

Equipment / Infrastructure Support for the Research, Development, Testing, Pilot Scale Production and Regulation of Vaccines in South Africa

Request for Applications (RFA)

Reference No: SAMRC-RFA-GIPD-06-2024

Release Date: 14 June 2024

Closing Date: 26 July 2024

1. Background and Context

Africa produces less than 1% of its annual vaccine requirements, which leaves the continent vulnerable, as witnessed during the COVID-19 pandemic when its governments struggled to source critical vaccines to save lives. The pandemic laid bare the urgent need for the continent to accelerate investments in building vaccine development and manufacturing capabilities to ensure a significant increase in the local manufacturing of the vaccines we consume in Africa.

Substantial investments have been made to date by the South African Government and other funders in research and development infrastructure as well as pilot facilities for vaccine development, testing and production in South Africa. However, there remain critical gaps and bottlenecks that hamper progress in establishing the country as a significant vaccine development and manufacturing hub. It is within this context that the Government of the Republic of South Africa, through its Department of Science and Innovation (DSI), has received a grant funding commitment from the Government of the Federal Republic of Germany, through its KfW Development Bank (KfW), for the support of vaccine development and production in South Africa (herein referred to as “the Project”). The South African Medical Research Council (SAMRC) has been appointed as the Project Executing Agency for the Project.

The purpose of the Project is to address the gaps and strengthen the infrastructure for vaccine research, development, pre-clinical testing, pilot-scale production and regulation in South Africa. This will contribute to the sustainable production of vaccines (beyond COVID-19) and will manifest South Africa’s leading role as a researcher and manufacturer of vaccines on and for the African continent. The long-term goal of the Project is to create a more resilient vaccine innovation and production landscape with a higher local content which allows South Africa to deal with current, and prepare for future, health threats.

Through this Request for Applications (RFA), we are inviting role-players (herein referred to as “Implementing Partners”) involved in vaccine research, development, pre-clinical testing and pilot-scale production requiring equipment and infrastructure support to strengthen their capacity to contribute to the country’s vaccine innovation and manufacturing ecosystem.

2. Objectives and Scope

World-class research and innovation in the area of vaccine research, development, testing, production and regulation requires substantial financial investment in cutting edge equipment and infrastructure. This Project will provide funding to support the acquisition or upgrade of equipment, and, in some areas, the upgrade of infrastructure needed to improve the vaccine development pipeline and innovation and manufacturing ecosystem in South Africa. The primary objectives of this project are:

- Improving research infrastructure at public universities and recognized research institutions to enable internationally competitive / world class vaccine research and development throughout the value chain to be conducted in South Africa;
- Establishing and/or improving and/or expanding GMP-accredited pilot production facilities for the smaller scale production of mRNA and non-mRNA-based vaccines, for example for clinical testing;

- Establishing and/or improving and/or expanding training facilities for vaccine research, development and manufacture to build human resource capacity;
- Increasing the capacity and efficiency of regulation of clinical trials and health product registration and use in South Africa;
- Ensuring optimal use and availability of research, development, testing and production infrastructure in the country and encouraging collaboration; and, thereby,
- Attracting, developing and retaining high-end scientific and technological skills and competencies; and
- Supporting and strengthening the objectives of the 2019 White Paper on Science, Technology and Innovation, the STI Decadal Plan 2022- 2032, NDP: Vision 2030 and the South African Research Infrastructure Roadmap.

Equipment and infrastructure for activities that do not relate to vaccine research, development, testing, production and regulation will not be supported. The support is also limited to organizations and activities based in South Africa.

3. Areas of Support

Following a feasibility study that was conducted by key stakeholders in 2021, the following priority areas have been identified to be addressed through this Project:

Table 1: Areas to be supported through the Project.

| No. | Support Area | Outcome | |
|-----|---------------------------|---|--|
| 1. | Pilot Vaccine Production | (a) | Procurement and installation of equipment at a pilot plant for active pharmaceutical ingredients (APIs) using mRNA technology. |
| | | (b) | Procurement and installation of equipment at a pilot plant for vaccine APIs with other than mRNA technology. |
| 2. | Research and Laboratories | Procurement and installation of laboratory equipment and support infrastructure (including IT) for upgrading and modernizing research facilities (including animal facilities) and laboratories, including the National Control Laboratory. | |
| 3. | Training | Procurement and installation of laboratory training equipment potentially attached to a pilot plant or equivalent facility. | |
| 4. | Regulation | Procurement and installation of equipment supporting the digitalization as well as the regulation capacities at SAHPRA ¹ . | |

The support is targeted at the vaccine research, development, testing and production value chain, including the following activities:

- Genetic sequencing for immunogen identification
- Immunogen design
- Development of vaccine platforms / technologies
- Development of vaccine candidates

¹ Note that this area of support is excluded from this RFA and will be through a directed RFA to the national regulator, SAHPRA.

