not be accepted.
    - Colour coding must not be used as an identifier of the content of a gas cylinder since colour codes vary from supplier to supplier.
    - If the labeling on the cylinder becomes unclear, it must be marked “CONTENTS UNKNOWN” and the manufacturer must be contacted regarding disposal.

2. Transportation

    - Cylinders must be transported with regulators and safety caps attached. The cylinder cap must be screwed all the way down to the neck ring.
    - Cylinders must be transported using a trolley to which it is safely secured.
    - The cylinders may not be moved or lifted using the protective cap.
    - Do not drop or bump cylinders.

3. Leaking cylinder

    - Tag leaking cylinders with stuck valves and move them to a safe, secure outdoor location.
    - If the contents are flammable, do not bring it into contact with any source of ignition.
    - Contact the supplier for removal.
    - Never attempt to repair cylinder valves.

4. Storage of cylinders

- Gas cylinders must be secured to a fixed support (solid wall) with a chain to prevent them from falling over.
- Cylinders must be stored in a well-ventilated area.
- Keep away from flames, sparks, or any sources of ignition and heat.
- Keep in an upright position.
- Keep away from dampness and corrosive chemicals or vapours. Corrosion may damage the cylinder.
- Store cylinders in compatible groups.
- Keep the valves of empty cylinders closed.
- Do not store flammable gas cylinders with oxygen or nitrous oxide cylinders.
- Oxygen cylinders must be kept a minimum of 6 meters away from flammable gas cylinders or combustible materials.

5. Use of compressed gas cylinders

- Do not use the cylinders for any other purpose than the supply of gas.
- Wipe outlets with a clean, dry cloth before attaching connections or regulators.
- Always use proper regulators for the gas in the cylinder.
- Make sure that the connectors are intended for gas supplies.
- Keep cylinders and valves away from oil and grease.
- Stand to the side of, and face away from the regulator when opening the cylinder valve.
- Open cylinder valves SLOWLY. Never use a wrench to open valves. Only open en close them by hand. If it cannot be operated by hand, have the valve repaired by the manufacturer.
- Shut off cylinder valves when not in use.

Class B Chemicals – Combustible and Flammable Material

Combustibles and flammables are materials that, under standard conditions, can generate sufficient vapour to cause a fire in the presence of an ignition source.

They can be divided into the following groups:

- Flammable gases
- Flammable liquids, i.e. acetone, ethanol, and glacial acetic acid
- Combustible liquids
- Flammable aerosols
- Flammable solids
- Reactive flammable materials

Flammable liquids

Flammable liquids can give off large volumes of flammable vapours at room temperature. These vapours, when mixed with air, can ignite – often violently. Spilled flammable liquids can, if not contained, flow a long way to an ignition source and then

flash back to the source of the leak. Spills on clothing can represent a serious risk of injury if ignited.

To control these risks:

- Store flammable liquids in separate storage areas or in purpose made bins or cupboards.
- Dispense and use flammable liquids in safe, well-ventilated spaces without any sources of ignition.
- Keep containers closed when not in use. When possible, self-closing lids should be used.
- Dispense liquids over a tray and keep some non-flammable absorbent material handy to mop up spills.
- Dispose of contaminated materials safely or call in disposal experts.

Flammable solids

Some types of plastic foam, packaging materials, polyester wadding and textiles will ignite easily and burn fiercely, giving off a dense black smoke.

It is important to:

- Not store these materials close to heaters or electrical equipment which could run hot and act as a local ignition source.
- Ensure that passages and exits from storage and work areas are kept clear of packaging materials, products containing flammable solids, etc. In the event of fire, passages and exits could become obscured by smoke, so they should be made easy to find.

General precautions for Flammable and Combustible Materials in the laboratory

1. Use

    - Know the location of the fire alarm and fire extinguishers.
    - Ensure that there are enough fire extinguishers in areas where flammable or combustible materials are used.
    - Use in well-ventilated areas or in chemical fume hoods.
    - Eliminate ignition sources form areas in which flammable or combustible materials are used.
    - Never dispose of flammable or combustible materials down drains or sewers.

2. Storage in laboratory

    - Minimize quantities of these materials in the laboratory.
    - Use approved containers to store these materials. They should safely relieve internal pressure when exposed to fire.
    - Store in flammable storage cabinets, or in vented cabinets underneath chemical fume hoods.
    - Never store flammable or combustible materials near oxidizing materials.
    - Label storage areas and cabinets clearly as DANGER – FLAMMABLE.

3. Bulk storage

    - Ensure that storage areas have enough fire extinguishers.
    - Ground metal containers whenever filling, dispensing or storing flammable liquids.
    - Use portable safety cans whenever possible for storing, transporting and dispensing flammable liquids.

Class C Chemicals – Oxidizing Materials 

Oxidizing materials include any compound that spontaneously evolves oxygen, either at room temperature or under slight heating. Oxidizing materials pose a serious fire and/or explosion risk in the presence of flammable or combustible materials. Many oxidizers may be highly corrosive or toxic.

Examples of strong oxidizers include:

- Chromic acid
- Any peroxide
- Sulphuric acid
- Any perchlorate
- Sodium hypochloride

General precautions for oxidizing materials in the laboratory

1. Always keep oxidizers away from flammable or combustible materials (e.g. methanol and acetic acid).
2. Store in cool and dry designated areas.
3. Keep away from heat, and any source of ignition.
4. Always wear the correct personal protective equipment (PPE).

Class D Chemicals – Poisonous and Infectious Materials 

Exposure to toxic chemicals or infectious material may be fatal, or cause permanent damage after exposure or over a period of time. These chemicals can be inhaled, ingested or be absorbed into the body through the skin. Repeated exposure to some chemicals may cause cancer, birth defects and sterility. Less toxic substances should always be selected if an alternative is available.

Examples of chemicals causing acute or immediate effects:

- Chloroform
- Ethanol
- Iodine
- Methanol
- Sulphuric acid

Examples of chemicals which may cause effects over long term exposure:

- Acetone
- Sodium azide
- Xylene
- Isopropanol

General precautions for toxic materials in the laboratory

1. Handle with caution. Always wear protective and suitable PPE.
2. Avoid inhalation by working in a fume hood, or well-ventilated area.
3. Cover work surfaces with dry, absorbent, plastic-backed paper. Dispose after each procedure.
4. Keep controlled substances in locked cupboards.
5. Wash thoroughly after handling.

Class E Chemicals – Corrosives

Corrosives are materials which chemically react at the point of contact to cause visible (often burn-like) damage to tissue. Examples include acids and bases.

General precautions for the use of Corrosive Materials in the Laboratory

1. Transportation
    - Use bottle carriers or Styrofoam crates.
2. Use
    - Wear appropriate PPE and consult the MSDS.
    - Limit the amount of corrosive chemicals to the amount required for procedure.
    - Keep containers closed tightly.
    - Use strong corrosives in chemical fume hoods.
    - Always add acid to water slowly (NEVER THE REVERSE), to avoid violent reactions and splattering.
    - Ensure that eyewash stations are readily accessible in areas where corrosives are used.
    - In the event of skin or eye contact, immediately flush with cool water for 15 minutes.
    - Remove all affected clothing and seek medical attention.
3. Storage
    - Store strong corrosives in well-ventilated areas away from flammable and combustible liquids and oxidizing agents. Store on one side of the cupboard under the fume hood.
    - Label the cabinet clearly as DANGER – CORROSIVE

- Never store strong alkaline solutions in glass containers. The glass will be etched and leachate will enter the solution. This will contaminate the solution and weaken the container.

Class F Chemicals – Dangerously Reactive Chemicals

Reactive chemicals react rapidly with themselves or other materials to release relatively large amount of energy. In some instance, the reaction may be violent enough to produce detonation.

Examples and Precautions when working with Reactive Chemicals

1. Pyrophorics

    - Hazard: Ignites spontaneously upon contact with air.
    - Example: Phosphorous, fine powders of metals such as magnesium, aluminium and zinc.
    - Precautions: Use and store in an inert environment.

2. Oxidizers

    - Hazard: Reacts violently with organic materials or strong reducing agents.
    - Examples: Perchloric acid, chromic acid.
    - Precautions:
        - Use minimum amounts per procedure.
        - Store away from organic materials, flammable materials and reducers.

3. Peroxidizables

    - Hazard: Reacts with oxygen to form peroxides which can explode with impact, heat or friction.
    - Examples: Diethyl ether, isopropyl ether.
    - Precautions:
        - Date all upon receipt and upon opening.
        - Dispose within 6 months of opening or 12 months of purchase.
        - Never open a container with crystal formation around the lid.

4. Water reactives

    - Hazard: Reacts with water to produce a flammable or toxic gas or other hazardous product.
    - Examples: Alkali metals such as lithium, sodium and potassium, and acid anhydrides such as acetic anhydride.
    - Precautions:

        - Avoid contact and handle away from water sources.
        - Use dry sand to smother fires.
        - Provide ventilation to disperse flammable gases.

Never store reactive materials, as listed above, with flammables, combustibles, oxidizers or corrosives.

HANDLING OF SAMPLES CONTAINING POTENTIAL INFECTIOUS MATERIALS

All specimens must be collected in solid, leak resistant containers Specimen containers must be securely sealed in a plastic specimen bag. The plastic bag should have a separate pouch for the specimen transport form. Procedures that have the potential to generate aerosols must be performed in a biological safety cabinet or behind a protective shield. Keep biological safety cabinets clear of clutter.

Pathogen Safety and Data Sheets (MSDS)

All staff must know the location of this PSDS manual in the event of accidents or incidents involving potential pathogens. Knowledge of the PSDS ensures that all employees are able to react correctly in a potentially hazardous or harmful situation.

SHIPMENT OF HUMAN PATHOGENS AND RELATED MATERIALS

Routine medical specimens assigned to BSL2 and being transported to laboratories or between laboratories within South Africa by clinicians, pathologists, or their delegates. e.g., messengers, are not subject to special restrictions but should be packed safely. Materials sent by mail or public transport are packed in accordance with postal and transport requirements as set out by IATA

Receipt of specimens containing infectious agents

Only specimen transport boxes for infectious materials must be used for transport of specimens intended for processing in the BSL2 laboratory. Transport boxes with CERI samples are received at the reception on the Ground Floor of the BMRI building. Transport boxes may be opened only by personnel trained to handle infectious material. The transport boxes must be placed inside a BSC before being opened. If breakage/leakage occurred in any of the specimen containers, the details must be noted, and the specimen must be discarded without processing. Care must be taken during this procedure to reduce aerosol production.

Dispatch of materials containing infectious agents

No material should be dispatched without the agreement of the receiving laboratory. Infectious material may only be transported in SABS approved transport containers designed for the purpose. Transport materials include sealable transparent plastic pouches, absorbent material, hard inner containers and transport boxes labelled with infectious material signs.

WASTE DISPOSAL

All General Waste is disposed of in the respective, appropriate, waste containers inside the various laboratory sections and office areas.

BIOLOGICAL WASTE

This section describes the way in which biological waste, as well as biologically derived waste, must be disposed of to prevent risk of infection and/or injury. All contaminated materials must be decontaminated prior to disposal. All biological waste must be collected, packaged, labelled, and disposed of in strict accordance with The Occupational Health and Safety Act (1993) of the RSA.

Liquid waste and solid waste are to be separated and discarded of in the respectful manner. The procedure on how to properly dispose of biological waste generated after the extraction of RNA/DNA (either manually or automated) or the waste generated by the various Sequencing platforms used at the CERI laboratory, is outlined below.

Liquid Waste

- All residual sample material, post-processing sample/product material and extraction/sequencing reagents used to process the samples, is to be inactivated with 10% bleach and/or 70% ethanol - based on the reactivity/compatibility of the waste products with the aforementioned inactivation reagents.
- Liquid waste generated from extraction and/or sequencing instruments, via the liquid waste outlet, is collected in a dedicated, clearly labelled waste drum/container to a maximum level of 75% as indicated by a line drawn on the drum/container.
- These drums/containers are to be put inside an appropriately sized drip-tray, so as to prevent accidental overflow of any liquid waste onto the laboratory floors, thereby preventing a potential injury whilst on duty.
- The drums/containers, once filled to the prescribed maximum capacity of 75% or to a level which still enables the drum/container to be lifted without causing injury to those who are responsible for the final removal thereof, are collected by Enviroserve.

Solid Waste

- Solid waste, such as the primary sample receptacle(s), used filter tips, used consumables and reagent plastics for example, is to be discarded in the appropriate biohazard waste bags, and secondary protective biohazard bags if required.
- Care must be taken so as not to puncture the biohazard waste bags upon removal of the filled biohazard waste bag(s).

Electronic Data Waste

- All successful sequencing files, after quality control has been applied, are sent to an international databank and the files kept indefinitely. The data files of those that were unsuccessful is kept for a minimum period of 5 years until it will be permanently deleted by those authorised to perform this action.

CHEMICAL WASTE

This section describes the way chemical waste is handled and ensures that the disposal of chemical waste is done in a manner that is safe, environmentally sensitive, and in compliance with government regulations and legislation.

Chemical waste is not to be disposed of down the drain or with regular waste. Chemical waste should not accumulate in the laboratory and is to be taken away for disposal based on the agreed upon waste volume capacity by an external waste disposal service provider. The contents of the waste/waste category is to be clearly

labelled prior to hand over thereof to the service provider. If there is any doubt of the correct disposal procedures of a specific chemical, the laboratory safety officer. Or designated other, must be consulted. Correct disposal procedures are also available in the MSDS of any specific chemical.

CHEMICAL HYGIENE/HAZARDOUS MATERIAL PLAN

A Chemical Hygiene Plan (CHP) is required by the Occupational Safety and Health Administration's (OSHA) "Occupational Exposure to Hazardous Chemicals in Laboratories" 29 CFR 1910.1450. The intent of this plan is to require those who work in the facility to identify hazardous chemicals in the laboratory and to specify that engineering controls, work practices, and personal protective equipment can protect laboratory staff and the building environment. Chemical hygiene is the responsibility of the Principal Investigator and Platform Manager who must ensure that staff know and comply with all chemical hygiene rules, that all laboratory personnel have access to the CHP and MSDS documents, and that protective clothing and equipment is available to the staff. They also ensure that staff receives the appropriate information, that training has been provided to the staff members, and that the laboratory facilities and training are appropriate and adequate.

In addition to providing the necessary documentation such as standard operating procedures (SOPs), emergency procedures and chemical hygiene plans, it is also their responsibility to perform regular biological/chemical hygiene inspections of the laboratory and equipment and be knowledgeable of all legal and departmental requirements concerning regulated substances.

HAZARDOUS CHEMICALS

According to the Occupational Safety and Health Administration (OSHA) a hazardous chemical is defined as any element, chemical compound, or mixture of elements and/or compounds which is a physical or health hazard. A chemical is a physical hazard if there is scientifically valid evidence that it is a combustible liquid, a compressed gas, explosive, flammable, organic peroxide, an oxidizer, pyrophoric, unstable or water-reactive.

A chemical is a health hazard if there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees. Included are:

- Biohazards
- Carcinogens
- Irritants
- Reproductive toxins
- Corrosives
- Sensitizers
- Radioactive material
- Neurotoxins (nerve)
- Hepatotoxins (liver)

- Nephrotoxins (kidney)
- Agents that act on the hematopoietic system (blood)
- Agents that damage the lungs, skin, eyes, or mucous membranes

The label should indicate whether the chemical is hazardous. If the danger of the chemical is uncertain, the user must refer to the Material Safety Data Sheet (MSDS)

QUALITY PROCESS

In order to ensure a safe working environment, it is necessary to establish and maintain standards, policies, procedures and work practices. In addition, a maintenance program must be in place for the laboratory and its equipment. Staff must be trained in safe working practices and procedures in compliance with established health and safety guidelines. An internal responsibility system must be in place that follows the guidelines of the safety committee. This section describes the quality process, outlining the responsibilities of management and staff for ensuring a safe working environment such as described in the Occupational Health and Safety Act (1993) of the Republic of South Africa.

It is the responsibility of the Principal Investigator and Management to:

- Establish and maintain standards, policies, procedures, work practices and maintenance of the laboratory.
- Take every reasonable precaution to ensure a healthy and safe working environment.
- Ensure that safety policies and procedures are implemented and adhered to.
- Review the safety manual.
- Appoint a safety officer and safety committee.
- Introduce new staff to safety regulations in the laboratory.
- Train staff continually in safe working practices and procedures.
- Take appropriate action to correct any actual or potential health and safety hazards.
- Update Material Safety Data Sheets.
- Have staff trained in fire safety.

It is the responsibility of All employees and Fellows/students to:

- Participate in safety training.
- Work in a safe and responsible manner.
- Report any actual or potential safety hazards to the laboratory manager.
- Prevent loss of, or damage to, laboratory property due to unsafe work practices.
- Use the personal protective equipment (PPE).

