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# Challenges of Biobanking in South Africa to Facilitate Indigenous Research in an Environment Burdened with Human Immunodeficiency Virus, Tuberculosis, and Emerging Noncommunicable Diseases

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The high burden of infectious diseases and the growing problem of noncommunicable and metabolic disease syndromes in South Africa (SA) forces a more focused research approach to facilitate cutting-edge scientific growth and public health development. Increased SA research on these diseases and syndromes and the collection of associated biospecimens has ensured a plethora of biobanks created by individuals, albeit without the foresight of prospective and collective use by other local and international researchers. As the need for access to high-quality specimens in statistically relevant numbers has increased, so has the necessity for the development of national human biobanks in SA and across the Continent. The prospects of achieving sustainable centralized biobanks are still an emerging and evolving concept, primarily and recently driven by the launch of the H3Africa consortium, which includes the development of harmonized and standardized biobanking operating procedures. This process is hindered by a myriad of complex societal considerations and ethico-legal challenges. Efforts to consolidate and standardize biological sample collections are further compromised by the lack of full appreciation by national stakeholders of the biological value inherent in these collections, and the availability of high quality human samples with well-annotated data for future scientific research and development. Inadequate or nonexistent legislative structures that specifically regulate the storage, use, dispersal, and disposal of human biological samples are common phenomena and pose further challenges. Furthermore, concerns relating to consent for unspecified future uses, as well as access to information and data protection, are all new paradigms that require further consideration and public engagement. This article reviews important fundamental issues such as governance, ethics, infrastructure, and bioinformatics that are important foundational prerequisites for the establishment and evolution of successful human biobanking in South Africa.

## Introduction

South Africa (SA), with a population of 60 million inhabitants, has one of the highest burdens of infectious disease, predominantly driven by the syndemic of human immunodeficiency virus (HIV) and tuberculosis (TB) and a growing problem of noncommunicable and metabolic disease syndromes. This creates a highly vulnerable and susceptible population that requires a focused research and development agenda to find indigenous solutions through national, continental, and international collaborations.[1,2]

Over the last 2 decades, biobanking has emerged as a complex science bringing together multiple biological, social science, and legislative disciplines in order to provide the basis and platform for the generation of science-based economies in an era of rapidly emerging genomic and

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proteomic epidemiological-based discoveries. Biobanking of high quality and well-annotated biospecimens provides an essential resource that would facilitate cutting-edge scientific research and public health development.[3]

Biological specimen repositories in SA are generated for a number of reasons and incentivized by a variety of stakeholders that are typically academic, government, and commercially driven, as is typically seen in more advanced science based economies.[4] Despite the scourges of HIV, TB, and now metabolic syndromes,[5,6] patient-driven advocacy groups supporting the collection of biological samples to accelerate discovery have not yet emerged as a powerful force on the landscape of South African biological research, as one has seen in more affluent global communities.[7] Typically, biobanks in SA are concerned with the storage of human, animal, and plant biodiversity biological specimens. However, for the purpose of this review, we will focus specifically on human biobanking.

We are aware that there are a number of biobanks operating on a smaller scale in SA, however limited information is available. These range from smaller collections associated with research projects within academic institutions, to large collections and well-archived diagnostic samples that are housed in the pathology departments within the numerous mega teaching hospitals in SA. More formal government-based blood, forensic, and plant biodiversity banks also exist while private nonprofit registries and private profit-based cord and stem cell banks, and those associated with clinical trials, are increasingly emerging. Table 1 lists examples of existing human biobanks in SA. However, little evidence is available on whether some of them are fully compliant with quality standards and conduct procedures in accordance with international and national biobanking best practices and guidelines such as those published by ISBER and NCI.[8,9]