- Development of vaccine delivery mechanisms and carrier molecules
- Formulation of vaccines
- Preclinical testing of vaccine candidates
- Immunogenicity assessment of vaccine candidates
- Data management for the above activities
- Pilot-scale manufacture of mRNA-based vaccines under Good Manufacturing Practice (GMP)
- Pilot-scale manufacture of non-mRNA-based vaccines under GMP
- Quality testing of vaccines
- Production of reagents for vaccine manufacture
- Laboratory training on vaccine technology (potentially linked to a pilot plant or equivalent facility)
- Regulation of clinical trials and vaccines (limited to the national regulator)
- Other vaccine-related research and/or development activities not listed above may be considered.

The Project, through a competitive peer review process, will make funds available to support the acquisition or upgrade of equipment, and, for public research institutions and national testing laboratories, the upgrade of infrastructure to support vaccine research and development through to manufacturing that usually requires significant capital investment. In addition, the Project is aimed at making world class training facilities available to capacitate specialized operators and dedicated personnel to operate and maintain such instrumentation and contribute to the vaccine innovation and manufacturing ecosystem.

4. Opportunity Description

This RFA seeks to identify and select eligible entities as Implementing Partners for the Project that will receive support for the procurement and installation of equipment specifically required for one or more of the activities listed above. This does not include the upgrading or modernizing of building infrastructure (construction or renovations), with the exception of public research institutions and national testing laboratories. Infrastructure requested under this RFA for research facilities and national testing laboratories may include relevant information technology (IT) upgrades.

The Project will cover the direct costs of the equipment and, where applicable, infrastructure upgrades, for successful awards. However, the Implementing Partner will be required to cover any import taxes levied for imported equipment, maintenance (except as covered under a maintenance plan included in the purchase price), servicing, insurance and back-up systems for the equipment. The funding will only be utilized for the purchase or upgrade of the equipment as set out in the successful applications and according to the recommendations of the review panel and Project Steering Committee.

The following are non-fundable activities / non-eligible costs under the Project:

- Import duties and other taxes
- Equipment maintenance, warranty, servicing, and insurance (unless provided for by the supplier as part of the procurement of the equipment)
- Back-up systems for the equipment
- Operational costs for the equipment
- Consumables, except as supplied on purchase of the equipment for training and commissioning

purposes

- Research activities
- Salary contributions
- Working capital
- Travel
- Other operational costs such as rent, administration, grant management, etc.
- Overheads

It is specifically recorded that this RFA is not intended to fund research projects.

As part of their applications, entities are required to list the items of equipment required, together with an estimated cost for each item, including VAT, based on current market prices, and a motivation for the need for the equipment listed and how it will contribute to the objectives of this Project. Where the requested equipment is brand or supplier specific, this needs to be noted and motivated. Where applicable, entities should also indicate any maintenance required for a specific item, the frequency and costs attached thereto and the entity's ability to make provision for such maintenance costs in the long term (i.e. when initial maintenance plans have expired). Public research institutions and national testing laboratories requiring infrastructure upgrades will need to provide details and a motivation for all proposed construction, renovation or IT installation and/or upgrade activities, together with an estimated cost.

Applications submitted to the SAMRC in response to the RFA may be for a single instrument or multiple complementary instruments that are collectively required to achieve a research, development, testing or production purpose. Applications may include significant information technology (IT) infrastructure (e.g. software systems) required to operate such instruments.

The **total cost** of acquisition may include a full 5-year maintenance plan and costs associated with the installation and commissioning of the equipment. There is no limit to the number of applications submitted by a single entity; however, entities submitting more than once application must ensure that such applications are coordinated through a central office to ensure that there is no duplication between applications or with equipment or infrastructure already available at the entity through other departments or units.