It is the responsibility of the Safety Officer to:

- Promote safe work practices and conditions.
- Conduct regular workplace inspections.
- Promote training programs to increase health and safety awareness at work.
- Recommend appropriate action on discovered or reported unsafe equipment, working conditions and actual or potential health and safety hazards.

It is the responsibility of the Medical Officer to:

- Review medical emergency protocols and inform staff of substance precautions as required.

It is the responsibility of the University of Stellenbosch (Health and Safety Unit, Risk and Protection Services) to:

- Provide training sessions for the use and handling of fire extinguishers.
- Conduct fire drills.
- Assist and guide employees in the case of workplace incidents.
- Provide health and safety inspection checklists for laboratories and offices.
- Remove bio-hazardous waste.
- Transport dangerous goods.
- Ensure air quality.

It is the responsibility of the Stellenbosch University Maintenance Department to:

- Address requests for necessary repairs in a timely manner.

GLP Summation

Good laboratory practice includes the following:

- The responsibility to be familiar with all laboratory procedures and equipment.
- Being aware of any actions taken or not taken.

- Hazardous substance
    - Be familiar with hazardous properties of all materials used in the laboratory.
    - Be familiar with safe handling, storage, disposal, and emergency procedures.
    - Treat all unknown materials as potentially hazardous.

- Emergency procedures and equipment
    - Be knowledgeable about incident reporting procedures, telephone numbers and location of telephones.
    - Be knowledgeable about exit and evacuation routes, sounds of fire alarms, the location of the fire alarm and fire extinguishers.
    - Be knowledgeable about the location of the eyewash station and spill clean-up procedures.
    - Be knowledgeable about the emergency first aid kit.
    - Be knowledgeable about operating procedures of all safety and emergency equipment.

- Personal Protective Equipment (PPE)
    - Wear appropriate PPE (e.g., laboratory coats, gloves, safety goggles if necessary).
    - Wear closed, flat shoes and secure long hair.

    - Restrain loose clothing and remove jewellery if working with chemical or bio-hazardous substances.
    - Leave laboratory coats in the laboratory.

- Ingestion of hazardous material
    - Do not eat, drink or smoke in the laboratory.
    - Do not apply cosmetics or contact lenses.
    - Do not store food or beverages in any refrigerator in the laboratory.

- Work Area
    - Keep work area neat, organized and free from clutter.
    - Clean and decontaminate work surfaces every workday.
    - Keep corridors free of obstructions.

- Chemicals
    - Use volatile, toxic and flammable chemicals in a chemical fume hood.

- Bio-hazardous aerosols
    - Procedures which can generate aerosols must be conducted in a biological safety cabinet.

- Pipetting
    - NEVER pipette by mouth.

- Access
    - Never allow unauthorized persons access to the laboratory.

- Equipment
    - Make sure all equipment is in a safe working condition before use.
    - Report faulty or malfunctioning equipment immediately.

- Accidents
    - Report all accidents and incidents that occur in the laboratory within 24 hours.

- Medical
    - Personnel working with potentially hazardous biological samples must receive medical clearance prior to starting work in the laboratory.

References:

1. National Health Act, 2003: Government Gazette, No. R 178, 2 March 2012
2. Title 29 of the Code of Federal Regulations (CFR) 1910.1450

ANNEX 3: LABOUR MANAGEMENT PROCEDURES

Overview of labour use on the project

Number of Project Workers:
Total estimated number of workers to be employed on the project: **14**.

Organization	Number of Individuals
CERI – *direct employees*	10
ACEGID – *contracted employees*	3
Individual Consultants -- c*ontracted*	1
Total	**14**

In addition to the personnel recruited specifically for the project, the project will be supported by the core project implementation team at CERI that includes the PI, the Head Bioinformatics, the Grants Manager, an Accountant and the Head Scientific Support.

Characteristics of Project Workers:
Workers will be professional office workers and laboratory personnel. There will be a mix of male and female workers all of whom are at least 18 years old.

Timing and Location of Labor Requirements:
Most project personnel will be based in South Africa. The project will also support ACEGID in Nigeria. The E&S consultant could be based elsewhere. Project activities will predominantly take place in South Africa with Nigeria contributing to some of the genomic sequencing. Most project personnel will be engaged throughout the duration of the project.

This document will be updated periodically throughout the project with detail on the location of individual consultants.

Direct Workers[4]:
We anticipate engaging the services of several Direct Workers for this project. Any personnel employed for this project will be on a fixed-term contract and will be employees of SU in South Africa. CERI plans to also contract directly with an Environmental & Social Impact consultant.

Contracted Workers[5]:
SU/CERI will also sub-contract ACEGID in Nigeria to support technological transfer in South Africa to Nigeria. ACEGID will exercises control over the work, working conditions, and treatment of the project workers in Nigeria.

[4] people employed or engaged directly by the Borrower (including the project proponent and the project implementing agencies) to work specifically in relation to the project
[5] people employed or engaged through third parties to perform work related to core functions of the project, regardless of location

Assessment of key potential labour risks
The project will include no civil works, and anticipated risks and impacts related to working conditions (including health and safety) are expected to be negligible. The current scope of engagement planned under the project includes CERI and ACEGID conducting genomics-based surveillance for disease-causing pathogens. The following potential labour-related risks are identified under the project:

Brief overview of labor legislation: Terms and conditions
All employees of SU are based in South Africa and are protected by the relevant labor legislation. Project workers will be provided with information and documentation that is clear and understandable regarding their terms and conditions of employment. The information and documentation will set out their rights under national labor and employment law, including their rights related to hours of work, wages, overtime, compensation, and benefits. Project workers will be paid on a regular basis as required by national law and labor management procedures. Deductions from payment of wages will only be made as allowed by national law or the labor management procedures, and project workers will be informed of the conditions under which such deductions will be made. Project workers will be provided with adequate periods of rest per week, annual holiday, and sick, maternity and family leave, as required by national law and labor management procedures. Where required by national law or the labor management procedures, project workers will receive written notice of termination of employment and details of severance payments in a timely manner. All wages that have been earned, social security benefits, pension contributions, and any other entitlements will be paid on or before termination of the working relationship, either directly to the project workers. SU will use the standard World Bank consultant agreement template for its contracts with independent consultants.

Brief overview of labour legislation: occupational health and safety (OHS)
All employees of SU are based in South Africa and are protected by the relevant labor legislation. In South Africa, the labour legislation relating to occupational health and safety is governed by the *Occupational Health and Safety Act (1993) of the Republic of South Africa.* SU will request confirmation from ACEGID of their compliance with applicable occupational health and safety laws. The OHS measures for this project will address: (a) identification of potential hazards to project workers, particularly those that may be life-threatening; (b) provision of preventive and protective measures, including modification, substitution, or elimination of hazardous conditions or substances; (c) training of project workers and maintenance of training records; (d) documentation and reporting of occupational accidents, diseases and incidents; (e) emergency prevention and preparedness and response arrangements to emergency situations; and (f) remedies for adverse impacts such as occupational injuries, deaths, disability, and disease. SU will use the standard World Bank consultant agreement template for its contracts with independent consultants.

Responsible staff
The table below summarises which individual within each organization will be responsible for the following:

- engagement and management of project workers
- engagement and management of consultants
- occupational health and safety (OHS)
- training of workers

- addressing worker grievances

Organization	Responsible Individual
CERI, Stellenbosch University	Tulio de Oliveira
ACEGID - *contracted*	Christian Happi
Individual Consultant	Tulio de Oliveira

Personnel introduction to the organizational environment
CERI has an orientation and induction session for all new members of staff for an introduction to the organization, lab sections, conditions of employment, staff facilities, health and safety requirements (including fire and emergency) including SUN occupational health services. The procedure is documented in CWI09 and the induction is recorded in the CERI Orientation Form (CF41).

Policies and procedures
CERI /SU will ensure that all applicable local, national, and international occupational health and safety standards are followed throughout this project through the implementation of Stellenbosch University Human Resources Policies and Procedures (Annex 2).

Age of employment
All personnel will be adults above 18 years old. Copies of individuals' government-issued identification is available upon request.

Grievance mechanism
Employees for this project will be made aware of the established mechanisms at SU to address any labor-related grievances. A **Grievance Procedure policy** is already in place and will be maintained throughout Project implementation. In addition, staff and students of SU can also report any incidences of unfair discrimination, harassment, gender-based violence, bullying, and victimisation to *unfair@sun.ac.za* or can report incidents of directly on the online platform at *https://ciims.sun.ac.za/ReportingPage/*. A copy of the Grievance Procedure policy is available in the CERI Grievance Redress Mechanism Standard Operating Procedure (ADM-GEN-01).

Contractor management
SU maintains procurement guidelines that are based on South African and international standards and are consistent with the World Bank's procurement guidelines. For this project, SU will abide by the WB guidelines and thresholds. SU will follow these guidelines in selecting contractors for this project and will use the standard World Bank consultant agreement template for its contracts with independent consultants. SU will closely monitor the performance of its consultants throughout the project.

ANNEX 4: ORIENTATION FORM

CERI	Form Number:CF41 Version: 1.0	Orientation Form	Stellenbosch UNIVERSITY IYUNIVESITHI UNIVERSITEIT

Item	Date	Employee Signature
General:		
The organization structure		
The objectives and strategy of the lab		
Introduction to colleagues		
Working hours / breaks / work outside of office hours		
Absence and illness procedures		
Meeting schedules		
Confidentiality agreement		
Personal details (personal address and telephone number)		
Necessary documents for personnel file		
Safety and Security:		
Emergency procedures		
Lab rules (noise levels, no running)		
Safety procedures when working with certain pathogens		
Personal protective equipment		
Discarding biohazardous and non-biohazardous waste		
Vaccinations required		
Health and safety SOP for reading		
Quality Management System:		
The Quality Manual		
Access to all SOPs		
Use and purpose of log sheets		
Technical work:		
Sample receipt and storage		
Stock ordering procedure		
Operation of equipment and access to relevant SOPs		
Software used on computer		
Cleaning schedule, including laundry of coats		

3. **Comments:**

_____

_____

_____

All other documents to be read, discussed and acknowledged during visit to relevant section / laboratory. The signatures below confirm that the items above were discussed during the orientation process at CERI.

	Name	Signature	Date	
Staff Member				
Laboratory Manager				

ANNEX 5: QUALITY MANUAL

CERI	Document Number: CM01 Version: 2.2	Quality Manual	Stellenbosch UNIVERSITY IYUNIVESITHI UNIVERSITEIT

CENTRE FOR EPIDEMIC RESPONSE AND INNOVATION, SUN

QUALITY MANUAL

Number	CM01	**Written by**	Yeshnee Naidoo
Version	1.0	**Reviewed by**	Yeshnee Naidoo
Version Date	02 December 2021	**Approved by**	Tulio de Oliveira
Next Review Date	02 December 2022	**Reviewed Date**	N/A

Revisions/Reviews	
Date	**Action**

	DATE	SIGNATURE
IN USE MASTER		
IN USE COPY		
RECALLED		
OBSOLETE		

Contents

ABBREVIATIONS

BOL	Book of Life
CERI	Centre of Epidemic Response and Innovation
EQA	External Quality Assurance
GCLP	Good Clinical Laboratory Practice
GLP	Good Laboratory Practice
ISO	International Organization for Standardization
KPI	Key Performance Indicator
PPE	Personal Protective Equipment
QCMD	Quality Control for Molecular Diagnostics
QMS	Quality Management System
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SLA	Service Level Agreement
SUN	University of Stellenbosch

REFERENCE DOCUMENTATION

ISO15189:2012 International Standard for Medical Laboratories
(NB. This Quality Manual is numerically aligned with the ISO 15189:2012 requirements)

CSOP01	Equipment
CSOP02	Health and Safety
CSOP03	Document and Record Control
CWI02	Establishment and Review of Service Agreements
CWI03	External Services and Supplies
CWI04	Resolution of Complaints
CWI05	Management of Non-conformances
CWI07	Training and Competency
CWI08	Internal Audits
CWI09	Personnel Introduction to the Organizational Environment
CWI10	Examination by Referral Laboratories
CWI12	Interlaboratory Comparisons
CWI13	Communication at CERI
CWI16	Operational Risk Assessments
CWI20	Management of Reagents and Consumables
CWI21	Ethics
CWI22	Risk Management
CWI23	Validation and verification of examination procedures
CF01	Personnel File Checklist
CF03	Preventive Action Report
CF04	Risk Assessment Worksheet
CF06	Shipment-to-Shipment Verification Record
CF09	Temperature Record
CF13	Laboratory Visitors Register
CF14	Non-conformance Report
CF15	Validation / Verification Report
CF17	Disinfection of Work Area
CF18	Data Backup Record
CF19	Lot-to-Lot Verification Record
CF20	Results Transcription Verification Record
CF21	Equipment Book of Life
CF27	Document Acknowledgement Form
CF29	Training / Observation of Procedure Form
CF31	Complaint Register
CF35	Confidentiality Statement
CF41	CERI Orientation Form
CF43	Stock Requisition Record
CF44	Reagent Preparation Record
CF45	CERI Indemnity Form
CF61	Client Communication Record
CF67	Error Log Sheet
CF77	Equipment Maintenance Schedule

Policy for responsible research and conduct at SUN
Research Policy at SUN
Rules on Academic entities within and alongside departments and faculties
Performance Management and Policy strategy at SUN
Purchasing and Tender Policy and Procedures at SUN
Conflict of Interest Disclosure at SUN

1. BACKGROUND AND SCOPE

The Centre for Epidemic Response and Innovation (CERI) is built on the existing molecular laboratory and teaching facilities at the Biomedical Research Institute building, Tygerberg-Stellenbosch University (SUN). The name – CERI- was used to reflect the joint partnership in collaboration with Stellenbosch University, a professionally run service component that is currently available for academic user, with the vision to include commercial and industrial users. Incorporating the joint partnership will generate operational excellence along with appropriate, proven technology and on-going innovation resulting in service excellence to the science community within South Africa and Africa.

This Quality Manual describes the Quality Management System (QMS) associated with whole genome sequencing at the CERI Laboratory.

2. CERI QUALITY STATEMENT

CERI strives to provide quality whole genome sequencing results and is committed to maintaining a QMS in compliance with the requirements of ISO15189:2012.

3. VISION OF CERI

The vision for CERI is to produce genotyping of superior quality, at an affordable cost, with decreased turnaround times, compared to other laboratories offering the same service in South Africa.
One of the main objectives of CERI is to become a leading regional and national facility that provides professional and accredited services to academic, commercial and industrial clients.

4.MISSION OF CERI

To provide cost-effective and professional whole genome sequencing, through competent and qualified professionals using state-of-the-art technology, supported by academic and internationally recognized research, training and innovation.

4.1 Values of CERI

- **Operational Excellence** – We provide comprehensive and high-quality laboratory testing data at the same speed, quality and price as the top genomics centers in the world.

- **Research and Innovation** – Continuous research and innovation at all levels in order to produce cutting edge research.
- **Integrity and Effective Communication** – To be successful it is essential to operate at the highest level of honesty, responsibility and trust. Effective communication is the basis of the personal and business relationships and to understand the perspectives of others by listening willingly and communicating honestly, with appropriate responsibility.
- **Continuous quality improvement** – We are continuously evaluating and implementing the best practices in laboratory testing across the testing spectrum.
- **Development of our staff** – Our staff are our most valuable resource and are supported and recognized for their accomplishments. Training and education are promoted to ensure the best skills are acquired for our staff
- **Tangible value creation -** To partner with academic and commercial collaborators and attract funding to ensure that CERI stays at the cutting edge of genomics.

5. SCHEDULE OF TESTS

The scope of tests services offered by CERI includes, but is not limited to, nucleic acid extraction and quantification, detection and resistance profiling, DNA sequencing, whole exome sequencing, cancer genomics and custom-designed laboratory investigations relevant to our clients. A full list of tests is available at *www.ceri.org*

However, CERI will focus on whole-genome sequencing projects as an initial application as we progress to method validation and training.

Information for Users of the CERI laboratory is available at *www.ceri.org.za* and contains all the tests offered by CERI, associated turnaround times, details of sample requirements, reporting of results and other relevant information pertaining to the examinations.

Management requirements
Organization and management responsibility
Organization
General

The location of the CERI laboratory is:

Biomedical Research Institute building (BMRI) at Tygerberg,
First floor, Room 1031.
Stellenbosch University, 44 Banghoek Rd,
Stellenbosch Central,
Stellenbosch,
7600

The CERI Laboratory will implement a QMS in compliance with ISO15189:2012 – Medical Laboratories – Requirements for quality and

competence, and basic guidelines for good clinical laboratory practice (GCLP) and good laboratory practice (GLP).