Despite a plethora and diversity of biobanks, the establishment of a national harmonized biobank in SA is still an emerging concept.[10] This has recently been accelerated by the launching of the H3Africa consortium,[11] whose mission is to accelerate the science of genomic research on the continent in the wake of the successful human genome project.[11] Inherent in this initiative is the formal establishment of strategically located biobanks across Africa and the formation of a bioinformatics network that will not only assist the biobanks with informatics capacity, but also primarily support the projects with the generation of quality assurance and storage of a huge amount of genomic data that will emerge from the funded projects. Two of the four proposed central biobanks that have been funded by the H3Africa project are located in SA and are anticipated to ramp up over a 2-year period into fully operational biobanks capable of receiving up to 100,000 samples a year from projects in SA and across the continent. Achieving these targets is hampered by myriad complex considerations associated with the concept of long-term storage of biological samples, namely ethical, legal, political, societal, religious, cultural, financial, and educational challenges not previously examined or debated to any great depth in Africa before. Thus, for the purpose of this article, we will focus on fundamental issues such as governance, ethics, infrastructure, and bioinformatics that are important foundational prerequisites that require deep consideration by any community considering the establishment of successful human biobanking. Of the two biobanks funded in SA, one principal investigator has opted to go the route of

Table 1. Examples of Known Human Biobanks in South Africa

| *Name* | *Biobank Type* | *Sample Source* | *Location* | *Website URL* |
|---|---|---|---|---|
| BARC SA | Private | Various | JHB | www.BARCSA.co.za |
| Fisher BioServices | Private | Various | JHB | http://www.fisherbioservices.com/services/biorepository |
| Cape Haematology, Medi-Clinic. | Private | Stem cell products | CT | http://www.capehaem.co.za/index.html |
| Cryo-Save-SA | Private | Cord Blood | JHB | www.cryo-save.com/labs |
| Netcells Biosciences | Private | Stem cells/Blood | JHB | www.netcells.co.za |
| Africa Centre | University Institution | Various | KZN | http://www.africacentre.ac.za/Default.aspx?tabid=460 |
| CLS | Public Private Partnership | Various | JHB | http://www.cls.co.za/Pages/default.aspx |
| SUN-IRG | University Institution | Various | CPT | http://www0.sun.ac.za/molbiogen/index.php/en/immunology-home |
| K-RITH | Independent Research Institution in association with KZN University | Various | KZN | www.k-rith.org |
| SANBS | National | Blood | Nation wide | http://www.sanbs.org.za/ |
| SAPS - FSL | National | Various | Nation wide | http://www.saps.gov.za/ |
| NHLS-NIOH | National | Pathology | Nation wide | http://www.nioh.ac.za/ |
| SABMR | Data registry | Bone Marrow donors | CT | www.sabmr.co.za |

*BARC - Bioanalytical Research Corporation, CLS – Clinical Laboratory Services, CT-Cape Town, JHB – Johannesburg, K-RITH - KwaZulu-Natal Research Institute for Tuberculosis & HIV, KZN-KwaZulu Natal, NHLS-NIOH-National Health Laboratory Service-National Institute for Occupational Health, SA – South Africa, SABMR – South African Bone Marrow Registry, SANBS - South African National Blood Service, SAPS-FSL -South African Police Service - Forensic Science Laboratories, SUN-IRG - Stellenbosch University Immunology Research Group*

establishing from scratch a greenfields H3Africa biobank, while the other has opted to adapt an existing drug trial biobanking facility to the needs of the H3Africa projects and harmonization processes.

## Governance

Typically, governance of biobanks globally is dictated by external and internal structures that ensure there is compliance with rapidly evolving principles of both global and indigenous standards of ethics and social justice. SA is subject to the same external governance structures ascribed to by the World Health Organisation (WHO) and the Helsinki Declaration. The Africa Union legislative structures have not as yet specifically addressed the concept of biological preservation of the continent's huge biodiversity repertoire or promoted the legislative instruments to encourage awareness of biological value and data protection directives to guide research and development in this arena. However there are instruments such as the Abuja declaration of 2001[12] and the Africa Health Strategy 2007 to 2015[13] that allude to the burden of human disease and the prerequisite that should be put in place for Africa as a whole to emerge as a science-driven economy capable of addressing its own health burdens through research and development. Embedded in these policies are the opportunities that prescribe to the formulation of legislative guiding principles that will create the opportunity for biological preservation and scientific discovery.