There is no maximum value for each application submitted; however, **the minimum value of an individual item of equipment shall not be less than R1,000,000 (one million Rand) including VAT.** Individual items of equipment below this threshold will only be considered in exceptional circumstances. Applicants should note that the DSI, SAMRC and KfW may, at their sole discretion, agree to fund all, part or none of the equipment (and/or infrastructure, where applicable) included in any one application without furnishing reasons. As such, it is important that each item is individually motivated.

The SAMRC reserves the right to make no awards and re-advertise a Request for Applications if it so wishes or to cancel the Project altogether.

All procurement under the Project will be managed by the SAMRC, working closely with the Implementing Partner. Equipment and infrastructure contracts will be paid for directly by the SAMRC and/or KfW to the supplier(s). It is important to note that **no funding will be transferred to the Implementing Partner**. The equipment and infrastructure will be procured on the Implementing Partner's behalf and provided to the Implementing Partner through an implementation agreement. In the case of private entities, the equipment and infrastructure will be owned by the SAMRC and made available to the Implementing Partner through a placement arrangement. Placement arrangements for equipment at private entities will be for an initial period of 5 years (post commissioning), whereafter the Project Steering Committee will decide on further arrangements to meet the objectives of the Project.

Although applicants will be required to provide written quotations for the specified equipment, these will be used for the purposes of estimating the potential value of the awards only. All procurement processes to be conducted for any contract financed under this Project will follow the relevant South African legislation (including but not limited to the Public Financial Management Act (PFMA) and the Preferential Procurement Policy Framework Act (PPPFA)) and the SAMRC's supply chain/procurement policies and procedures, taking into account certain minimum standards required by KfW, as defined in the KfW Procurement Guidelines. For items costing R1 million or higher (total value of the contract, inclusive of VAT), an open tender process will be followed. For items costing less than R1 million (total value of the contract, inclusive of VAT), a request for quotations process will be followed using the national Central Supplier Database; however, such items will only be considered for support in exceptional circumstances. Where the requested equipment is brand specific or should be provided by a preferred supplier, this needs to be noted and motivated. Such requests will need to follow a sole- or single-source supplier process.

The awarded Implementing Partners will actively participate in the procurement process for their approved equipment and, where relevant, infrastructure upgrades. Any changes to the specifications for the approved instrument(s) after award will require additional approvals and may require the Implementing Partner to cover any additional costs that may be incurred as a result of the changes.

This is a once-off Project spanning a maximum period of three (3) years. If the acquisition and commissioning of the equipment and or/infrastructure has not been completed within the Project period, the SAMRC and DSI reserve the right to cancel and/or redirect the award.

5. Eligibility

Public and private entities registered and with their principal place of business in the Republic of South Africa and/or established in terms of legislation enacted in the Republic of South Africa that are involved in the following areas of vaccine research, development, testing and production are eligible to apply:

- Genetic sequencing for immunogen identification
- Immunogen design
- Development of vaccine platforms / technologies
- Development of vaccine candidates
- Development of vaccine delivery mechanisms and carrier molecules
- Formulation of vaccines

- Preclinical testing of vaccine candidates (animal research facilities)
- Immunogenicity assessment of vaccine candidates
- Data management for the above activities
- Pilot-scale manufacture of mRNA-based vaccines under GMP*
- Pilot-scale manufacture of non-mRNA-based vaccines under GMP*
- Quality testing of vaccines and pharmaceuticals
- Production of reagents for vaccine manufacture
- Laboratory training on vaccine technology (potentially linked to a pilot plant or equivalent facility)
- Other vaccine-related research and/or development activities not listed above may be considered.

*Pilot production facilities that are not GMP-accredited must submit plans and a timeline for obtaining GMP accreditation.

The Project is aimed primarily at South African Public Universities and South African Public Research Entities, namely Science Councils, National Facilities, and other recognized research institutions as declared by the DSI. It is also aimed at national laboratories involved in the testing of vaccines and other biologicals and, for infrastructure upgrades for regulation, the national regulator, i.e. the South African Health Products Regulatory Authority (SAHPRA). Private entities registered in South Africa with some existing infrastructure for pilot production of vaccines and/or relevant training may apply.