5.1 Legal entity

CERI is a Centre of SUN, where SUN remains the legally registered body. CERI therefore is financially self-sufficient but not legally independent.

5.2 Ethical conduct

CERI management ensures that all staff is suitably qualified and conducts themselves in an ethical manner:

- All relevant professional qualifications, training and experience of key managerial and technical staff are available in individual Personnel Files. Staff should read and understand the following policies:
    - The Policy on research ethics on the ethical code of conduct.
    - The Policy on Disclosure of Interests.
- All CERI staff are required to sign a Confidentiality Statement (CF35) which is available in the individual Personnel Files.

5.3 Laboratory Director

The Director of the CERI laboratory is responsible for the overall operation and administration of the laboratory. The Director also provides leadership of the organisation. The contact details of the Director are as follows:

Professor Tulio de Oliveira
University of Stellenbosch
(021)-808-4370
deoliveira@ukzn.ac.za & *tuliodna@gmail.com*

The responsibilities of the Director, as well as those duties delegated to other qualified personnel, are documented in the respective individuals job descriptions.

6. MANAGEMENT RESPONSIBILITY

6.1 Management commitment

CERI laboratory management demonstrates their commitment and support of the QMS in the following manners:

- Conducting ISO15189:2012 Accreditation (Quality) Meetings on a monthly basis, at minimum.
- Establishment of a Quality Policy, documented herein, which is read and understood by all relevant staff.
- Establishment of the Quality Objectives (contained herein) and appropriate planning during Management Review Meetings.
- A laboratory organogram documenting interrelationship of all personnel is available.
- Job descriptions documenting the responsibilities and authorities for all personnel is available in personnel files.

- Establishment of communication processes (CWI13 – Communication Processes at CERI). Communication is also via distribution of Laboratory and Accreditation Meeting minutes.
- Annually allocating sufficient funding to support the accreditation process (accreditation training and application fees) and training to support competency of laboratory personnel to perform the assigned duties (records of which are filed in individual Personnel Files).
- Ensuring adequate levels of funding and staffing are available to audit laboratories and manage the QMS.

6.2 Needs of users

CERI Management is aware of the needs of clinicians, researchers and other users of the services in the following ways:

- Establish a Service level agreement (SLA) with Users in the form of the signed quotation (CF65) that explain the needs, requirements, terms and conditions.(In Progress).
- Different meetings held with different Users / research collaborators at different levels.
- By using the "*Contact Us*" link available on the CERI website.

7. QUALITY POLICY

The intent of the CERI laboratories QMS is detailed in this Quality Manual**.**

CERI Quality Policy Statement:

The management and staff of the CERI Laboratory are committed to providing a quality, affordable and sustainable Whole genome sequencing services, which supports continuous improvement and good professional practice.

This is achieved by:

- Maintaining a QMS that continually improves the effectiveness of the laboratory service to our users.
- Ensuring that the CERI QMS is compliant with the requirements of ISO15189:2012 for Medical laboratories and other regulatory authorities.
- Using validated methodology deemed fit for its intended use for Whole genome Sequencing.
- Ensuring that all laboratory staff comply with the QMS and providing training and support to do so.
- Ensuring that quality objectives are devised which improve the QMS and that these objectives are reviewed at least annually.
- Supporting education, research and training to promote the adoption and application of innovative technology.
- Ensuring professional behaviour and ethical standards of business conduct.
- Ensuring that all CERI staff members are aware of this Quality Policy by reading and acknowledging the contents thereof.

7.1 Quality objectives and planning

The CERI Laboratory has established the following measurable Quality Objectives, which supports the continual improvement of the QMS:

i. Provision of accurate and timeous results
   - ✓ IQCs will be included in every batch (100% of the tests), and the results must be acceptable before they are released.
   - ✓ Turnaround time must be within 10 working days (80% of the time)

ii. All methods used should be fit for their intended purpose
   - ✓ Only methods validated and signed off by authorized personnel may be used – 100%

iii. Sequencing done by authorized, trained and competent staff members
   - ✓ Only personnel that are trained and deemed to be competent in the assays may perform the test and generate the result – 100%

These are monitored and reviewed at the Quality and Management Review Meetings.

Laboratory management ensures that planning of the QMS is carried out to meet the requirements and the quality objectives.

Laboratory management also ensures that the integrity of the QMS is maintained at all times, even when changes to the quality management system is planned and implemented. This is achieved by making updates to documentation related to the QMS (Quality Manual, SOPs, WIs), available to staff for reading, understanding and acknowledging (CF27). Plans and changes to the QMS are also discussed at the Quality and Management Review Meetings or laboratory meetings, the minutes of which are distributed to relevant staff members. In addition, the CERI Laboratory will support all changes to the QMS which require training and competency activities.

7.2 Responsibility, authority and interrelationships

CERI has a clearly definable management structure in place. The generic roles and responsibilities of all staff are defined in their job descriptions. Local conditions may dictate that additional functions are required of certain individuals.

8. COMMUNICATION

CERI management manages the diverse internal and external communication needs of the laboratory in the following manners, where the effectiveness of the QMS is discussed:

- Formal Laboratory and Quality Meetings with minutes (annual, monthly, weekly)
- Informal verbal (brief notes are made)
- Email
- CERI website

CERI management is also responsible for the content of the website. General communications are coordinated and sent via email to all staff members. Newsletters will be published on a monthly basis and circulated to internal and external parties detailing the highlights / achievements, new tests available, scientific output, training opportunities and other relevant information. Communication to Users of the laboratory services regarding changes in test methods or laboratory practices are done via the CERI website, via email or meetings held with the Users. The documented procedure for Communication at CERI can be found in CWI13.

9. QUALITY

The CERI laboratory Manager and quality assistant is to ensure that all processes needed for the QMS are established, implemented and maintained. The CERI laboratory has dedicated team of quality assistants. The role also involves improving a QMS and all quality related matters. The Laboratory Manager reports to the Director, at the level at which decisions are made on laboratory policy, objectives and resources, on the performance of the QMS and any need for improvement. The laboratory Manager also promotes the awareness of User needs and requirements throughout the organisation.

9.1 Quality management system

General requirements:

The CERI management will establish, a documented (Quality Manual and supporting procedures), and will implement and maintain the QMS in accordance with the requirements of ISO 15189:2012.

All documents relating to these requirements must be read and understood by all CERI staff members and are readily available for implementation of these policies and procedures.

The CERI laboratory has:

- Determined the processes needed for the QMS and ensures their application throughout the laboratory as documented in this Quality Manual and other relevant SOPs.
- Determined criteria and methods needed to ensure that both the operation and control of these processes are effective by implementing the ISO 15189:2012 Standard in the CERI Laboratory.
- Ensures the availability of resources and information necessary to support the operation and monitoring of these processes by annually allocating sufficient funding to support the operational process.

9.2 Documentation requirements

General

The QMS documentation consists of 3 tiers (levels) as follows:

Level	Document type	Description
1st tier	Policies / Manuals	Provides a statement of intent that a particular course of action will be followed; e.g. policies and

		generic structure of the CERI Laboratory including the quality policy statement and quality objectives. Identified by a unique number with a CM prefix
2nd tier	Standard Operating Procedures (SOPs) and Work Instructions (WIs)	SOPs provide instructions for a procedure or task, or reference to documents of external origin. It is a practical way in which a policy is translated into action. Provides information on how to carry out an intent. Identified by a unique number with a CSOP prefix. The WIs provide practical day-to-day instructions i.e. the procedural or step-by-step instructions that can relate to an SOP. Identified by a unique number with a CWI prefix.
3rd tier	Templates and records	Used for recording of data and can be worksheets, log sheets, order forms, complaint forms, etc. These provide evidence of fulfilment of intent. Identified by a unique number with a CF prefix.

The structure of the documentation and its associated responsibilities relating to the QMS is described in the CERI Document Control SOP (CSOP03).

10. QUALITY MANUAL

The CERI laboratory uses this Quality Manual (CM02) to describe and document the following:

- Reference to the Quality Policy
- The scope of the QMS which includes all management and technical requirements as stipulated by ISO15189:2012 requirements.
- A presentation of the organization and management structure of the laboratory and its place in SUN (parent organization) is shown in Figure 1.
- A description of the roles and responsibilities of laboratory management (comprised of the Laboratory Director and Laboratory Manager) for ensuring compliance with the ISO15189:2012 Standard. This will be documented in the job descriptions of each individual.
- A description of the structure and relationship of the documentation used in the QMS (CSOP03)
- The documented standard operating procedures and work instructions established from the QMS, and forms and records of the managerial and technical activities that support them.

All laboratory staff have access to and are instructed upon orientation on the application of the Quality Manual and reference documents.

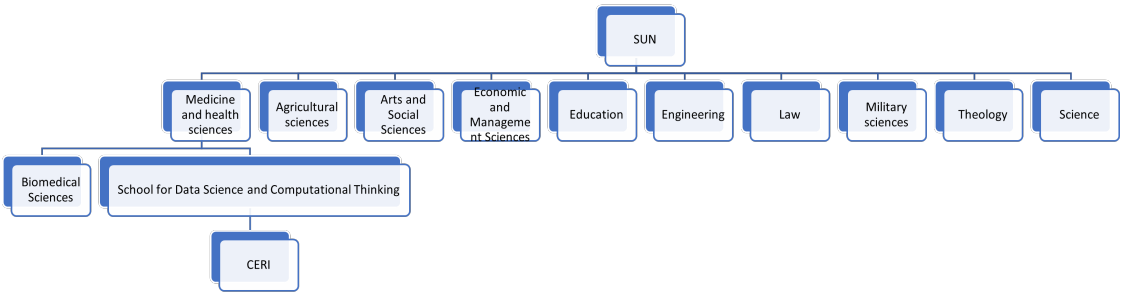


Figure 1. Organogram of University of Stellenbosch Colleges, Schools and Centres

10.1 Document control

CERI uses the Document Control SOP (CSOP03) to control documents required by the QMS. This SOP covers:

- Document structure
- Writing, reviewing and approval
- Distribution
- Making changes
- Periodic reviewing
- Recalling and obsoleting
- Storage and disposal.

10.2 Examination by referral laboratories

If due to any unforeseen circumstances, CERI Laboratory cannot perform Whole genome sequencing, this may be referred to an external institution / service provider. The CERI laboratory has a documented procedure for the selection and evaluation of referral laboratories in order to ensure that good quality results are provided to our clients. This procedure is documented in the Examination by Referral Laboratories work instruction (CWI10). Performance of the referral laboratories is reviewed regularly. Records of the referral are then archived as per the Document Control SOP (CSOP03).

10.3 External services and supplies

The policies and procedures for the selection and use of purchased external services and suppliers are in accordance with the SUN Policy on Procurement available from the following website: *www.sun.ac.za/policies*

The Laboratory Manager is responsible for compiling a list of distributors and manufacturers of critical services, reagents and products and to request that new distributors and manufacturers to be registered following the guidelines of the SUN Policy on Procurement.

10.4 Resolution of complaints

CERI will maintain records of complaints received. The Laboratory Manager is responsible for summarising the complaint and reporting them to the Director on a quarterly basis (every 3 months).

Complaints and anomalies are addressed and resolved as soon as possible. The procedure for the management of complaints and other feedback received from laboratory staff or other parties are documented in CWI04 – Resolution of Complaints work instruction.

10.5 Identification and control of nonconformities

The procedure describing the management of non-conformities and / or non-conforming activities arising from the CERI Laboratory are detailed in CWI05 (Management of Non-Conformances work instruction). It is the responsibility of the Laboratory manager and quality assistant/s to verify that all corrective and preventative actions are completed within the stipulated time frames.

Non-conformances must be reviewed at least every quarter (every 3 months) by the Laboratory Manager to detect trends and identify opportunities for improvement. Every effort must be made to determine and eliminate the root cause of non-conformance. Results of root-cause analysis and actions taken must be recorded and monitored for effectiveness by the Laboratory Manager.

10.6 Corrective action

Procedures for corrective actions are referred to in CWI05 (Management of Non-Conformances work instruction). The Laboratory Manager is responsible for monitoring and reviewing the effectiveness of corrective actions at eliminating the root cause of the non-conformance. The results of the corrective actions are submitted to the Laboratory Director for review at least every quarter (every 3 months).

10.7 Preventive action

The CERI laboratory management must endeavour at all times to identify potential improvements and sources of preventive action, in a pro-active approach to prevent NCs from occurring. The improvement plans and strategies will be communicated to staff members in laboratory and / or Management Review Meetings.

Preventive actions (PA) plans must be developed and implemented by laboratory management and monitored by the Quality Manager.

The procedure for the development, implementation and monitoring of preventive action is documented in in CWI05 (Management of Non-Conformances work instruction). These actions are recorded in the relevant section in CF03 (Preventive Action Report).

10.8 Continual improvement

All operational procedures must be reviewed at least annually during the Management Review meeting in an effort to identify all potential sources of non-conformities and opportunities for improvement.

Continual improvement plans can also be identified during training, audits, and risk assessments or from quality objectives and trend analyses.

It is the responsibility of the Laboratory Management to evaluate the effectiveness of the action plans for improvement of quality in services offered by the CERI Laboratory. The Laboratory Director is responsible for determining the cost-effectiveness of these plans for improvement. If the action plans for improvement are deemed appropriate and effective, they must be implemented within agreed and realistic time frames.

In order to continually improve, the CERI Laboratory provides staff members with access to appropriate educational and training opportunities.

11. CONTROL OF RECORDS

CERI aims to maintain a records system such that all information pertaining to all procedures. This record system enables the laboratory to identify source(s) of any error, and where appropriate, to repeat the test under conditions as close as possible to the original conditions. The quality and technical 4th tier documentation are suitably archived on-site, and are checked during internal audits.

The procedure for identification, collection, indexing, access, storage, retention times, maintenance, amendment and safe disposal of records is described in the Document and Record Control SOP (CSOP03).

11.1 Evaluation and audits

General

CERI monitors and evaluates the QMS to demonstrate that all the processes (pre-examination, examination and post-examination) are being conducted in a suitable manner and meets the needs and requirements of Users, ensures conformity to the QMS, and continually improves the effectiveness of the QMS by:

- Scheduling of audits
- Monitoring quality indicators
- Conducting Management Review Meetings to review the QMS

Periodic review of requests, and suitability of procedures and requirements

This is done as part of the Management Review Meeting on an annual basis, or when a need arises to review the suitability of the procedures.

11.2 Staff suggestions

CERI staff members are encouraged to make suggestions during weekly Laboratory Meetings that will contribute to the improvement of the services provided. Staff suggestions are and are evaluated and where possible, implemented.

11.3 Internal audit

Internal audits of all activities, including the performance of all tests, are performed at least annually at the CERI Laboratory. The internal audits address both management and technical aspects of all areas that are relevant to the services offered by the CERI laboratory.

The Laboratory Manager will be responsible for the planning and organisation of the quality audit schedule, and for ensuring that the appointed auditors are independent of the area to be audited. Auditors must have received appropriate training.

Where deficiencies or opportunities for improvement are noted, management undertakes to implement appropriate corrective and preventative actions. It is the responsibilities of the Laboratory manager to verify that all corrective and preventative actions are documented and carried out within agreed and specified time frames.

Annual reviews of audit findings must be presented at the CERI Management Review Meetings.

The procedure for internal auditing describing the audit criteria, scope, frequency and methods are documented in CWI08 – Internal Audits work instruction.

11.4 Risk management

CERI follows SUN's procedure on Operational Risk Assessments (CWI16) and follows a Risk Management procedure (CWI22) for performing operational risk assessments. During the weekly laboratory meetings, all staff are encouraged to identify risks in the environment and work processes. Any risks arising are minuted and assessed by the Laboratory Manager and staff. Measures are implemented to reduce or control the risk and where appropriate to monitor the risk. Each risk is formally rated according to the consequence and likelihood as outlined in CWI22. These are noted on a Risk assessment worksheet (CF04) and recommendations are made to address the risk.

11.5 Quality indicators

CERI has established quality indicators to monitor and evaluate the performance throughout critical aspects of pre-examination, examination and post-examination processes.
Quality indicators monitored in the CERI Laboratory include, but are not limited to:

Quality Indicator	Testing Phase	Measuring Tool	Objective
External Quality Assurance	All	EQA trends	95% average pass rate
Internal audits (pre-accreditation)	All	Data from Management Review meeting minutes	<5 repeat NCs per audit
Internal Quality Control	Examination	Trends	<5% IQC failures per month
Turnaround time	Post-examination	Project TAT reports	TAT is met 95% of the time per month

Non-conformances and complaints	All	Non-conformance register, data from Management Review Meetings	All resolved within 21 working days, unless an extension is granted.