The SA Department of Science and Technology (DST), through various subprograms and public entities, is committed to supporting the generation of a strategic knowledge and scientific discovery-based economy, through sustainable utilization of its biodiversity, promoting value and indigenous knowledge systems secured by intellectual property management policies as outlined in its 2011/2012 annual report.[14]

The DST has clearly articulated that underpinning many of these programs is the need to have oversight over the formalization of central biobanks that will serve the function of keeping well-preserved specimens and data as national assets for the purpose of added value and for posterity, thereby creating the opportunity for accelerating indigenous discovery in an environment that is regulated and protected against biopiracy. This concept is generally understood as the act of gaining access to biological materials such as genetic material or cell lines from which some academic or commercial benefit may be derived by a technologically advanced country or organization without the intention of fair compensation to the peoples or nations from whose territory the materials originated. It refers to a process through which researchers representing governments, universities, or research institutions traverse the globe establishing networks with the specific aim of obtaining biological and genetic material that are deemed to have intellectual or commercial value within the historical context of dispossession.[15] An example of this was well articulated by a benefit audit of a research project recently conducted in Cameroon, which showed very little acknowledgment of the investigators involved with gathering the material in the form of names on publications as an example.[16] Wonkam et al. refer to this as a "biotechnological gold rush".[16]

The responsibility for human biobanking by definition lies within the purview of the South African Department of Health (DOH) and the National Health Laboratory Services (NHLS) that is responsible for the training and performance of all public diagnostic services across SA. The NHLS is a public health laboratory service with a network of laboratories across SA. It was established in 2001 by an Act of Parliament to provide diagnostic pathology laboratory services to the national and provincial health departments. Its activities comprise diagnostic laboratory services, research, teaching, and training. The core function of NHLS is to support the mandate of the DOH and is the largest diagnostic pathology laboratory service in SA. The NHLS employs 6700 staff over 349 laboratories across nine provinces in SA and serves 80% of the South African population. A major mandate of the NHLS is the training of pathologists and medical technologists in conjunction with the nine university medical schools and universities of technology across SA. NHLS scientists conduct research specific to South African health issues, such as tuberculosis, meningitis, malaria, pneumonia, HIV/AIDS, and cancer. These researchers make major contributions to national and international medical literature and form a huge archive of hospital-based biological specimens. The NHLS already houses and supports central biobanks, such as the National Institute for Occupational Health (NIOH) biobank located in Johannesburg, and the recently funded H3Africa NHLS Stellenbosch University biobank based in Tygerberg Hospital in Cape Town. What is not clear is how the strategic visions of the DST, DOH, and the NHLS for harnessing the biological value inherent in our communities will form synergies with the externally funded initiatives such as the H3Africa towards the creation of centralized biobanks. Formal discussions are currently underway by the major stakeholders and the external funding agencies, to chart a common agenda to synchronize oversight, governance, and access to scarce financial resources.

## Legal and Ethical Considerations

In SA, all matters relating to the use of blood and blood products, cell-based therapy, tissue transplants, information derived from genetic research, biological tissue banking, use, and dispersal and disposal of human biological samples are governed by the National Health Act (NHA), Act No 61 of 2003,[17] which superseded and replaced the Human Tissue Act No 65 of 1983.[18] Specifically, the legal aspects of using human biological material are governed by Chapter 8 and ethics guidelines are governed by Chapter 9 of the NHA. Other bodies that are involved in the ethics surrounding research are the Health Professionals Council of South Africa (HPCSA) and the South African Medical Research Council. The South African Intellectual property Rights from Publicly Financed Research and Developmental Act (IPR Act) regulates intellectual property rights, patents, and benefits applicable from human biological material.[19]