Applicants must be employed at an eligible entity and must be the persons that will be actively involved in the utilization and management of the equipment in line with the objectives of the Project. For research equipment and infrastructure applications, the applicant must have held a doctoral degree for at least five (5) years prior to the submission of the application and must demonstrate their continued employment at the entity for at least three (3) years from the time of submission of the application. In instances where the primary applicant will not be in his/her position at the entity for at least three (3) years from the time of submission of the application, a co-applicant must be included as a potential successor to take over the management of the equipment. The applicant must have a demonstrated track record in research and/or training and/or production (as applicable) relevant to the proposed use of the equipment and infrastructure.

In addition to the primary applicant, the application may include one or more co-applicants with demonstrated applicable track record and who will co-support the utilization and management of the equipment in line with the objectives of the Project. The co-applicant(s) may (preferably) be from the same entity as the applicant or from a different entity that proposes to collaborate with the primary entity on the utilization and management of the equipment in line with the objectives of the Project.

Applicants are required to provide proof of registration / establishment of the entity in terms of legislation, an organizational profile and a clear description of their involvement in one or more of the above-listed activities.

6. Application Process and Timelines

All applications and supporting documents for this RFA must be submitted online using the following link: https://redcap.link/vaccine_support. The due date for applications is **26 July 2024, 23:59 (SAST)**. No late or incomplete applications will be accepted.

A virtual, non-compulsory briefing session will be held via Microsoft Teams on **Wednesday, 26 June 2024 from 10h00 – 11h30**. Please register for attendance using the following [Registration Link](#).

Any queries in relation to this RFA may be emailed to vaccine.equipment.rfa@mrc.ac.za.

Applicants must clearly indicate for which area of support, i.e. 1(a); 1(b); 2; or 3 in Table 1, they are applying. Applicants may apply for more than one area of support; however, **a separate application must be submitted for each area of support**.

All applications must be approved by the relevant authorized representative of the entity submitting the application through a signed Declaration and Letter of Commitment uploaded on the system. Such authorized representative must be at the level of Deputy Vice Chancellor for public universities and the Chief Executive Officer or Chief Financial Officer for research entities, national laboratories and private entities.

Applications must be submitted using the online form with supporting documents to be uploaded on the system. No applications submitted via email only will be accepted. All sections of the application must be comprehensively and accurately completed. It is important to include all relevant information and detail that will enable the merits of the application to be evaluated. The application must be accompanied by the following supporting documentation:

- CVs of the applicant and any co-applicants – CVs must be up to date and demonstrate experience and a track record relevant to the application;
- Proof of registration and/or establishment of the entity in terms of legislation;
- For non-public entities, an organizational profile, including ownership and governance structure;
- Detailed quotes for the proposed equipment / infrastructure upgrades and pictures, where available;
- Completed [Summary Spreadsheet](#) summarizing the items requested and estimated costs; and
- Declaration and Letter of Commitment signed by the DVC, CEO, CFO or equivalent to provide the necessary infrastructure, personnel and funds for the management and utilization of the equipment funded through the Project. The letter may be in a format determined by the applicant but must contain at least the following commitments / declarations: *(i) approval of the content of the application; (ii) that the entity understands the conditions of the awards and will comply with the obligations of the Implementing Partners in the event that an award is made, including providing suitable infrastructure and housing for the equipment; and (iii) that the entity will make financial provision for the costs not covered by the Project that are required to meet the intended purpose, including the import taxes, maintenance, insurance, operational costs, etc.*

Applications, supporting documentation or information submitted after the closing date will not be considered, unless additional information not specified above is later requested by the SAMRC. Applicants

are advised to complete and submit their applications well before the closing date to avoid any IT or connectivity issues on the closing date which may prevent submission and to allow for sufficient time for their entity's internal review and approvals, taking note of the entity's closing date for such approvals.

Applicants must ensure that the equipment requested is not already available within their departments or institutions and/or between regional institutions. Availability of equipment may be checked, for example, using the National Research Equipment Database (<http://eqdb.nrf.ac.za>).

The timelines for the application and award process are shown in Table 2.