The quality indicators are reviewed at least once a year to ensure their continued appropriateness.

11.6 Reviews by external organizations

Review of the CERI laboratory includes assessments by external organisations including, but not limited to, accreditation assessments, regulatory agency inspections, financial / funding institutions, etc. Whenever non-conformities or potential non-conformities are identified, CERI will file a non-conformance using CF14.

11.7 Management Review

General

The CERI laboratory reviews the QMS on an annual basis (at least) to ensure its continuing stability, adequacy, effectiveness and support of User requirements.

NOTE: Pre-accreditation of the CERI Laboratory will require more frequent meetings (± every 3 months) until accreditation is obtained.

Review input

The input to the Management Review includes the results of evaluations of the following:

- Periodic review of requests, and suitability of procedures and sample requirements
- Assessment of user feedback
- Staff suggestions
- Internal audits
- Risk management
- Use of quality indicators
- Reviews by external organisations
- Results of participation in inter-laboratory comparison programmes
- Monitoring and resolution of complaints
- Performance of suppliers
- Identification and control of non-conformities
- Results of continual improvement including current status of corrective actions and preventative actions
- Follow-up actions from previous Management Review Meetings
- Changes in the volume and scope of work, personnel, and premises that could affect the QMS
- Recommendations for improvement, including technical requirements

Review activities
The Management Review analyses the input information for causes of non-conformities, trends and patterns that indicate problems in the process.

This Management Review includes assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives.

Review output
Whenever changes and / or improvements to the QMS are required as outputs from the Management Review, a detailed plan which includes quality goals, objectives and action items are documented. It is the responsibility of the Laboratory Manager to verify that all required actions are completed within specified time frames.

In addition, the laboratory manager and staff (quality assistant) is responsible for ensuring that all findings and actions that arise from the Management Reviews are recorded (by taking minutes) and communicated to all staff.

12. TECHNICAL REQUIREMENTS

12.1 Personnel

General
CERI conditions of employment, Human Resources policies and procedures are aligned with SUN and available at: www.sun.ac.za

The CERI Laboratory has a documented procedure for the management of personnel – CWI09 (Personnel Introduction to the Organizational Environment work instruction). Each CERI staff member has an individual personnel file, where relevant documentation as required by the ISO15189:2012 requirements are filed. A Personnel File Checklist (CF01) is used to indicate the information that is required.

12.2 Personnel qualifications

CERI has documented the personnel qualifications for each job description. The personnel qualifications reflect the appropriate education, training and demonstrates the skills required, which are relevant to the tasks being performed.

Every staff member making judgements with reference to examinations must have documented records of having been deemed competent in that particular examination, or must be able to show that they are appropriately supervised by a competent staff member.

12.3 Job descriptions

Job descriptions are available for each member of staff. The job description details the required responsibilities, authority and tasks of the associated post.

12.4 Personnel introduction to the organizational environment

CERI has an orientation and induction session for all new members of staff for an introduction to the organization, lab sections, conditions of employment, staff facilities, health and safety requirements (including fire and emergency) including SUN occupational health services. The procedure is documented in CWI09 and the induction is recorded in the CERI Orientation Form (CF41).

12.5 Training

It is the responsibility of the Laboratory Manager to ensure that all staff undergo the required training to perform the relevant tests and to familiarize themselves with the QMS. Staff are required to familiarize themselves with CERI documentation (Quality Manual, Health and Safety Manuals and all other relevant policies and procedures).

It is the duty of each individual staff member to maintain their own training records, and to ensure the accuracy and validity of these records.

Most training is done in-house (CF29 – Training / Observation of Procedure Form is completed), but certain training sessions require specialist training where staff members are required to attend external training courses.

These include, but are not limited to:

- The quality management system
- Assigned work processes and procedures
- The applicable laboratory information system
- Health and safety, including the prevention or containment of the effects of adverse incidents
- Ethics
- Confidentiality of patient information
- On-going continual professional development (CPD)

Personnel that are undergoing training shall be supervised at all times.

12.6 Competence assessment

Only authorized and competent staff may perform the pre-examination, examination and post-examination aspects of the Whole genome sequencing tests. The Laboratory Manager is responsible for ensuring that the competency of each member of staff is checked after training, in order to assess the competence of each person to perform the assigned managerial or technical tasks according to established criteria. Re-assessment shall take place every 2 years. Re-training shall occur as required.

Staff competency is done according to CWI07 – Training and Competency.

12.7 Personnel records

Each CERI staff member has a Personnel File, wherein training records are filed according to C01 – Personnel File Checklist. These records are readily accessible to relevant personnel and includes, but is not limited to:

- Relevant educational and professional qualifications
- Training records
- Competency records
- Current registration with the relevant professional bodies
- *Curriculum Vitae* showing previous employment and experience
- Continuing education and achievements
- Untoward incidents or accident reports and exposure to occupational hazards
- Immunization status
- Orientation records (CF41)
- Indemnity form (CF45)
- Reviews of staff performance
- Signed confidentiality statement (CF35)

It is the responsibility of each individual staff member to ensure that there is a record of his / her own training record and to ensure the accuracy of these records.

13. ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

General

It is the responsibility of CERI management to ensure that the laboratory environment is appropriate and adequate for the type of work performed, without compromising the quality of the reported results and / or the safety of the laboratory personnel. The procedures relating to Health and Safety in the CERI Laboratory is documented in CSOP02 – Health and Safety SOP.

Visitors are required to sign the CERI Laboratory Visitors Register (CF13) and must be accompanied by a CERI member of staff. Wearing of personal protective equipment (PPE) is mandatory in laboratory sections., refer to the Health and safety manual for code of conduct procedure for visitors or contractors.

13.1 Laboratory and office facilities

The laboratory and office facilities are separated to prevent potential contamination between areas. Access to all office and laboratory areas is restricted to CERI laboratory and administrative staff only. Information and laboratory resources are therefore safeguarded from unauthorized access.

Sufficient biosafety hoods are available to enable the safe processing of samples. Laboratory sections are divided into pre-amplification (“clean” / amplicon-free) and post-amplification (“dirty” / amplicon) areas with a uni-directional workflow to prevent amplicon contamination between the different areas.

Air-conditioning is available in laboratory areas where the performance of tests can be adversely affected by room temperatures which exceed 26°C.

The CERI laboratory and office facilities has sufficient lighting, ventilation and other suitable environmental conditions to ensure the correct performance and analysis of results.

13.2 Storage facilities

The CERI Laboratory has sufficient and appropriate storage available for different temperature requirements (room temperature, 4°C, -20°C, -80°C) to ensure the continuing integrity of sample materials, documents, equipment, reagents, consumables and any other items that could affect the quality of results.

Samples are separated and stored appropriately to prevent cross-contamination.

13.3 Staff facilities

CERI management has ensured that all staff are provided with environmental conditions that are conducive to the proper performance of their duties. There is sufficient access to drinking water, washrooms, kitchen and storage facilities for personal belongings. The CERI Laboratory also provides sufficient space for staff activities such as meetings and presentations, as well as quiet (study) areas.

13.4 Facility maintenance and environmental conditions

Laboratory areas are maintained in a clean condition and recorded on CF17 (Disinfection of Work Area). Laboratory temperatures are monitored, controlled and recorded on CF09 (Temperature Record). There is effective separation between laboratory sections in which there are incompatible activities (pre-amplification, amplification and post-amplification sections). CERI also provides quiet and uninterrupted work / study areas.

The CERI laboratory and office facilities has sufficient lighting, ventilation and other suitable environmental conditions to ensure the correct performance and analysis of results.

14. LABORATORY EQUIPMENT, REAGENTS AND CONSUMABLES

CERI laboratory has the responsibility to maintain all equipment and instrumentation. The quality of all equipment, reagents and consumables are monitored by inspection upon receipt as well as internal quality control processes.

14.1 Equipment

General

CERI is mandated with the responsibility of maintaining all laboratory equipment and instruments. The procedure for the selection, purchasing and management of equipment is documented in SUN refer to the Purchasing and Tender policy and Procedures available at www.sun.ac.za/polices.

Every instrument or equipment in use is labelled and has a book of life detailing the instructions for use, maintenance requirements and records. Under circumstances where CERI needs to use equipment outside its permanent control, laboratory management shall ensure that the requirements of ISO15189:2012 are met. The laboratory shall replace equipment if needed to ensure the quality of examination results.

14.2 Equipment acceptance testing

All equipment is checked, commissioned and subjected to acceptability testing by doing an equipment verification before use and recorded on CF15 – Validation / Verification Report. This is done to ensure that the equipment is fit for its intended use (as specified by the manufacturer) and that it complies with the requirements for the relevant examinations. These records are kept in the book of life.

14.3 Equipment instruction for use

Only trained and authorized personnel are responsible for the operation of CERI equipment. Records of training are kept in the staff members personnel file.

User manuals with instructions on the use, safety and maintenance of equipment, including any relevant manuals and directions for use provided by the manufacturer of the equipment is readily available in the equipment book of life. These documents are acknowledged as read by signing CF27 (Document Acknowledgement Form).

The procedure for the safe handling, transport, storage and use of equipment to prevent its contamination or deterioration is documented in CSOP01.

14.4 Equipment calibration and metrological traceability

Calibration and subsequent verification of critical equipment used to below for all general laboratory equipment and in the relevant WIs.

Metrological traceability is demonstrated by having calibrations performed by SANAS-accredited service providers (e.g. LabFix for pipette and thermometer calibrations) or by the manufacturer themselves.

Traceability for Sequencing assays is established through the use of reference materials *via* participation in proficiency testing (QCMD Programme which agrees with ISO/IEC17043:2010).

15. EQUIPMENT MAINTENANCE AND REPAIR

CERI has a servicing schedule for preventative maintenance, which at a minimum, follows the manufacturer's recommendations. This is updated annually and is recorded in Equipment Maintenance Schedule (CF77).

Whenever equipment is found to be defective, it will be taken out of service and labelled with "not in use" until it is repaired. A verification of the repaired equipment is then done to ensure that it meets the specified acceptance criteria. This verification is also done for any equipment taken out of the direct control of the CERI laboratory.

It is the responsibility of the CERI personnel working with the equipment to ensure that appropriate personal protective equipment is supplied to service

personnel. All equipment requiring servicing or repair will be decontaminated. Records of decontamination are filed in the equipment book of life.

15.1 Equipment adverse incident reporting

Equipment malfunctions and corrective actions are recorded on CF07(Non-Conformance Record). Minor incidents related to equipment (e.g. centrifuge errors, thermometers requiring reset, transcription errors, etc.), which can be resolved immediately, are logged on CF22 – Error Log Sheet. These documents are filed in the respective instrument book of life. Any instrument which is found to be operating outside of the acceptable parameters is either repaired by the supplier, or retired and marked as “not in use” if found to be economically unviable. Power interruptions that may result in failure or damage to the equipment is prevented by connection to uninterruptible power supplies and emergency plug points. This will also ensure an orderly shutdown of systems without data loss.

Adverse incidents and accidents that can be attributed directly to specific equipment will be investigated using CF07 or CF22 and reported to the manufacturer and appropriate authorities, as required.

15.2 Equipment records

Records are maintained for each instrument which are filed in the book of life. Details of the equipment’s identity, manufacturer’s name, model and serial number (or other unique identification), contact information for the supplier, receipt date and date of entering into service, location and condition when received (new, used or reconditioned) and servicing frequency are featured on CF13 (Equipment Book of Life).

The equipment verification showing the initial acceptability for use after installation, any calibrations, reports and certificates are filed in the book of life together with maintenance records, equipment performance records that confirm the equipment’s on-going acceptability for use.

Records of equipment malfunctions and errors which detail any damage to, malfunction, modification or repair to the instrument are also filed in the book of life.

The book of life is readily available in the laboratory where the instrument is placed for the life span of the instrument, as specified in the Document and Record Control SOP (CSOP03).

16. REAGENTS AND CONSUMABLES

General

The CERI Laboratory has a documented procedure for the reception, storage, acceptance testing and inventory management of reagents and consumables. This procedure is documented in CWI20 – Management of Reagents and Consumables.

16.1 Reagents and consumables - reception and storage

All reagents and consumables are inspected upon receipt (CF07 - Stock Receipt Checklist) to ensure that they conform to the specifications on the order.

The receiving staff member inspects the stock to ensure that it is acceptable (checks for leakages or damage, ensures that the cold chain is maintained, etc.), indicates the receipt date and stores the reagents and consumables, according to the manufacturer's instructions.

16.2 Reagents and consumables - acceptance testing

The acceptability of kits used in sequencing assays is verified for performance for every new lot or shipment by running a sample with known results from a previous batch with IQC material before use in the examination. Results are recorded on CF19 – Lot-to-lot verification record and CF06 – Shipment-to-shipment verification record for lot and shipment variations, respectively.

16.3 Reagents and consumables - inventory management

An inventory control system for in-use reagents and consumables is in place. This system allows for segregation of uninspected and unacceptable reagents and consumables from those that have been accepted for use. This procedure is documented in CWI20 – Management of Reagents and Consumables.

16.4 Reagents and consumables - instructions for use

Instructions for the use of reagents and consumables (package / product inserts) are signed, lot number indicated, dated, and filed each time a new kit is opened. These are readily available in the different sections. Instructions on the use of the kit / reagent for specific tests are available in the relevant work instructions.

16.5 Reagents and consumables - adverse incident reporting

The CERI laboratory shall investigate any malfunctions (including incidents and accidents) that can be attributed directly to the consumable or reagents and report this to the manufacturer and appropriate authorities. CF14 (Non-Conformance Report) is completed and the corrective actions are recorded.

16.6 Reagents and consumables – records

Reagents and consumables are managed according to CWI20 - Management of Reagents and Consumables WI.
Records are maintained for each kit or reagent as follows:
Upon receipt of stock at the KRISP Laboratory, the following information is recorded LIMS:

- Supplier name
- Quantity
- Expiration date
- Lot number
- Cost center

Each time a new kit or reagent is opened, the following information is recorded on KF43 – Stock Requisition Record:

- Name of kit / reagent

- Lot number
- Date received at the KRISP Laboratory
- Expiry date
- In-use date

Manufacturer's instructions in the form of package inserts are filed as per 5.3.2.5, above.
Validation / verification reports of the kit / reagents initial acceptability for use is available in the BOL.
Performance records for lot and shipment verifications (CF06 and CF19) are filed.

CF44 – Reagent Preparation Records must be completed for all reagents that are prepared in-house (e.g. TBE buffer) and must contain the following information

- Name of person preparing the reagent
- Date prepared
- Expiry date
- Lot number

17. PRE-EXAMINATION PROCESSES

General

The CERI Laboratory has documented procedures CWI06 and CWI17 for processes and work instructions, respectively, to ensure the validity of the test results.

Information for patients and users

The CERI laboratory has information available for users of the laboratory services:
This following information is available online at *www.ceri.org.za*:

- The location of the laboratory
- Opening hours of the laboratory
- Scope of services offered
- Samples types and volumes required
- Turnaround times
- Test prices
- Instructions for transportation of samples and any special requirements
- Sample acceptance and rejection criteria
- Availability of clinical advice on test requests and result interpretation
- The laboratory's complaint procedure

17.1 Examination Processes

Selection, verification and validation of examination procedures
General

The sequencing procedure used in the CERI Laboratory will be validated and demonstrated to be fit for its intended use. Any new methodologies will also be subject to verification / validation before its implementation, and CF15 –

Validation / Verification Report is completed. General guidelines for conducting validations or verifications for new examination procedures is documented in CWI23 – Validation and Verification of Examination Procedures WI.

17.2 Validation of examination procedures

- The Sequencing assays will be validated for use at the CERI Laboratory following supplier training , installation and QC certificates.
- The following performance characteristics were examined during the validation:
  - Sensitivity
  - Specificity
  - Accuracy
  - Intra-assay precision
  - Inter-assay reproducibility
- Reference samples, external quality assurance samples and internal quality controls were included in the validation.
- The results of the validation confirmed that the modified method is fit for its intended use.
- The procedure used for validation is documented in a Validation Plan and the results of the validation was recorded on CF15 Validation / Verification Report. These documents together with all supporting information and data, will be available at the CERI Laboratory.

17.3 Measurement uncertainty of measured quantity values

- External factors that may affect the outcome of the results are samples with a low viral load (< 1000 copies/ml), inappropriate specimen collection procedures and compromised specimen storage conditions.
- Multiple freeze-thaw cycles of the primary / extracted samples can result in sample disintegration and lead to false negative results.

17.4 Documentation of examination procedures

For the purpose of sequencing assays. Well documented SOPS's will be written . These outlines the necessary steps for loading libraries of the installed sequencing instruments. Please refer to SOP for Sequencing.