Although the NHA in Chapters 8 and 9 addresses research surrounding biological material and the ethics involved, it has failed to keep abreast of a rapidly changing paradigm in science and the complex interrelationship between science, the law, and social justice. The NHA was approved in 2004 by the president of SA; however Chapter 8 was not enacted at that stage as it was believed to require significant revision. Since then, several sections of Chapter 8 were revised and it was enacted on 1 March 2012.[20] Despite these revisions, there are still many discrepancies and shortcomings in Chapter 8

of the NHA. However, it will only be revised with the entire act, which is pending.[21] Many aspects of the current NHA as it relates to biobanking and the use of cell-based therapies are ambiguous and require further clarity and precise definitions to avoid misinterpretation by the law. For instance, there is legislation regarding tissue banking and transplantation in the NHA; however biobanking per se is not directly addressed. The NHA does not comment on national policies surrounding biobanking in South Africa. Questions that still need to be addressed are governance and policies that will be required for the existence of national biobanks. Other areas of ambiguity are definitions of various terms as suggested by Pepper et al.[21] The definition of 'stem cells' as 'cells that have both the capacity to self-regenerate as well as to differentiate into mature specialized cells' is consistent in three of the regulations published on 2 March 2012; however a cell has been given different definitions in other regulations published on the same day.[22] This kind of discrepancy will not hold up well in a court of law and definitely requires urgent revision of the act.

All health-related research in terms of the Health Act No 61.2003 must be approved by an accredited research ethics committee. All health-related biomedical and social research at any of the academic institutions in SA requires ethical clearance by an accredited Health Research Ethics Committee (HREC) before the research commences. HREC are registered with the South African Department of Health's National Health Research Ethics Council (NHREC) and with the academic Office for Human Research Protection.

The need for informed consent is considered an ethical hallmark of all research on human subjects and is enshrined in many international guidelines such as the Declaration of Helsinki[23] and Council for International Organizations of Medical Sciences Guidelines (CIOMS).[24] It requires that all participants be informed of any risks inherent in the research, and these risks must be voluntarily accepted,[25] and is based on the principle that all individuals have the right to decide what is done with their body.[26] The difficulty with biobanking research is that the future uses of research may not be known at the time of the collection of the biological samples and thus if any future research proposes to use the samples beyond that detailed in the consent form, all participants must be contacted and their reconsent obtained. Due to the onerous task that this presents, alternative forms of consent have been proposed.

Broad consent occurs where the participants' consent to the use of their sample for unspecified future uses. As the participant is not informed about the research at the time of donation, they cannot be aware of the risks or benefits of the research and their consent is not truly informed as required by the Declaration of Helsinki. It would appear that, in order to comply with the Declaration, each participant must be recontacted to reobtain their consent. However, S. 25 of the Declaration does state that there are situations in which it may not be possible and REC approval will suffice. Due to the potential social value of biobanking and the fact that the use of the sample contains little risk for the participant, it has been suggested that for biobanking, we need to move away from the "one study/one informed consent" paradigm,[27] and recontacting the participant is not necessary. Furthermore, the broad consent model is preferable as it has the advantage of simplifying the consent process and has even received the support of the WHO.[28]

Another option is tiered consent whereby participants select from a range of options in the consent document: they can opt for broad consent, opt to be recontacted prior to secondary use of their samples, opt for an REC to consent on their behalf,[29] or they can consent to certain disease-specific research.[30] Such a model does not completely eradicate the need for reconsent, as there may be an option for reconsent in certain circumstances. However, it does reduce the need for recontact and reconsent and it also presents the participant with a range of consent options, thus striking a balance between progress and science and respecting the autonomy of participants.[31] The South African NHA 2003 does not consider the issue of secondary uses of samples and simply states that prior to the use of a biological sample, informed consent must be obtained. The Ethics in Health Research Guidelines does state that each research institution should draft guidelines as to when reconsent is required and when a waiver of consent may be obtained,[32] however this raises the possibility that there will be differing ethical guidelines as to consent across research institutions.