Table 2: Estimated application and award timelines.

| Process Stage | Due Date |
|---------------------------------|-------------------------|
| RFA Release Date | 14 June 2024 |
| Non-compulsory briefing session | 26 June 2024 |
| Application Due Date | 26 July 2024 |
| Review of Applications | August 2024 |
| Approvals | August – September 2024 |
| Notification of Awards | September 2024 |

7. Evaluation of Applications

This is a competitive call for applications and only those demonstrating a clear need for the listed equipment and/or infrastructure and with demonstrable contribution and benefit to the South African vaccine innovation and manufacturing ecosystem may be selected for funding. The purpose is to ensure that support is provided to entities that will contribute to the long-term sustainable development and production of vaccines in South Africa.

There will be a two-step review and evaluation process:

1. Internal SAMRC screening for responsiveness to all the specified administrative and procedural provisions required in the RFA.
2. Peer review to assess the scientific and economic merit (and other review criteria as specified below) of applications found to be responsive to the RFA.

7.1 Internal screening

All applications will be screened by the SAMRC for completeness and responsiveness to the RFA and its administrative requirements/provisions. If the application is found to be incomplete or unresponsive to the provisions described in the RFA, or was submitted after the deadline, the application will not be processed further.

Internal screening will be done using the following criteria:

- Was the application received on or before the closing date?
- Do the entity and applicant meet all eligibility criteria according to the Project guidelines?
- Is the requested equipment and/or infrastructure relevant to the vaccine research, development,

testing and production areas listed in the RFA?

- Is the application complete, with all sections filled in, and endorsed by the entity's relevant authorized representative in a signed letter?
- Have all required supporting documents been provided?

7.2 Peer Review

Each application that passes the internal screening will be peer reviewed, taking into account at least the following criteria:

Significance/ Relevance/ Impact:

- The potential impact of the requested equipment / infrastructure on the vaccine research, innovation and manufacturing ecosystem in South Africa, including the potential to address unanswered questions; advance the scientific field; design, develop, test and/or produce new vaccines or biologicals or reagents for such production; and/or increase technical capability and skills in the field.
- The demonstrated need for the requested equipment / infrastructure in relation to existing equipment / infrastructure, current gaps and challenges, existing and planned research and development programs and available expertise.

Entity and Applicant(s):

- The entity and applicant's history, relevance and impact in the vaccine research, innovation and manufacturing landscape.
- Existing capacity and infrastructure of the entity relevant to their specific area of vaccine development, testing and/or production and how the requested equipment / infrastructure will fit with this.
- Commitment of the entity to achieving the objectives of the Project.
- Availability of appropriate and necessary infrastructure and support to house and maintain the equipment.
- Experience and track record of the applicant(s) in vaccine research, development, testing and/or production.
- Availability of personnel with the necessary expertise and capacity to manage and operate the equipment.

Equipment Management Plan

- Alignment of the requested equipment / infrastructure with other equipment and infrastructure available within or outside the entity.
- Plans for ensuring availability of and access to the equipment.
- Availability of suitably qualified personnel to operate and manage the equipment.
- Plans for maintenance, operation and repair of the equipment, inclusive of the necessary technical expertise for these tasks.
- Financially viable costing for maintenance, operation, use and repair of the equipment that ensures sustainability as well as affordability and access.

Capacity Building:

- Plans for training to be provided/received in terms of operating the equipment.

- Use of the equipment by students and researchers, including individuals from designated groups, particularly young, black and female researchers as well as researchers with disabilities.
- Access to the equipment for external parties, including researchers from Historically Disadvantaged Institutions.
- Potential for new local and international collaborations.

Costs:

- Estimated costs for the equipment / infrastructure.
- Cost / benefit and/or potential return on investment (monetary and non-monetary).

Applications will be scored according to the guide in Table 3.

Table 3: Scoring Guide for Applications.

| Criterion Strength | | Score | Descriptor |
|--------------------|--|-------|--------------|
| High | Applications that are exceptionally strong and well-motivated, meet and/or exceed all criteria for support, are led by an internationally recognized applicant with a relevant track record and experience, address a critical infrastructure gap, have a strong management plan, and have high potential for contribution to the vaccine innovation and manufacturing ecosystem in South Africa and research, societal and/or economic impact. May have minor or no weaknesses. | 10 | Exceptional |
| | | 9 | Outstanding |
| | | 8 | Excellent |
| Medium | Applications that are good and well-motivated, meet all of the criteria for support, are led by a nationally recognized applicant with a relevant track record and experience, address a critical infrastructure gap, have a satisfactory management plan, and have potential for contribution to the vaccine innovation and manufacturing ecosystem in South Africa and research, societal and/or economic impact. Has weaknesses in one or more criteria that bring down the overall strength and impact of the application. | 7 | Very Good |
| | | 6 | Good |
| | | 5 | Satisfactory |
| Low | Applications that are weak and not well-motivated, do not meet all of the criteria for support, are led by an applicant without demonstrated track record or experience of relevance to the objectives, do not address a critical infrastructure gap, do not have a satisfactory management plan, and/or have little potential for contribution to the vaccine innovation and manufacturing ecosystem in South Africa or potential for research, societal and/or economic impact. | 4 | Average |
| | | 3 | Fair |
| | | 2 | Marginal |
| | | 1 | Poor |