17.5 Ensuring quality of examination results

General

The CERI Laboratory ensures the quality of examination results by performing examination processes under defined conditions as stated in the CWI31-Genotyping Workflow and SOP.

17.6 Quality control

General

The CERI Laboratory is committed to carrying out appropriate internal quality control (IQC) procedures to monitor the analytical performance of the laboratory tests. Each examination procedure incorporates these IQCs to verify the attainment of the intended quality of results.

17.7 Quality control materials

Sequencing: Internal positive and negative controls which are included with every batch of samples tested.

Quality control data
The CERI Laboratory prevents the release of results in the event of IQC failure. This is documented in CWI31. CF14 (Non-Conformance Report) is completed. Invalid IQC results due to quality control failure are indications that examination results are likely to contain significant error. The results of the run are rejected and the relevant samples re-examined after the error condition has been corrected and within specification performance is verified.

The technical personnel and laboratory manager review the IQC data at regular intervals to detect trends in examination performance that may indicate problems in the examination system. When such trends are noted, preventative actions shall be taken and recorded.

18. INTERLABORATORY COMPARISONS

Participation
The CERI laboratory will be setting up Interlaboratory with the KRISP laboratory on an annual basis. Results of the EQA programmes are monitored and reviewed and corrective actions are implemented whenever predetermined performance criteria are not fulfilled, in the event of which, CF14 (Non-Conformance Report) is completed and filed.

The procedure for interlaboratory comparisons, which includes defined responsibilities and instructions for participation, and any performance criteria that differs from the criteria used in the interlaboratory comparison programme is documented in CWI12 – Interlaboratory Comparisons work instruction.

Samples used in the interlaboratory comparisons shall, as far as possible, mimic the sample used for the routine examination process and have the effect of checking the entire examination process, including pre-examination, examination and post- examination processes, wherever possible.

18.1 Alternative approaches

Where EQA programmes or interlaboratory comparison samples are not available, the CERI Laboratory shall use alternative appropriate materials for determining the acceptability of examination results. Examples of these include:

- Certified reference materials
- Samples previously examined
- Exchange of samples with other laboratories

Analysis of interlaboratory comparison samples
Interlaboratory comparison samples are integrated into the routine workflow in a manner which follows, the same workflow for whole genome sequencing.

There is no communication with other participants of the interlaboratory comparison regarding the sample data until the results of the programme have been submitted. Interlaboratory samples are not referred for confirmatory examinations before submission of the results.

18.2 Evaluation of laboratory performance

The performance of the CERI laboratory in the interlaboratory comparison shall be reviewed and discussed with the relevant staff members. These are recorded in the minutes of laboratory and / or Management Review Meetings, or via email correspondence with relevant staff.

When the results of interlaboratory comparisons are not valid (non-conformities are present), corrective actions are implemented and documented on CF14.

Post-examination processes

Review of results

Result reports are compiled and reviewed by authorized personnel, and checked against IQC, before release to the User. All results are subjected to a (at least 10%) transcription check per batch to evaluate possibility of transcription errors and identify potential transcription error trends. A staff member other than the person initially releasing the result does this. Results are then sent off to the Pathologist for further review and authorization of the result. A detailed procedure will be outlined and documented as an SOP and work instruction.

19. REPORTING OF RESULTS

General - *After the completion of a sequence run, the raw sequence reads will be transferred to the CERI server which is housed at the South African Medical Research Council (SA-MRC). Having our data on the SA-MRC server means that the data is ultra-secure and that we are fully compliant with the Protection of Personal Information Act (POPIA) of 2013. Prior to data processing, all sequence reads will be uploaded to an appropriate BioProject on the Sequence Read Archive (SRA,* https://www.ncbi.nlm.nih.gov/sra*).*

*For data processing, short sequence reads will assembled into a contiguous genome with costume pipelines such as GenomeDetective (*https://www.genomedetective.com*) or using the GATK software suite (*https://gatk.broadinstitute.org/hc/en-us*) from the Broad Institute.*

Report content

- All CERI personnel are required to sign CF35 - Confidentiality Statement to maintain the confidentiality of patient information and results.
- Access to the KRISP LIMS requires individual logins which are password protected.
- The Miseq,NextSeq and NovaSeq instruments on which the raw data is stored, does not contain any patient data. This instrument is password-protected thereby restricting unauthorized access.
- The above instruments are safeguarded against any tampering by access control using individual logins. An audit trail of events is also available on the instrument.
- The software in which the data is analysed does not contain any patient data.
- Authorized CERI personnel are able to review the sequence data and analysis but an audit trail of events is available.

- The manual entry of results onto CF16 is checked for accuracy by performing transcription checks using CF20 – Results Transcription Verification Record.
- Raw sequence data is backed up on an external hard drive. Records of backup are recorded in CF18 – Data Backup Record.

Approval

Approved By: _____ Date: _____

Author _____
Print Name and Title

Approved By: _____ Date: _____
Director

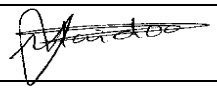
_____
Print Name and Title

ANNEX 6: HEALTH AND SAFETY STANDARD OPERATING PROCEDURE

CERI	Document Number: CSOP02 Version: 1.2	Health and Safety	Stellenbosch UNIVERSITY IYUNIVESITHI UNIVERSITEIT

CENTRE FOR EPIDEMIC RESPONSE AND INNOVATION, SU
HEALTH AND SAFETY-Temporary labs

Standard Operating Procedure

Number	CSOP02	**Written by**	Yeshnee Naidoo	
Version	1.2	**Reviewed by**	Cheryl Baxter	
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Revisions/Reviews	
Date	**Action**
21/04/2022	Amendments have been made on pages 13, 14 and 16, these are highlighted in yellow Version number changed from 1.0 to 1.1 Page numbers were added and numbering of headings was updated
06/05/2022	**Amendments on page 10 14.2 Evacuation Routes Third Floor Added 14.2.1 Evacuation Routes First floor and images of routes on page 12 and 13**

Contents

LIST OF ABBREVIATIONS

BSL	Biosafety Level
HBV	Hepatitis B Virus
HSR	Health and Safety Representative
IOD	Injury on Duty
MSDS	Material Safety Data Sheet
PPE	Personal Protective Equipment
SOP	Standard Operating Procedure
TB	Tuberculosis
SUN	University of Stellenbosch

DOCUMENTATION

CF17	Disinfection of Work Area
CF23	Safety Checks Record
CF25	First Aid Box Checklist
CF27	Document Acknowledgement Record
CF28	Safety Assessment Checklist
CF41	Orientation Form
CF45	Indemnity Form
CF52	Injury on Duty Register
CF76	Equipment Decontamination Form

1. PURPOSE

This document describes the processes and procedures in place to ensure the health and safety of all staff members in the laboratory. Safety practices with a laboratory is essential as it reduces incidents, staff and laboratory personal should adhere to these safety precautions therefore reducing laboratory associated risks. The CERI laboratory ensures that all staff are educated regarding certain hazards. All staff, students and laboratory personnel must be familiar with each procedure outlined in this document and sign an acknowledgement form.

2. SCOPE

This Standard operating procedure is applicable to all staff and covers the general safety procedures that are in place in the CERI Laboratory, which promote a healthy and safe working environment. These procedures are guided by the Occupational Health and Safety Act (1993) of the RSA.

3. RESPONSIBILITY

- The Laboratory Manager is responsible for ensuring that all staff members are familiar with this SOP.
- All staff must read and sign to acknowledge reading this SOP using CF27 – Document Acknowledgment Record.
- The Health and Safety representative (HSR) is responsible for implementation of Health and Safety practices at the CERI Laboratory (see also Section 7).
- The HSR and / or Laboratory Manager is responsible for conducting the Safety Assessment according to CF28 (Safety Assessment Checklist)

4. BACKGROUND

The most common laboratory injuries are as follows:

- Cuts (from broken glassware, pipettes, glass cover slips, scalpel blades, etc.)
- Needle-stick injuries (during re-capping of needles, disposal of sharps, etc.)
- Eye splashes (with infectious bodily fluids or toxins and chemicals)
- Falling (off chairs, down stairs, by tripping, slippery floors, high-heeled shoes and shoes without rubber soles)
- Blunt trauma / crush injuries (knocking head on open cupboard doors, dropping objects onto feet, fingers in door jam, etc.)
- Other (TB acquisition, allergy to latex, burns)

Examples of unsafe activities include, but are not limited to:

- Operating equipment / analysers without training
- Using unsafe or poorly maintained equipment
- Distracting or startling other members of staff
- Failure to use personal protective equipment (PPE)
- Poor housekeeping
- Inadequate lighting
- Use of high heels and open shoes
- Use of cellular phones in a “no cell phone” zone

Any unsafe conditions or acts must be brought to the attention of the Platform Manager and / or Health and Safety Representative.

5. GENERAL SAFETY RULES

Each staff member is required to sign the Indemnity Form (CF45), and must be orientated and inducted using the Orientation Form (CF41), according to the following:

- Obey all safety rules, signs and regulations as per legislation, policies and SOPs.
- The emergency evacuation route. Keep fire equipment, fire exits and passages clear from clutter.
- Location of fire equipment and first aid facilities
- General waste and biohazard waste
- Washing of hands with disinfectant before leaving the laboratory
- Keeping the work place clean and tidy
- Closing biohazard bins once they are 75% full
- Disinfection of work areas with extran and / or 70% alcohol (record of CF17 – Disinfection of Work Area)
- Keep laboratory doors closed at all times to prevent unauthorized access

The following activities are prohibited in the laboratory:

- Eating, drinking, smoking
- The application of make-up
- Answering the telephone / handling of doors and clean stock / reagents with gloves
- Touching of eyes, nose, mouth or face while working. Long hair must be tied back.
- Use of PPE in non-biohazardous areas (eating areas, administrative areas, toilets, etc.)
- Use of cellular phones, MP3 / iPods as frequencies may cause interference with the analyzers

Personal Protective Equipment

- PPE is used by staff, students, and visitors (e.g. service engineers) to prevent exposure to hazardous substances or infectious agents, and to prevent occupational illness.
- PPE may include laboratory coats, safety glasses, gloves and face shields (where appropriate).
- Closed shoes must be worn in the laboratory areas.
- Laboratory coats must be buttoned fully and the sleeves tucked into the gloves to prevent contamination of personal clothing.
- No laboratory coats should be worn outside of its designated laboratory areas.
- Dirty laboratory coats are placed in a designated box when there are more than five dirty laboratory coats to be laundered.

Duties of the Health and Safety Representative

The HSR is responsible for the following duties:

- Continuous monitoring of CERI and the investigation of complaints by staff related to Health and Safety at work
- Submit a report to the Laboratory manager for each incident and non-conformance arising from Health and Safety issues.
- Review of Health and Safety procedures
- Plan and co-ordinate Health and Safety training
- Participate in Health and Safety audits and / or inspections
- Ensures that all CERI staff observe the Health and Safety rules
- Participation in the orientation and induction of new staff members
- Maintenance of all Health and Safety-related documents
    1. Monitor the functioning of the eye-wash (monthly) and emergency release (monthly) (CF23 – Safety Checks Record) and conducting safety assessments (every six months).
    2. Monitoring the contents of the Frist Aid Box (CF25 – First Aid Box Checklist).

6. OCCUPATIONAL HEALTH

6.1 Hepatitis B Vaccination

HBV vaccine is offered to all CERI laboratory staff members without immunity to HBV, on a voluntary basis. Blood tests for baseline Hepatitis B surface antibody titres are done via the Medical Campus Clinic), where a vaccine will also be administered, if required. Antibody levels are checked every five years to see if booster doses of vaccinations are required. Records are filed in the respective staff personnel files.

6.2 Medication for Current Medical Conditions

Any staff member who is taking medication which has side effects that are not a threat to the health and safety of the staff concerned, or to other staff in the CERI laboratories, is allowed to carry out normal duties. Management and the HSR should be aware of the condition and be able to offer support, encouragement and counselling especially to those who are on anti-TB treatment, anti-retroviral treatment or cytotoxic drugs.

7. INJURY ON DUTY

CERI is able to identify any injuries reported, and to implement corrective actions and prevent re-occurrences of incidents, to provide staff with an understanding of the IOD procedures and documentation and with the knowledge of what to do in the event of an IOD. CERI will follow SUN Incident / Accident Reporting Responsibilities (CWI18) for IODs. It is the responsibility of the injured staff member to report injuries to the Laboratory Manager and / or HSR. All documentation relating to IODs are filed in an IOD file. CF52 – Injury on Duty Register is used to record IODs at the CERI Laboratory.

7.1 Procedure for an IOD

- Report the injury to the Laboratory Manager / HSR ASAP, before the end of the working day

- The First Aider must administer first aid immediately at the scene, if necessary
- In the event of a cut or need stick injury, encourage bleeding under running water.
- For skin splashes, wash the affected area immediately with disinfectant soap and water.
- For eye-splashes:
- using the eyewash station, rinse the affected eye(s) with cool tap water for approximately 15 minutes
- remove contact lenses (if applicable) if they do not come out during the flushing
- do not rub the eye – this may cause further damage
- seek emergency medical assistance.

7.2 Guidelines during Office Hours (08h00 – 17h00)

- **Light injuries** - Report to the Line Manager and the Division Medical Officer to provide treatment
- **Less serious injuries –** Report to the Line Manager and transport the injured person to Campus Health Services (CHS) at the Tygerberg Student Centre (TSS) Room 3035.
- **Serious Injuries** – Report to the Line Manager and arrange ambulance transport at (10177) (ER 084 124) to Louis Leipoldt Medi-Clinic, Broadway Street, Bellville (021-9493681). Also contact CHS at 938 9053/9590. Alternatively contact the Remuneration Division (808-4552) to report the IOD.

7.3 Guidelines after office hours (17h00 – 08h00)

- Report all injuries or occupational diseases to Risk and Protection Services Education K-Ground Room 0044 (938 9507)
- Refer all other injuries requiring medical help to Medi-Clinic Emergencies, Louis Leipoldt Hospital, Broadway.
- Transport employees with serious injuries to Medi-Clinic by ambulance.
- Report the injury at CHS (see contact details above) to complete the employer report on the injury within 24 hrs.
- Contact CHS with enquiries (808-3322/3496/3490).

7.4 Rules Regarding Sick Leave, Remuneration and Benefits During Absence After IOD

When an injured person is booked off by a doctor due to IOD, this sick leave is not captured on the system against the person's sick leave or any other kind of leave to which the person is entitled but is only documented by the department, and a copy of the doctor's certificate is sent to the Remuneration Division

8. INCIDENT INVESTIGATION

- The level of investigation conducted, depends on the seriousness of the accident or incident.
- Once the injured person has received medical attention, the accident scene must me secured, and any hazards or dangers still present, must be neutralized.
- The Safety Officer must take down the names of all persons who witnessed the accident, or may have knowledge of the accident.
- Do not restart any equipment involved in the accident, unless cleared by the laboratory manager or a safety officer.

- Investigation may include: Completed incident report, witness statements, and descriptions of all equipment involved.
- Incident reports can be requested from Mr Neilen Maikoo neilendra@sun.ac.za.
- Once the investigation is finalized, management, together with the safety committee, will decide on a corrective action to be taken, if necessary to prevent incidence from happening again.

Occupational Disease

8.1 Latex or Other Allergies

- There is an increased incidence in allergies to latex gloves due to sensitization of soluble latex protein in latex rubber.
- Non- latex gloves must be used for staff suspected of having a latex allergy.

9. WASTE MANAGEMENT

- All General Waste is disposed in black dust bins inside the lab and office areas.
- Biohazard Waste is collected by BCL (*https://www.bclmedicalwaste.co.za/*) and Enviroserve services after logging a collection request via email. A collection certificate is issued and filed onsite.
- Hazardous Chemical / Liquid Waste is collected by Enviroserve after logging a collection request via email.

10. EQUIPMENT

- Staff operating equipment should not wear loose clothing or dangling jewellery or have long, untied hair, as these could potentially get caught in the moving parts of certain equipment.
- No staff member shall be under the influence of alcohol or any other intoxicating drugs during the operation of equipment.
- All staff working with equipment must be suitable trained to do so.
- An Equipment Decontamination Form (CF76) must be completed before any service personnel handles the equipment for repairs or servicing.
- The Laboratory Manager informs all staff of maintenance activities in the laboratory that could pose a risk to the health and safety to laboratory personnel (such as decontamination of biosafety cabinets).

11. FIRE SAFETY

All staff and students working in the building must be make themselves familiar with evacuation routes and fire classification. The names of first aiders and fire marshals on the third floor are listed below, the CERI laboratory will appoint a First Aider, SHE representative and Fire Marshal as training needs to be conducted.