The main risks with biobanking are those posed by unauthorized access to information, a matter of confidentiality and exploitation.[33] Indeed, under the WHO guidelines, broad consent is only possible where samples are anonymized. Access to data must be limited to ensure that certain third parties cannot access the information, and genetic results must be kept confidential to ensure that there is no risk of stigmatization or discrimination. To ensure confidentiality, samples can be anonymized whereby all data identifying the individual are removed[34] or the samples can be single or double coded and the sample can only then be identified by breaking the unique code.[35] While the anonymization of data is "legally and ethically expedient" as it ensures that the sample cannot be re-identified,[36] the difficulty is that this limits the usefulness of the sample[33] and the participant cannot withdraw their sample.[37] Thus, the CIOMS guidelines acknowledge that there are instances in which a sample may not be anonymized but coded and this enables the reconsent of participants as well as enabling them to withdraw their consent in the future. Neither the NHA 2003 nor the National Guidelines address these issues. They state that genetic material must be kept confidential but are silent as to whether samples can be anonymized or coded.

## Infrastructure

To ensure proper preservation and protection of valuable biospecimens, it is essential to have a well-developed and reliable infrastructure that adheres to international guidelines and best practices. Key infrastructural issues relating to biobanking operations include the availability of constant power, efficient transport logistics, the availability of liquid nitrogen and dry ice, as well as the location of the biobank in terms of climate conditions. According to the United Nations, SA is classified as a middle-income country[38] with a well-developed energy and transport sector and therefore has the capacity and potential to provide support for large-scale biorepository development and maintenance.

Eskom is SA's main electricity supplier, providing 95% of the country's electricity requirements.[39] The National Energy Regulator of South Africa (NERSA) is responsible for licensing the distribution of electricity to different regions in SA, and under the NERSA license the standard of services

provided must meet the requirements as set out in the Electricity Regulation Act.[40] Since 2007, South Africa has faced electricity supply challenges that are mainly due to increasing consumer demand, aging infrastructure, and limited coal supplies. Providing secure energy has therefore become a priority of the SA government, with capacity-building plans including investments in renewable electricity generation systems that could be used to complement the existing supply systems.[41] Due to possible short-term electricity shortages, backup generators and energy storage devices are important for ensuring a stable power supply for biorepository operations. Liquid nitrogen (LN2) is also readily available in most areas in SA, with companies such as Air Products South Africa (Pty) and African Oxygen Limited (Afrox) being two of the main providers. Long-term storage of samples in LN2 storage tanks could therefore serve as a more reliable alternative to storage in −80°C freezers.

SA has a modern transport infrastructure with an extensive network of road, rail, and air transport systems that would support collection and distribution of samples to and from a centrally located biorepository. A well-developed road infrastructure would support collection of biospecimens from more remote locations, while air links connect major cities in a hub and spoke-like distribution, allowing speedy transport between major depots. South African Airways (SAA) is the national carrier and has regular flights between SA's 10 airports. SAA is the largest air carrier in Africa and in 2012 was voted the best airline in Africa for the 10$^{th}$ year running by Skytrax.[42] Courier companies such as World Courier, Marken, and DHL specialize in transporting biological samples according to IATA regulations and offer a strong SA and African hub network with advanced data freight management services. Despite the fact that SAA has an extensive route network operating to 28 cities on the continent, transport of biological samples between SA and other African countries is still a challenge, with poor infrastructure and prohibitive transport costs being the main problems.[43] External operating environments within Africa can negatively impact the reliability of these services and compromise transport efficiencies of the operators. Innovative approaches to biospecimen collection and transport may be necessary to ensure faster and more cost-effective transport to and from biorepositories in SA and beyond into Africa as a whole.