8. Selection of Awardees / Implementing Partners

The decision on which equipment / infrastructure and Implementing Partners to support will be made by a Project Steering Committee comprising representatives from the DSI and SAMRC, with observers from KfW,

taking into consideration the recommendations of the peer reviews, the availability of funds and the objectives of the funding instrument. Awards will also require approval from the SAMRC's Executive Management Committee. The selection of awards may also consider additional factors, such as geographical and institutional diversity and transformation.

9. Obligations of the Implementing Partners

The successful Implementing Partners will be required to enter into an agreement with the SAMRC and DSI to manage the award. The agreement will include confirmation of the commitment from the Implementing Partner with respect to the installation, maintenance and use of the equipment as well as the final approved management plan.

Implementing Partners will be required to:

- Pay any import duties, taxes and other costs that are not covered by the Project award;
- Provide for all maintenance, servicing, insurance, and backup systems related to the equipment;
- Develop a financial model for the maintenance, upgrade and other related operational costs for the sustainable management of the equipment;
- Provide appropriate building infrastructure to house the equipment in accordance with the supplier specifications;
- Ensure that the equipment is fully commissioned within two (2) years of the award having been made;
- Provide appropriately qualified personnel to operate and maintain the equipment; and
- Provide training on the use of the equipment.

Implementing Partners will be expected to optimally utilize the equipment and infrastructure to:

- Contribute meaningfully to the South African vaccine innovation and manufacturing ecosystem;
- Generate new knowledge in the form of peer reviewed publications and other published outputs;
- Generate new intellectual property which may or may not be registerable under applicable legislation, managed, where applicable, in compliance with the *Intellectual Property Rights from Publicly Financed Research and Development Act No. 51 of 2008*;
- Contribute towards the development of human capital in terms of staff trained to use the equipment and postgraduate students trained and/or obtaining a postgraduate degree through the use of the equipment;
- Ensure the translation of research findings into research, societal and, where applicable, economic impact towards improving the health and quality of life of South Africans and advancing the objectives of the applicable national policies, strategies and development plans.

10. Monitoring and Evaluation

The SAMRC will monitor and evaluate the progress of awarded Implementing Partners funded under this Project as follows:

- All Implementing Partners will be required to submit progress reports to the SAMRC from the date of award for a period of five (5) years post the year of commissioning of the infrastructure and equipment.

The format for the report will be provided by the SAMRC and will include reporting on, *inter alia*:

- Progress on equipment installation and commissioning;
 - Progress on infrastructure upgrades, where applicable;
 - Details on the institutional maintenance plan, insurance and utilization plan for the sustainable management of the equipment and how the costs for these, including other related operational costs are being financed;
 - Details on utilization to date by personnel, students, fellows, researchers and, where applicable, external parties, including collaborators;
 - Relevance and impact of the utilization to date to/on the vaccine research, development, testing and manufacturing ecosystem in South Africa;
 - Details on any completed or planned training of personnel and students on use of the equipment;
 - Publications emanating from research utilizing the equipment and infrastructure;
 - Intellectual property developed as a result of utilization of the equipment and infrastructure; and
 - Any funds leveraged as a result of utilization of the equipment and infrastructure.
- The SAMRC will undertake institutional visits as and when required to ensure that the infrastructure and equipment are being properly maintained, accessible, well-utilized, and operated by appropriately trained personnel, and the extent to which the infrastructure and equipment are being used for training and capacity development. The SAMRC reserves the right to recall the equipment in the event that it is not adequately housed, insured, maintained operated, or utilized for its intended purpose and more specifically in line with the objectives of this Project.