SHE Representative	Ingrid Webster
First Aiders	Dr Amanda Genis
Fire Marshals	Dr Hanel Sadie van Gijsen/ Dr Lihle Qulu
	Dr Erna Marais/ Mr Leslie van Rooyen (until Dec 2021)/ Dr Bonge Skosana

See below table for Fire Classification:

Classification of Fire	Examples	Extinguishers
Class A	Ordinary combustibles - Wood, paper, cloth, etc.	Pressurized water and dry powder
Class B	Flammable liquids -Gases, greases and paints	Dry powder and carbon dioxide
Class C	Electrical – Instruments and computers	Carbon dioxide
Class D	Combustible Metal Fires	Chemical powders

11.1 Procedure for Extinguisher operation and evacuation drill

	Water	Carbon dioxide	Dry powder
	• Pull pin • Aim Nozzle • Squeeze handle • Sweep extinguisher	• Pull pin • Aim nozzle at base of fire • Squeeze handle	• Pull pin • Aim nozzle at base of fire • Squeeze handle
Discharge range	9 – 12 m	1 – 3 m	2 – 6 m
Discharge time	60 sec	30 sec	30 sec
Inspected	Annually	Annually	Annually

If there is a fire in the laboratory, stay calm and raise the alarm immediately (Blow on the whistle placed in designated areas in the laboratory). Make sure that everyone in the laboratory is aware of the fire.

Notify USBD x9507 who will raise the fire alarm

- Notify the safety officer if in the laboratory.
- If time allows, close doors and windows, and switch off all electrical equipment.
- If time allows, safeguard money/important documents and take essential personal belongings.
- The fire alarm will sound and all persons to follow the safety signs to the evacuation routes.
- Use an appropriate fire extinguisher if there is a reasonable chance of putting out the primary fire with one extinguisher, or to gain time to evacuate people from the area.
- Do not use lifts in vicinity of fire.
- Keep calm and don't run.
- Evacuate via the nearest evacuation route as directed by the safety officer. See diagram below for safest escape route. If passage marked route 1 is filled with smoke, follow routes 2 or 3 to leave the building safely.
- Move, crouched or crawl, if the escape route is filled with smoke. Place a wet cloth over the mouth and nose to prevent smoke inhalation.
- **Gather outside at the designated assembly point and wait for the safety officer to do a roll call.**
- When all personnel have safely left the Division, the safety officers check if the laboratories and offices are empty, before leaving the building via safest evacuation route to the designated assembly point for the education block.

11.2 Evacuation Routes Third Floor

The below routes must be used by personnel and students of General laboratory 3.1, 3.2 as well personnel and students in the connecting offices and open plan areas.

Route 1

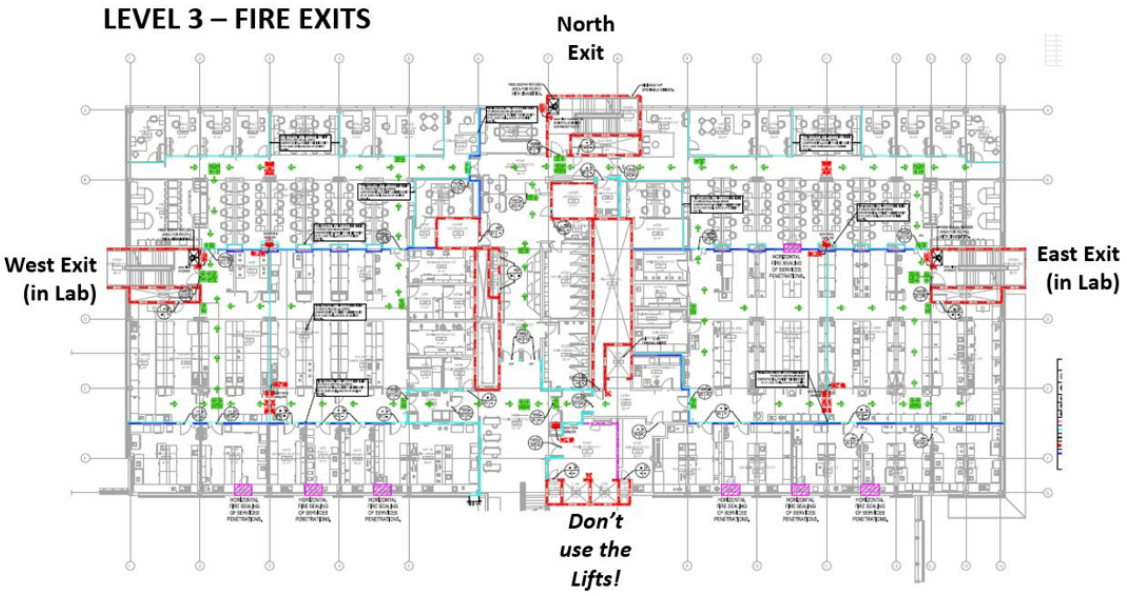
- Exit the General Laboratory 3.1 West through fire exit door closet to the weighing room 3017.
- Take the stairs down to the basement floor and exit the building to your right to the assembly point on the rugby field.

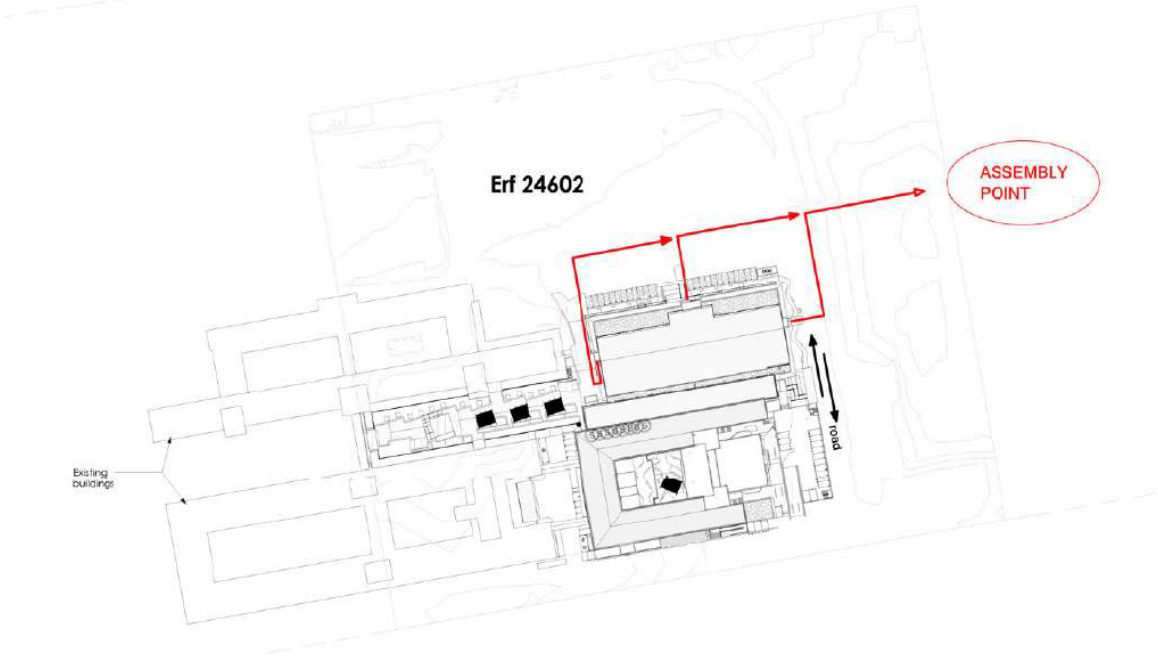
Route 2

- Exit through the fire exit door next to the seminar room 3032 and exit down the stairs to the assembly point on the rugby field.

Route 3

- Exit General laboratory 3.2 East by the fire exit door in the north east corner of the lab and exit down the nearest stairs to the assembly point on the rugby field.





11.2.1 Evacuation Routes First floor

In the event of a fire in the BMRI Building, the following routes must be used by all personnel, students and visitors of the Level 1 General laboratory and offices.

Route 1

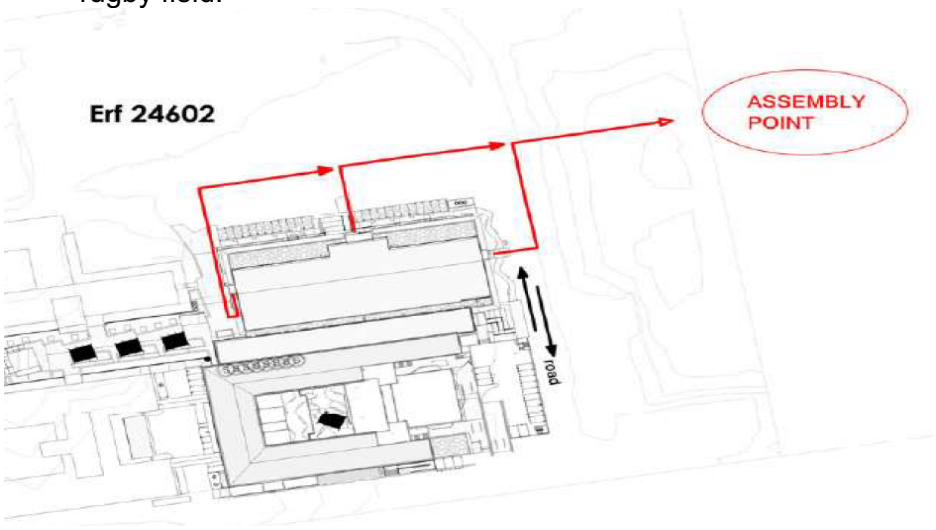
In the event of a fire in the laboratory, exit the laboratory through the emergency door labelled **1035 Staircase 1.3**, situated at the back of the laboratory. Exit the building, then assemble on the rugby field.

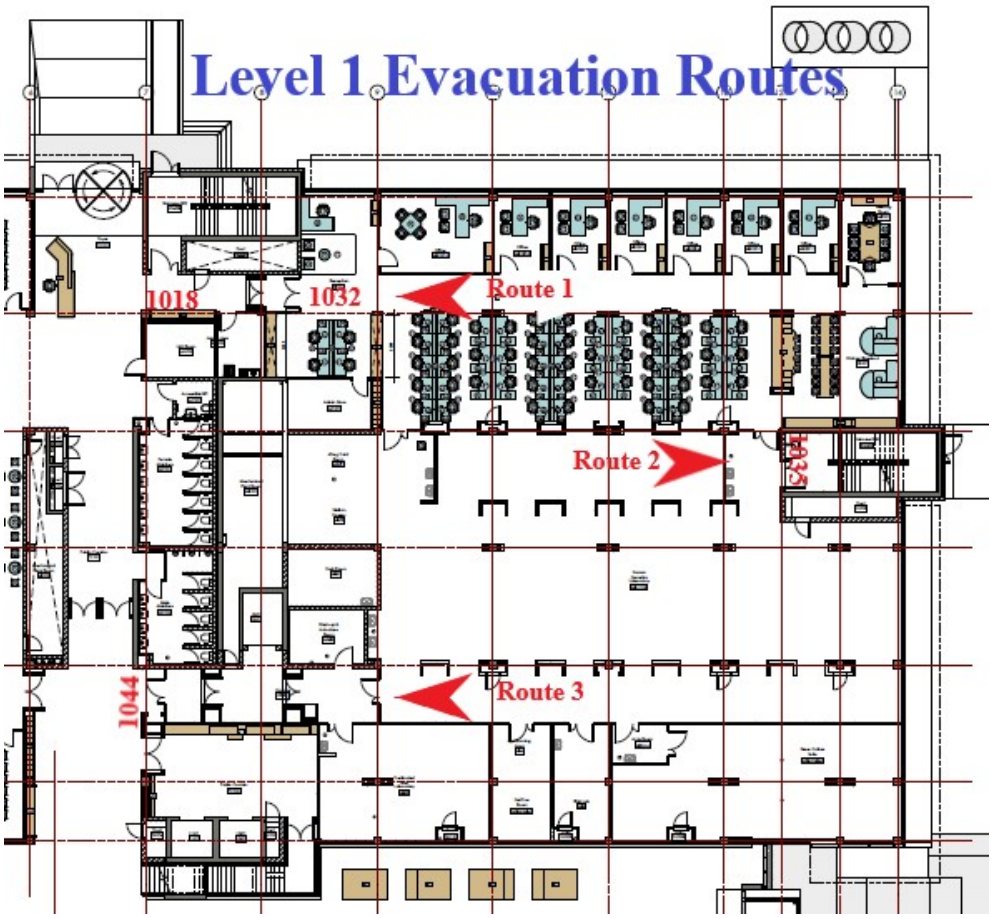
Route 2

If the office area is filled with smoke, exit the **door 1032**, then exit the building through the emergency exit on your right-hand side, **labelled 1018 Staircase 1.2**. Once outside, assemble on the rugby field.

Route 3

If the emergency door at the back of the laboratory or the front of the offices are not accessible, exit the laboratory through **door 1034 and door 1044**. This will take you to the open reception area, where you can exit to the parking lot and continue to the rugby field.





11.3 Procedure for Emergency Evacuation
The CERI laboratory will follow the SUN Emergency Procedures (CWI19).

In the event of an emergency necessitating an evacuation of the premises the following guidelines should be observed:

When notified by the sounding of the alarm, or instructed by the Emergency Officer or the Head of Department, leave the building immediately do not ask questions. “STAY CALM”.

Proceed to the nearest emergency exit and leave the building through the shortest pre-determined route.

If you are aware of any disabled persons in the area, bring it to the attention of the person in charge or assist that person to safety.

- DO NOT stop to search for friends, the fastest way for them to be located is for everyone to proceed to the assembly point.
- DO NOT GO BACK INTO THE BUILDING
- DO NOT RUN – Move at a steady rate in a downward movement.
- DO NOT USE LIFTS – You could get trapped
- DO NOT TALK UNNECESSARILY – As you may miss vital instructions
- Follow instructions from the persons in charge of your department.

- Remain at the Assembly point where a role call will be taken

12. MEDICAL EMERGENCIES AND FIRST AID

First aid is administered to reduce contact time with the exposure thereby reducing. preventing further risk and injury.

Procedure to follow should the following injuries occur:

- **Needle stick injury:** Do not squeeze or rub the injury site. Wash injured area immediately with copious amounts of soapy water and disinfectant (example: Dettol). Do not use strong solutions, like bleach or iodine, which could worsen the injury or irritate the skin.
- **Contaminated intact skin:** Wash area with soap and water.
- **Contaminated open wound:** Wash injured area with copious amounts of soapy water and disinfectant (example: Dettol). Do not use strong solutions, like bleach or iodine, which could worsen the injury or irritate the skin.
- **Splash of mucosal membrane (mouth / nose):** Clear out any foreign fluid and rinse thoroughly with water or normal saline. Repeat rinsing several times. Do not use soap or disinfectant in mouth or nose.
- **Splash in eye(s):** gently irrigate eye(s) with normal saline or water. Sit in a chair and tilt the head back – have a colleague pour water or normal saline over the eye while pulling the eyelids up and down, until eye is cleared properly. Do not use soap or disinfectant on the eye(s). Do not remove contact lenses – perform thorough irrigation as described above and then remove contact lenses once the eye has been cleaned.

12.1 Reporting of Exposures:

Follow the steps below for reporting:

- Report the incident immediately to the **divisional safety officer and medical officer**. Blood tests on source study participant must be arranged: Hep B and C status; HIV status after counselling and RPR (two sterile 5ml red top tubes). This applies if the staff member was working with clinical samples.
- If the source study participant is known to have HIV infection or the status cannot be determined, the employee must be counselled about the risk of transmission after the specific injury and post-exposure prophylaxis (PrEP) offered.
- The PrEP starter pack (three-day supply) is available from the medical officer. The PrEP drugs must preferably be started within 1hr after exposure (maximum 4 hours).
- If the source patient is HIV negative, PrEP is not indicated. If the employee is HIV positive, PrEP is not indicated.

Injury must be reported as soon as possible or within 24h to:

- Your own HIV insurance broker *OR*
- If you have HIV insurance through the University: Marlene Vermeulen – Alexander Forbes Risk Services, Stellenbosch (021) 809 5545 OR Elizna de Lange – Stellenbosch University (021) 808 2809 (If you do not report the incident within 24h, you forfeit any claim under this insurance)
- Report of incident must be filled and filed at the First Aider /Safety officer.