Unlike many other infrastructure sectors in SA, the telecommunications sector is dominated by the private sector. Due largely to the recent increase in the use of mobile phones and broadband networks in the country, telecommunications has become one of the fastest growing economic sectors in SA.[44] Recent increases in the number of undersea data cables connecting SA to the rest of the world have also led to improved internet access and speed. Until recently, Telkom has been the only fixed-line provider in the country and has developed an extensive network over a number of decades.[41] However, the demand for faster broadband has meant an increase in the use of wireless broadband which, although faster, is not as reliable as the fixed-line service. The replacement of current ADSL lines with fiberoptic cables will see a 10-fold improvement in speed, up to 100 Megabits per second (Mbps). However, these replacements will take a number of years, meaning that Telkom's monopoly on the fixed-line industry will continue to affect competitiveness in the telecommunication industry.

## The Biorepository Laboratory Information Management System (LIMS)

The successful implementation of a LIMS in a biobank assumes good laboratory practices that include the use of Standardized Operating Procedures (SOP) and standardized nomenclature.[45] However, biobanks evolve as biospecimen collections expand. Very often, these specimen collections do not adopt a standardized labeling system or an electronic tracking system, with the result that sample collections reside in freezers and/or laboratory corridors in a disorganized manner and are usually not subject to internationally-recognized quality management systems. These *ad hoc* repositories capture a wealth of genetic material but cannot be used by the scientific community in general because of the lack of a query interface that easily captures the underlying sample history and phenotypes. The wealth of genetic material in SA has ensured that there is a plethora of biobanks, albeit biobanks that were created by individuals without the foresight of prospective use by other researchers. Therefore, an opportunity exists in SA for a coordinated effort aimed at developing SOPs at the level of collection, processing, management, and storage of samples and associated data.

In resource-limited settings, it is helpful to assess both open-source (OS) and commercial-off-the-shelf (COTS) LIMS products as alternative options to facilitate SOPs implementation. Factors to consider include cost, flexibility, ease of implementation, as well as customization and security. The cost of COTS software includes the initial cost of acquiring the system, as well as the cost of maintenance and support throughout the software's life cycle (i.e., licensing fees).[46] OS software are usually available free of charge, however costs are incurred when customizing the software according to a biorepository's needs, as well as managing and maintaining the system. While there are many OS LIMS systems, none of these can claim to manage the needs of a biobank (i.e., customized modules to track the biospecimen from the time of sample collection, to shipping, to sample preparation and analysis). For example, software such as CaTissue provides a Java-based application to handle sample storage but does not manage kit collection and shipping.[47] BIKA LIMS,[48] on the other hand, has been developed for sample processing in a laboratory but does not have any modules for kit collection, shipping, and tracking chain-of-custody. While both CaTissue and BIKA lack specific functionality with regards to biospecimen handling, both these applications are open source and allow for community-based customization. The time taken, and cost of, customizing these OS LIMS have to be weighed against the cost of a biobank-ready LIMS product. Our observations to date suggest that COTS LIMS have a layer of customization that must be fine-tuned for specific laboratory needs.

The harmonization of information as it pertains to sample collection, labeling, preparation, and storage facilitated by a biobank-accredited LIMS will ensure interoperability among biobanks both within SA and internationally. Furthermore, adopting a data standard within a biobank will facilitate the integration of research data with the biospecimens, as has been achieved with a federated database model implemented by the Karolinska Biobank.

## Sustainability

In the continuing volatile global economic environment, with slow recovery, and some countries affected worse than others, creative strategies from team leaders are required to develop sustainability. Strategies in public biobanking operations on the continent are particularly vulnerable to long-term financial and other sustainability issues.