In addition, the Project and Implementing Partners may be periodically evaluated by independent reviewers / technical experts as determined by the DSI and KfW.

11. Additional Considerations

11.1 Compliance with Applicable Laws and Regulations

It is the responsibility of the Implementing Partner to ensure that all research, development, testing and manufacturing activities undertaken with the use of the infrastructure and equipment funded by the Project comply with the applicable laws and regulations of South Africa. These include laws, regulations and ethics approvals applicable to research on human and animal subjects, where relevant.

11.2 Environmental, Social and Health & Safety Compliance

In addition to the above, Implementing Partners are required to comply with certain Environmental, Social and Health & Safety obligations as follows:

- 11.2.1 Implementing Partners shall at all times carry out their business and operations in compliance with all applicable national and, where applicable, international environmental, occupational health & safety and social laws and regulations. International standards include the World Bank Environmental and Social Standards² and the World Bank Group General and sector-specific

² <https://www.worldbank.org/en/projects-operations/environmental-and-social-framework>

Environmental, Health & Safety (EHS) Guidelines³

- 11.2.2 Implementing Partners shall co-operate with the SAMRC in ensuring compliance with any measures and actions as may be required by KfW with regard to the implementation of an Environmental and Social Commitment Plan (ESCP) as well as in the Environmental and Social Impact Assessment (ESIA) including the Environmental and Social Management Plan (ESMP) and Stakeholder Engagement Plan (SEP) for the Project.
- 11.2.3 Implementing Partners shall comply with all applicable South African labour legislation as well as the Fundamental Conventions of the International Labour Organization (ILO).
- 11.2.4 Implementing Partners shall ensure that occupational and public health and safety provisions are consistent with national requirements and international good practice standards. These conditions shall be put forward to contractors, subcontractors, and to suppliers, in particular those for major supply items.

11.3 Intellectual Property

Any intellectual property generated as a result of utilization of the equipment and infrastructure funded under this Project must be managed and utilized for the benefit of the Republic of South Africa. Where the recipient of the funds is a public university or research entity, the provisions of the *Intellectual Property Rights from Publicly Financed Research and Development Act No. 51 of 2008* shall apply.

11.4 Change of Leadership

In the event of the applicant leaving the Implementing Partner for whatever reason, the SAMRC must be informed, in writing, within 30 days prior to the departure. The Implementing Partner must inform the SAMRC of alternate arrangements for the continued sustainable management of the research equipment, use of the equipment and alternate leadership, which must be approved by the SAMRC. A revised agreement and/or management plan may be required. The awarded equipment will remain with the Implementing Partner and will not move with the applicant.

12. POPIA Compliance

As of the 1st of July 2021, the new Protection of Personal Information Act (POPIA) came into full effect. The law is designed to protect how all juristic persons use, store and process data. You can read the full details on the act here: <https://popia.co.za/>. SAMRC as a responsible statutory science council complies with POPIA.

The SAMRC will receive personal information through the applications submitted to the SAMRC in response to this RFA. The personal information requested on the application template is necessary for the SAMRC to fully evaluate the application for funding. This information will be shared with external reviewers, as well as the SAMRC management for the purposes of processing the application. The SAMRC will process this personal information strictly in accordance with POPIA. The SAMRC undertakes specifically to process the

³ <https://documents.worldbank.org/en/publication/documents-reports/documentdetail/157871484635724258/environmental-health-and-safety-general-guidelines>

personal information on the basis that (a) it was provided voluntarily and (b) the information will be processed only as far may be necessary and within the limitation and ambit of the purpose of evaluating the application for funding (*i.e., the purpose with which the personal information was received*). The SAMRC confirms that it is lawfully processing the information since the purpose of processing is to seek quality applications for funding which the SAMRC is mandated to do in terms of Section 4 of the SAMRC Act 58 of 1991, thus the SAMRC is fulfilling its legislated and lawful mandate, and strategic objectives as provided for in the SAMRC Act.

By submitting your application to the SAMRC, you acknowledge and agree to the use of your personal information as outlined above. Should you not approve of such use of your personal information then please refrain from submitting an application.

13. Contacts

Any enquiries with regard to this funding instrument may be addressed to:

Sumaya Behardien
SAMRC Grants Innovation and Product Development (GIPD)
Email: vaccine.equipment.rfa@mrc.ac.za