12.2 Visit A Doctor or Emergency Unit

- Campus Health (Sr Anneke van Heerden) contact number: +27 21 808 3494/6
- The following tests and appropriate treatment will be arranged:
- ***Blood tests on employee:*** Hep B surface antibody and Hep C antibody status; HIV status after counselling, baseline liver functions, full blood count, pregnancy test (if applicable)
- A final decision can be taken regarding the need to continue PEP for a full month and if the basic two drug regimen or an expanded three drug regimen is indicated. The employee must be counselled on the side-effects of anti-retroviral therapy.
- If the employee is not HBV immune, he/she must receive HBV Immunoglobulin and the first dose of HBV vaccine within 24 hours of exposure (and subsequently complete the vaccine course).
- If the source study participant's hepatitis status is negative (and result is available within 24h) or if the employee is HBV immune, no immunoglobulin or immediate vaccine is indicated. (It is, however, advisable that the employee with no HBV immunity receive the vaccine to be protected from future exposure). There is no treatment or vaccine for Hepatitis C exposure.

12.3 Follow-Up Visits to Attending Clinician

- The full course of HBV vaccines must be given (at baseline, 1 and 6 months after exposure) and Hep C antibodies must be checked at 2 weeks, 4 weeks and 8 weeks after exposure.
- Follow-ups must be attended to check drug side effects. Repeat liver function tests and full blood count in 2 weeks. HIV serology will be repeated at 6 weeks, 3 months, 6 months and 12 months.

13. CHEMICAL SAFETY

13.1 Procedure for Handling of Chemicals

- All Material Safety Data Sheets (MSDS) are available to all staff in the CERI laboratories. These read, signed and filed (CF27 - Document Acknowledgement Record) by the staff handling these chemicals.
- The following rules must be observed:
  - Regard all chemicals as poisonous
  - Ensure that solutions stored in bottles for use on the bench are clearly marked with the reagent name, concentration, date, expiry date, and name of person preparing the reagent (if applicable)
  - Never touch a chemical with bare hands. Use gloves and another PPE.
  - Never pour water into any acid. Use a funnel to pour chemicals as far as possible.
  - Do not use chemicals from unlabelled bottles. These should be discarded.

13.2 Procedure for Storage of Chemicals

- Chemicals should be stored according to the manufacturer's instructions.
- Combustible material and flammable liquids should not be stored in the same area.
- Flammable liquid storage should not exceed 100 litres.
- All chemicals should be labelled with the date of receipt, date opened and expiry date.
- Chemicals must be stored away from light, temperature variations and vibrations.
- Corrosive liquids should stand in shallow metal or plastic containers to contain accidental spills or breakages.
- Flammable liquids should be stored in appropriate flameproof lockers.

14. PROCEDURE FOR CLEANING UP OF CHEMICAL SPILLS

Chemical spillages must be attended to immediately. Reference to the chemical MSDS is made for first aid, clean up and disposal procedures

14.1 Procedure for Biological Spills

- A spill kit is available in designated sections of the laboratory.
- Decontamination of small biological spills is done by pouring 5% sodium hypochlorite solution (biocide) onto the spill. For metal surfaces, use 70% alcohol.
- Ensure the appropriate PPE is used.
- Mop up and wash with detergent and water.
- Dispose of material in bio-hazard bin.
- Inform the HSR immediately so that a risk assessment can be done.
- All dirty lab coats, this would include dirt from dust and frequent use in the laboratory must be removed from the lab and sent for laundry. Disinfect area exposed to biological matter with 70% alcohol and then use soap and water.

15. VISITOR AND CONTRACTOR SAFETY

Visitors and contractors entering the Medical Physiology laboratories have a risk to be exposed to hazards that employees have been trained to avoid. All staff and students must make sure that safety policies are adhered to in order to minimize these risks. This policy offers guidelines to reduce the risk of hazard exposure to visitors and contractors while they are in the Medical Physiology laboratories.

Responsibility

Management and employees have equal responsibility to ensure that safety policies are adhered to when visitors and contractors enter the laboratory.

If visitors and contractors do not comply with these policies, they should be asked to leave.

All visitors must sign in on the log found at the entrance to the laboratory. This is very important – if there is an emergency and we need to evacuate the building, we need to be able to grab the log on the way out and use it for roll call at the assembly point.

A visitor is anyone who will be in the lab for an hour or more – e.g. contractors coming to service instruments, students who are working in our lab for the day. This applies to external visitors only (i.e. not from SU).

If you are "hosting" a visitor, it is your responsibility to get the person to sign the log, to show them the location of the emergency exits and inform them of the evacuation procedures. You are also responsible for them should there be an evacuation.

Procedure

Visitors

Have a responsibility to:

- Observe and adhere to policies and procedures where applicable.
- Work in a safe and responsible manner.
- Report any actual or potential hazard to his/her supervisor.
- Prevent loss of, or damage to, University property due to unsafe and irresponsible working manner.
- Use personal protective clothing and equipment.
- Not create hazardous distraction to employees.

Contractors

Have a responsibility to:

- Adhere to applicable safety regulations.
- Provide personal protective equipment as applicable for their trade.
- Comply with safety requirements for any area that they enter.
- Comply with instructions given by a designated supervisor.

Management

Have a responsibility:

- Inform visitors and contractors of safety regulations and guidelines.
- Inform personnel and students of any visitors and contractors.
- Explain potential hazards to which they may be exposed to.
- Explain how to respond if any hazardous exposure occurs.
- Show location of emergency equipment.
- Explain evacuation plan.
- Inform visitors and contractors of hours of operation, and contact person in case of emergency.
- Provide advice on disposal of possible wastes.
- Inspect work site to ensure compliance with safety regulations.

Employees and Students

1) Allow contractors space to perform their duties.
2) Refer visitor or contractor questions to management.
   Assist visitors and contractors in evacuating the laboratory in case of an emergency

16. MATERIAL SAFETY DATA SHEETS (MSDS)

Scope

All staff and students must know the location of the MSDS manual in the event of accidents or incidents involving chemicals or hazardous substances. Knowledge of MSDS ensures that all employees know how to react in a potential hazardous or harmful situation.

Responsibility

All staff and students are responsible for keeping these folders up to date and to know its whereabouts.

Procedure

1) All staff must familiarize themselves with the contents of the MSDS file that will be located in the sequencing room.
2) If a new reagent is received and the MSDS is not in the folder in the laboratory, add the MSDS to the folder, and make an entry into the table of contents.

17. PERSONAL SAFETY

Scope

Personal safety and theft reduction are shared responsibilities. All employees and students should have their identification cards with them at all times for quick identification. By following these guidelines you will improve your own safety, as well as make the Medical Physiology laboratory a safer work space.

Responsibility

All personnel and students are responsible for their own safety.
It is the responsibility of the University of Stellenbosch Risk Services to lend support when needed.

Procedure

1) If you encounter any emergency, call the University of Stellenbosch Risk Services (USRS/USBD) at x9507.
2) Alternatively use the Stellenbosch University Emergency Procedures guidelines found in all offices and laboratories.
3) Emergencies include: fire, smoke or smell of gas; life safety; bomb threats; serious accidents; crime in progress; suspicious persons.
4) NEVER ENDANGER YOURSELF OR ATTEMPT TO DEAL WITH HAZARDOUS/SUSPICIOUS SITUATIONS YOURSELF!
5) Always be aware of what is going on around you.
6) Follow your instincts, and if you feel at risk, leave the situation or area immediately.
7) Watch out for one another.
8) Lock away all personal belongings.
9) Ask identification of any unidentified person entering the laboratory or offices.
10) Report any unauthorized entry to a locked or secure area to USBD.

11) If you have to work after hours, be extra careful. If you suspect that you are being followed, immediately head to a place where there are other people.
12) Try to stay in well- lit areas.
13) Let someone know that you will be working after hours, and when you expect to leave.
14) Lock office when you are alone.
15) If you enter an elevator and feel uncomfortable with the person riding with you, leave before the door closes, or get off at next floor.
16) Stand with your back to the elevator wall closest to the control panel. If you feel threatened, press the alarm button, and as many floors as possible.
17) If the elevator should break down with you inside, press the alarm button and wait for help.
18) Never pry open the elevator doors or try to escape through the roof hatch.
19) Have your car keys ready before you reach your car.
20) Visually check the interior of your car before getting in.
21) Avoid using bank machines when the building is deserted.
22) Be aware of people around you and during usage of bank machine.

ALWAYS FOLLOW YOUR INSTINCTS!

REFERENCES:

Laboratory safety manual of the Centre for Epidemic Response and Innovation (Temporary lab)

ANNEX 8: GRIEVANCE FORM TEMPLATES AND PROCEDURE

GRIEVANCE FORM

Reference No:	
Full Name Note: you can remain anonymous if you prefer or request not to disclose your identity to the third parties without your consent	First name _____ Last name _____ ❑ I wish to raise my grievance anonymously ❑ I request not to disclose my identity without my consent
Contact Information Please mark how you wish to be contacted (mail, telephone, e-mail).	❑ By Post: Please provide mailing address: _____ _____ _____ _____ ❑ By Telephone: _____ ❑ By E-mail _____
Preferred Language for communication	❑ Afrikaans ❑ English ❑ Other, Specify _____
Description of Incident or Grievance:	What happened? When did it happen? Where did it happen? Who did it happen to? What is the result of the problem?
Date of Incident/ Grievance	
❑ One time incident/grievance (date _____) ❑ Happened more than once (how many times? _____) ❑ On-going (currently experiencing problem)	

What would you like to see happen to resolve the problem?
Signature: _____ Date: _____
Please return this form to: Suzette Grobler, Grievance Officer, CERI, Tel.: +2731 83 459 8625 or E-mail: groblers@sun.ac.za

MINUTES OF COMPLAINTS COMMITTEE MEETING

Date:

In attendance:

Venue:

Personal particulars of aggrieved person(s)

Name and surname: _____

Company / organization: _____

Short description or summary of the reason for the grievance

_____

_____

Desired outcome:

_____

_____

Recommendation or agreement according to which the grievance was handled or resolved

_____

_____

OR:

Brief summary of the reasons why the grievance could not be handled or resolved at this level (if applicable):

_____

If not resolved, was the grievance referred to an impartial arbitration Yes ☐ No ☐

Signature(s) of complainant person(s) **Date**

1. -

2. -

_____ _____

Signature of Director or mediator **Date**

Stellenbosch
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forward together
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Grievance Procedure

Reference number of this document	IR0153
HEMIS classification	
Aim	To grant any employee who has a grievance or problem that has arisen from their employment at Stellenbosch University (SU) the right and the opportunity to lodge their grievance and discuss it with an eye to resolving it, if possible, to mutual satisfaction
Type of document	Procedure
Accessibility	General (external and internal)
Implementation date	February 2012
Review date/frequency	As the need for amendments arises
Previous reviews	
Owner of this procedure	Vice-Rector: Social Impact, Transformation and Personnel
Institutional functionary (curator) responsible for this procedure	Chief Director: Strategic Initiatives and Human Resources
Date of approval	
Approved by	SU Council
Keywords	policy, procedure, provisions

The core of the procedure

A grievance is regarded as any feeling of dissatisfaction that an employee may experience concerning their employer, workplace, colleagues or any other aspect of their employment.

No matter that can be dealt with by means of collective bargaining or consultation (or a combination of the two), no matter related to the outcome of collective bargaining or consultation (or a combination of the two) and no appeal against disciplinary measures or termination of employment **is to be considered a grievance for the purposes of this procedure** and therefore will not be handled with reference to this procedure.

This procedure also does not apply to grievances that have arisen from sexual harassment; Stellenbosch University (SU) handles such grievances with reference to the document **Sexual Harassment: Policy and Procedure for Staff**, which was drafted specifically for that purpose.

1. INTRODUCTION

SU accepts that employees who are aggrieved by any aspect of their employment are experiencing a problem, since such grievances directly affect people's job security, job satisfaction and relationships at work.

2. BASIC PRINCIPLES OF THE PROCEDURE

2.1 All staff members, whatever their post level, are granted **the right and the opportunity** to air their grievances without fear of victimisation.

2.2 SU acknowledges that all staff members have the need for grievances to be dealt with and, if possible, resolved by means of the following:

- 2.2.1 opportunities for staff members to turn to a higher authority should they feel that their grievances were not considered with the required insight or empathy;
- 2.2.2 free access for staff members to staff meetings for the purposes of advice and support regarding the resolution of grievances;
- 2.2.3 this procedure being available to all staff members;
- 2.2.4 grievances being dealt with consistently, equitably and speedily; and
- 2.2.5 allowing groups who feel aggrieved to lodge their grievances by means of one or two representatives.

3. AIM OF THE PROCEDURE

The aim of this procedure is to offer all staff members the following:

3.1 a formal channel for bringing their grievances to the attention of their immediate superiors or, if necessary, a higher authority;

3.2 a procedure for handling and resolving grievances at the earliest opportunity possible; and

3.3 a procedure for resolving grievances as equitably as possible in the circumstances.

4. PROCEDURAL STEPS

All periods indicated below are the maximum time allowed for the relevant step in the procedure for resolving grievances, unless a different arrangement has been made with the employee concerned.

If the grievance is resolved at some point in the process, this must be recorded in the minutes and signed by both parties. If the process fails to produce a resolution, the minutes just need to state this. Both parties must receive a copy of the minutes. Annexure 1 contains documentation in this regard.

Step 1

SU staff members who have a grievance must lodge it firstly by completing paragraphs 1 to 3 of Annexure 1 and submit it with their **immediate superior** (or with the person designated by the superior to handle grievances in his or her absence). However, if the grievance is about the immediate superior concerned or their delegate, or about a person at a higher level of seniority than the immediate superior concerned or their delegate, the aggrieved person must lodge the grievance at such higher level. The person with whom the grievance was lodged must perform the following tasks during the grievance interview to the best of their abilities but within their delegated powers:

a. Listen in private to the staff member's case.
b. Encourage the staff member to put their case openly and honestly.
c. Obtain all facts about the grievance and differentiate between facts and opinions.

The person with whom the grievance was lodged must try to resolve it as speedily as possible, but at least within five working days after the grievance has been lodged in writing, unless a different arrangement has been made with the employee concerned.

The person with whom the grievance was lodged must complete and sign the applicable section of Annexure 1 and have the aggrieved person sign it, too.

The aggrieved person may be assisted or accompanied by a fellow staff member of their choice.

Step 2

If the **immediate superior** (or their delegate, in their absence) fails to resolve the grievance or if the grievance concerned was about the staff member's immediate superior or their delegate, or about a person at the same or a higher level of seniority than the immediate superior concerned or their delegate, the staff member may refer the matter in writing to the next **higher managerial level** with notification to their immediate superior or their delegate.

The higher-level manager must try to resolve the grievance as speedily as possible, but no longer than five working days after the grievance has been referred in writing, unless a different arrangement has been made with the employee concerned. The outcome of step 2 must also be documented in Annexure 1 and signed.

The aggrieved person may be assisted or accompanied by a fellow staff member of their choice.

Step 3

If no agreement has been reached by this stage, or if the grievance is about a person at a higher level of seniority than the staff member's immediate superior or their delegate, the grievance must be referred to the **third managerial level**.

The third-level manager must try to settle the grievance within five working days after it has been referred, unless a different arrangement has been made with the employee concerned. The outcome of step 3 must also be documented in Annexure 1 and signed.

The aggrieved person may be assisted or accompanied by a fellow staff member of their choice.

At this point the third-level manager or the aggrieved person may appeal to the Division of Human Resources (HR) for assistance in the form of mediation.

Step 4

If the grievance cannot be resolved at third-level management to the aggrieved person's satisfaction, or if the grievance is about a person at third-level management, the manager or the employee must refer it in writing for resolution to the vice-rector who oversees the division concerned. In the case of a division that reports directly to the Rector, grievances must be referred for resolution to the person that the Rector has designated for this purpose.

The vice-rector concerned or the person that the Rector has designated must try to resolve the grievance as speedily as possible, but no longer than ten working days after the grievance has been referred in writing, unless a different arrangement has been made with the employee concerned. The outcome of step 4 must also be documented in Annexure 1 and signed.

The aggrieved person may be assisted or accompanied by a fellow staff member of their choice.
At this point the internal procedure is concluded.

SU requires grievances to be recorded as grievances at the University. In this regard SU requires both the aggrieved person and the line manager concerned to report the grievance to HR by sending a copy of the document(s) used to lodge the grievance to the Director: Employee Relations.

5. SUPPORTING DOCUMENTS

Item no.	Name of document	Status *(e.g. identified, in process or approved)*
	None	

6. RELATED DOCUMENTS

Item no.	Name of document	Status *(e.g. identified, in process or approved)*
	Annexures 1, 2 and 3	Identified

MINUTES OF GRIEVANCE PROCEDURE

Personal particulars of aggrieved person(s)

Name and surname

Environment/Department/Division

Short description or summary of the reason for the grievance:

Desired outcome:

1. Level at which the grievance was lodged initially: Step 1

2. Level at which the grievance was resolved: Step 2

3. Recommendation or agreement according to which the grievance was handled or resolved

OR:

Brief summary of the reasons why the grievance could not be handled or resolved at this level (if applicable):

The grievance was referred for the next step in the procedure.