Sustainable development is about enhancing human well-being and quality of life for all time, in particular those most affected by poverty and inequality. Each generation has to use resources efficiently in all endeavors and create new cross-generational infrastructure that addresses inefficiencies in health delivery, disease monitoring, and deliver new cost-effective solutions to diseases both current and those that will affect the future of the people, our planet, and prosperity.[49]

Biobanking in Africa is one such essential newly emerging asset that needs expansion in SA. Public biobanks rely on multitudes of external support, primarily institutional and governmental. This financial and resource need creates a dependency in their conception phase. Particularly in SA, funding is primarily from the United States government-funded structures such as the National Institutes of Health (NIH) and other similar agents. The Wellcome Trust in the United Kingdom is also a strong supporter of biobank development in Africa. Further limited financial resources mean that networks, while being collaborative, are at another level competing for the same external resources in a bid to reach self-sustainability from initial funders. Funding is both time restricted and usage restrictive. Another aspect is that business planning and operations management first commence meeting funders' requirements and are "project driven".[50]

Thus, to attain sustainability, large central academic biorepositories need to switch to "central general" biobanking of specimens and develop a "paying customer base" through considerations of revenue generation and diversification of services to develop a business model. In SA, developing public benefit biobanks that incorporate all aspects of business planning requires attention to the initial architecture of the project and incorporating SMART modeling along the entire value chain. SMART modeling refers to a well-formulated set of objectives under the headings of Simple, Measurable, Achievable, Realistic, and Time Bound.[51] It is a benchmarking framework tool that can be used to test the value chain along its stages. The outcome should be that each process and stage is mutually exclusive and comprehensively exhaustive. Any business plan should take cognizance of on-going skills development and training as well as creating jobs. Within the community that the biobank operates, the value chain should incorporate small business or enterprise development, a key focus of the SA government.[52] Various government funding programs are available to support tangible projects that are incorporated within the business model. Companies are allowed to contribute 1% of their net profit after tax towards such projects. Thus, the concept of Public Private Partnerships (PPPs) becomes critical to sustainability and accessing funds. Long-term projects such as biobanks require a continuous source of funding, particularly in the early start-up stage. Reliance on one stream or solely government sourced funding may lead to lack of ability to grow the project or attract private investors, particularly as government funding is seen as an interim initiative at most to create awareness and confidence in the project. Such partnerships, once structured, enable projects to leverage and access funds allocated by government towards Enterprise Development. This year there is a surplus of ZAR 21 billion available for such funding.[53] These programs are not clearly understood or implemented; hence large pools of funds lie unused each financial year.[52]

Another aspect of sustainability is costing planning and data systems together with clear governance and strong ethics management policies. Excellent data systems and data gathering that meet a client's requirements will result in return business and attract interest in the biobank.

In summary, any combination of business models, while for the public benefit, has to incorporate nominal and marked up prices for services, data, consulting, processing, storage, logistics, and procurement management (unpublished data). Central biobanks can also consider offering management services to smaller biobanks, thereby consolidating operations and creating expansion through this mechanism.

## Conclusion

The concept of centralization of biological repositories is not new but rapidly gaining momentum for a myriad of reasons. Most of these are related to the concept of harmonization and standardization, enabling access to interrogation of larger cohorts of well-preserved and synchronized specimens and data to improve returns on investment and increase opportunities for discovery of relevant genetic associations with disease. SA, which is one of 54 African countries, has a fairly well-developed infrastructure for scientific discovery through storage and interrogation of human biological samples. But as a scientific community, it is still grappling with many of the legal and ethical considerations necessary to lay the foundation for a rapid advancement in genomic discovery and applications. It is hoped that with concerted and focused attention on the need to address a myriad of indigenous high burden disease entities, South Africa will enter the global community of genomic discovery and partner with international collaborators to find cost-effective solutions to prevailing and crippling epidemics. This process is well on its way with the launching of the H3Africa consortium project, among others, which have kindled a renewed interest by national stakeholders and academic institutions to ensure that strategic planning, oversight mechanisms, and legislative structures are rapidly adapted and formalized to address biobanking needs and to prevent ambiguity in governance and social injustices.

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