Signature(s) of aggrieved person(s) **Date**

1. _____

2. _____ _____

3. _____

4. _____

_____ _____

Signature of line manager or mediator **Date**

MINUTES OF GRIEVANCE PROCEDURE: Step 2

Personal particulars of aggrieved person(s)

Name and surname

Environment/Department/Division

Short description or summary of the reasons why the grievance could not be handled or resolved at the previous level, but was referred for the next step:

Desired outcome at this level and the extent to which it must resolve the grievance(s):

Recommendations and agreement if the grievance was handled or resolved at this level: OR
Brief summary of the reasons why the grievance could not be handled or resolved at this level (if applicable):

The grievance was referred for the next step in the procedure.

Signature(s) of aggrieved person(s) **Date**

1. _____

2. _____

3. _____

4. _____

Signature of line manager or mediator **Date**

If the grievance could not be resolved at this level, the internal process is regarded as concluded, leaving the aggrieved person(s) free to take the matter further outside the University.

	Date lodged or referred	Date resolved or referred for the next step	Signature of aggrieved person	Job title, name and surname of the person who has handled the grievance	Name of the person against whom the grievance was lodged	Signature of the person handling the grievance
Step 1						
Step 2						
Step 3						
Step 4						

ANNEX 9: WASTE MANAGEMENT PLAN

The Waste Management Plan (WMP) is intended to serve as a guideline for the project Management for the effective management of wastes.

Objectives of the WMP

The objectives of the WMP are to:

- Make sure to minimize waste by practicing reduction, reuse, and recycling. Also, review and approve all orders for materials, chemicals, and supplies to limit environmental impact.
- When waste cannot be reduced, reused, or recycled, it must be legally and safely disposed of in registered facilities.
- Avoid any negative impacts on the environment, including human health, flora, fauna, air, and water resources.
- Make sure to process waste through treatment and disposal according to global industry standards.
- Develop a monitoring system to track waste generation, handling, and disposal. Assess compliance with the Waste Management Plan (WMP) and its directives.
- Make a waste management plan that minimizes handling and promotes recycling.

Waste Identification

Waste streams likely to be generated by the project during it operations include:

- **Domestic Waste:**
    - **Used Equipment and Devices:** As technology evolves, older equipment and devices used in genome sequencing may be replaced or discarded, generating electronic waste.
    - **Packaging Materials:** Genome sequencing labs receive reagents, chemicals, and equipment that are often shipped in packaging materials. Proper disposal or recycling of packaging materials is important.
    - **E-Waste:** Laboratories use various electronic equipment and devices, and these may eventually become obsolete, generating electronic waste.
    - **Solid Waste:** General solid waste like paper, packaging, and non-hazardous waste generated in the lab environment.
- **Hazardous Waste:**

- **Chemical Waste:** Genome sequencing protocols involve the use of chemicals for DNA extraction, purification, and sequencing reactions. Chemical waste can include solvents, reagents, acids, bases, and other substances used in the process.
- **Biological Waste:** Biological waste such as unused or contaminated samples, tissues, cells, and consumables. Depending on the nature of the research, some biological waste could be considered hazardous.
- **Plastic Consumables:** Genome sequencing involves the use of single-use plastic consumables, such as pipette tips, tubes, plates, and other plastic labware. These items contribute to plastic waste generation.
- **PCR and Sequencing Reaction Waste:** The PCR amplification and sequencing reactions generate by-products, including excess primers, nucleotides, and other reaction components. These waste materials may need to be properly disposed of.
- **Liquid Waste:** Depending on the protocols used, labs generate liquid waste containing residual chemicals, buffers, or other substances. Proper disposal or treatment of liquid waste is important to prevent environmental contamination.
- **Personal Protective Equipment (PPE):** Labs require PPE such as gloves, lab coats, and safety goggles. Disposal of used PPE must be done in accordance with biohazard or chemical waste disposal protocols.

Waste Management Hierarchy

Reduce	This is the primary step in waste management: investigating ways to prevent or limit waste generation to minimize waste.
Re-Use	Feasible ways to reuse discarded items will be considered. If not possible, external options will be evaluated, such as making the item available to the community, provided it is safe for the environment and community health.
Recycle	When reuse is not possible, the waste item will be recycled through treatment or modification to create a new product for similar or different purposes.
Treat and Dispose	If the previous levels of the hierarchy cannot be applied, then the disposal option will be considered. This will involve transferring waste to a landfill or designated dumpsite after treatment to neutralize reduce the toxicity of the waste.

Waste Handling and Transportation

Housekeeping employees trained in safe waste management practices will handle waste on-site. Waste will be categorized and primarily separated at the

source using labelled, color-coded receptacles. All staff will be trained on good waste management practices, made aware of the Waste Management Plan contents, and provided Personal Protective Equipment if directly involved in handling waste. Materials Safety Data Sheets will be available for all hazardous wastes.

Licensed waste contractors will collect and transport waste for recycling and / or disposal to designated facilities. Contractor licenses will be confirmed before services are contracted. Environmental, occupational, community health, and safety measures will be monitored during collection, and wastes will be transported in enclosed vehicles.

Waste handling and transport measures will include the following:

- A regular schedule will be set up for collecting and disposing of household waste.
- Waste generators will be provided with appropriate waste disposal containers;
- For domestic waste collection, only enclosed refuse vehicles or vehicles equipped with tarps will be used.
- Waste handling will be minimized in as far practicable, and
- Waste containment will be maximized

Housekeeping

All work areas must be kept tidy, free of debris, and rubbish. If housekeeping is inadequate and compromises safety and cleanliness, the Environmental Officer will notify the site supervisor to halt work until the area is tidy and safe. The EHS Manager will perform regular site inspections to ensure satisfactory standards are maintained. All workers must be familiar with waste management methods.

Waste Storage

All waste will be stored in an environmentally responsible manner, complying with at least the following requirements:

- Ensure that there are proper labels and signage in place to indicate the storage of any hazardous or dangerous waste.;
- To prevent any harm to sensitive environments, drains or waterways, waste storage areas will be situated at a safe distance.;
- Waste will be sorted for reuse/salvage.
- Hazardous and domestic waste must be kept separate.
- Bins and receptacles will be placed to allow for easy collection.

Organisational Responsibilities

Management

The Lab supervisor and Sustainability Manager are responsible for implementing the WMP throughout the project, including waste disposal and segregation. Waste collection is overseen by the Sustainability Manager.

The Lab Supervisor will monitor contractors' and end-users' compliance with the waste management system, including waste segregation, housekeeping, and waste storage areas. The sustainability Manager will maintain records of waste generated.

Contractor Responsibility

The waste management contractor is responsible for the collection, transport and disposal of the waste generated by the Project in compliance with this WMP.

The contractors will provide training for workers in relation to waste management issues. Training will include but not be limited to:

- Waste segregation and its importance;
- Differences between wastes streams and an overview of incompatible wastes;
- Good housekeeping practices;
- Safe waste handling practices, and
- How to read and understand Safety and Data Sheets (SDS)

Workers' Responsibility

Workers have varying degrees of responsibility towards the successful implementation of the WMP. Workers play roles in one or more of the following waste management aspects:

- Housekeeping – maintaining clean and tidy working environments at all time
- Consciously implementing the waste hierarchy into decision making during implementation of the project.
- Segregating waste at source through disposing of wastes in the designated labelled bins.
- Waste management training and awareness campaigns on correct waste management practices

Monitoring

Waste disposal will be monitored to ensure efficient management and no negative impact on the environment or communities. Records will detail waste streams, volumes, non-compliance issues, and waste contractors' qualifications, collection, and disposal routines. The records will identify system lapses for correction.

As part of the waste monitoring program, both scheduled inspections and spot checks will be conducted to monitor storage areas and check the conditions of bins. Correct waste segregation will be monitored and corrections made where necessary. The contractor is responsible for ensuring personnel are familiar with the correct waste handling and disposal methods. Collection and disposal routines will also be monitored for effectiveness through site inspections and review of waste management records.

ANNEX 7: TRAFFIC SAFETY MEASURES

When transporting hazardous or sensitive materials, it is crucial to prioritize traffic safety measures to ensure the well-being of both the transportation personnel and the public. Here are some essential traffic safety measures to consider when transporting samples:

- **Proper Packaging and Labelling:** It is of utmost importance that samples are packaged and labelled appropriately. This includes the inclusion of hazard symbols, handling instructions, and emergency contact information. This labelling must be clear and accurate to ensure that emergency responders and transportation personnel are able to handle the samples with the utmost safety and care. By adhering to this protocol, we can help to minimize the risk of any accidents or mishandling of the samples.
- **Route Planning and Risk Assessment:** When it comes to transporting samples, it's important to prioritize safety and carefully assess the suitability of the chosen route. This means taking into account various risk factors, such as road conditions and traffic density, as well as the proximity of the route to sensitive areas like schools, hospitals, or residential neighbourhoods. By doing so, you can help ensure that the transportation of your samples is as safe and secure as possible, minimizing the risk of accidents, spills, or other potential hazards. Plan routes carefully and prioritize safety above all else.
- **Vehicle Inspection and Maintenance:** Conduct routine inspection and maintenance of transportation vehicles to avoid any potential accidents and breakdowns. It is highly recommended to thoroughly check the critical systems of the vehicle, including the brakes, tires, and lights, as they play a critical role in ensuring safe and reliable transportation. Regular maintenance can help identify any issues beforehand and prevent them from turning into bigger problems, ultimately saving time and money. Therefore, it is essential to prioritize vehicle maintenance to ensure the safety of all passengers and drivers.
- **Communication and Coordination:** Maintain a transparent and open line of communication with local law enforcement and emergency services when it comes to the transportation of samples. It is crucial to share all pertinent information such as the designated route, schedule, and any potential hazards that may arise during the transportation process. By doing so, we can ensure a safe and efficient transfer of the samples while minimizing any possible risks or delays.
- **Driver Training:** Drivers who are responsible for transporting hazardous materials should have a comprehensive understanding of safe driving practices, emergency response procedures, and proper handling of samples. This level of training is essential to ensure the safety of all individuals involved, as well as the environment. Proper preparation and education can prevent potential accidents and minimize the impact of any unforeseen incidents that may occur during transportation. Therefore, it is imperative that all drivers who handle hazardous materials receive extensive, specialized training to ensure

the safe and responsible management of these materials.

- **Emergency Equipment:** Confirm that the transportation vehicle is equipped with all necessary emergency equipment such as fire extinguishers, spill kits, first aid supplies, and personal protective equipment (PPE). Furthermore, drivers should receive prior proper and adequate training in the use of these essential items. This promotes a safe and secure working environment for all individuals involved in the transportation process.
- **Speed and Following Distance:** Always maintain safe driving speeds while on the road. In addition, it is equally important to maintain an appropriate following distance between yourself and the vehicle in front of you. This will help ensure enough time to react to any unexpected incidents or sudden stops that may occur while driving. By adhering to these safety measures, risk of accidents are minimized.
- **Weather and Visibility Conditions:** When driving in adverse weather, reduce speed and exercise extra caution based on conditions such as rain, snow, and fog..
- **Emergency Response Plan:** It is important to create a detailed emergency response plan that includes procedures for dealing with accidents, spills, leaks, and other incidents. Drivers must be trained on the plan and know how to respond effectively.
- **Regular Communication:** Maintain communication with transportation personnel using mobile phones or two-way radios to provide updates on progress throughout the journey.
- **Documentation:** It is important to keep detailed records of the transportation process, such as departure and arrival times, routes taken, stops made, and any incidents encountered. This documentation can be useful for accountability and future planning.

ANNEX 8: RESOURCE EFFICIENCY AND POLLUTION PREVENTION MANAGEMENT

1. Introduction

The Resource Efficiency and Pollution Prevention Management Plan outlines the Project's commitment to optimizing resource use, minimizing waste, and preventing pollution in the operations of our genome sequencing laboratory. This plan encompasses strategies and actions to enhance resource efficiency, promote sustainable practices, and minimize environmental impacts.

2. Objectives

- Optimize energy and water consumption to reduce operational costs and minimize environmental footprint.
- Minimize waste generation through proper waste management practices, recycling, and reuse.
- Implement sustainable procurement, laboratory practices, and pollution prevention measures.
- Foster a culture of resource efficiency, pollution prevention, and environmental stewardship among lab staff.

3. Resource Efficiency and Pollution Prevention Strategies

Energy Efficiency:

Conduct regular energy audits to assess energy usage and identify areas where improvements can be made. Installing efficient lighting, utilizing energy-saving equipment, and maintaining equipment for optimal performance are recommended measures. By enacting these practices, the Project can reduce its energy consumption and costs while contributing to environmental sustainability.

Water Conservation:

Effective management of water usage is crucial for any laboratory. It is imperative to detect and repair leaks as soon as possible to prevent wastage and promote responsible water use among lab staff. This can be achieved through campaigns and training programs aimed at educating employees on water conservation best practices. By implementing these measures, labs can reduce their environmental impact. It is therefore important for lab managers to prioritize water management and take proactive steps to ensure that their operations are as sustainable as possible.

Waste Reduction and Recycling:

The Project's Waste Management Plan (WMP) and Health and Safety Management Plan provides details on the sorting and recycling of various materials, such as plastic, glass, paper, electronics, etc. This approach ensures that waste is handled in an environmentally responsible manner while conserving natural resources and reducing landfill waste. The Project's approach to waste management involves regular waste audits, employee training, and the use of appropriate recycling bins.

By implementing these plans, the Project can demonstrate its commitment to sustainability and contribute to a cleaner and healthier environment for all.

Chemical Management and Pollution Prevention:

Prioritize the utilization of eco-friendly reagents, chemicals, and materials in laboratory processes. Proper storage, labeling, and disposal practices must be implemented to prevent pollution (See Project WMP). Additionally, spill response plans should be developed, and personnel should receive comprehensive training to ensure quick and effective action in the event of a spill. These measures are crucial to promoting sustainability and reducing the environmental impact of laboratory operations.

Sustainable Procurement:

It is recommended to prioritize the acquisition of laboratory equipment and instruments that are energy-efficient. In the procurement of reagents, consumables, and chemicals, it is advised to take into account their environmental impact and lifecycle assessments. It is advisable to collaborate with suppliers who prioritize sustainability and ethical practices.

Laboratory Practices:

In order to enhance the efficiency of laboratory operations, it is recommended to optimize the protocols employed in experiments to minimize the consumption of reagents and materials, while upholding the quality of generated data. Additionally, implementing sample tracking and inventory management systems can mitigate the wastage of samples. It is also advisable to promote efficient use of equipment by scheduling and coordinating usage to avoid unnecessary energy consumption. These measures can be instrumental in streamlining laboratory processes, reducing costs and improving productivity.

Capacity Building and Training:

Laboratory personnel should be provided with training on resource-efficient laboratory practices, waste reduction, and recycling. To ensure that sustainability is ingrained into the culture of the lab, integrate resource efficiency education into lab training programs and onboarding for new employees. Furthermore, workshops and seminars should be organized periodically to keep staff up-to-date on sustainable practices and technologies. This approach will help ensure that the lab operates in an environmentally responsible manner while also contributing to the organization's overall sustainability goals.

4. Monitoring and Reporting

- Establish key performance indicators (KPIs) to track energy and water consumption, waste generation, pollution prevention measures, and procurement practices.
- Regularly monitor and analyse data to identify trends, deviations, and opportunities for improvement.

- Produce annual resource efficiency and pollution prevention reports summarizing achievements, challenges, and future goals.

5. Continuous Improvement

Conduct periodic reviews of the Resource Efficiency and Pollution Prevention Management Plan to ensure its effectiveness and relevance. In addition, engage lab staff in regular feedback sessions and suggestion channels to continuously improve resource efficiency practices and pollution prevention measures.

Stay updated on emerging technologies and best practices in genome sequencing in order to identify opportunities for further resource optimization and pollution prevention. By following these practices, it is possible to improve resource efficiency and prevent pollution in a sustainable and effective manner.

6. Community Engagement

Collaboration with other departments within CERI/SU, community organizations, and stakeholders is crucial for promoting resource efficiency, pollution prevention, and environmental sustainability. Participation in outreach events, workshops, and educational programs is essential for disseminating knowledge and inspiring sustainable practices within the community.

7. Conclusion

The Resource Efficiency and Pollution Prevention Management Plan reflects the Project's dedication to responsible resource management, waste reduction, pollution prevention, and sustainable laboratory practices in our genome sequencing operations. By optimizing resource use, minimizing waste, preventing pollution, and fostering a culture of environmental responsibility, the Project contributes to a cleaner, greener, and more sustainable future.