



## OPEN ACCESS

## EDITED BY

Ana Tavares,  
New University of Lisbon, Portugal

## REVIEWED BY

Alexis Mendoza-León,  
Universidad Central de Venezuela, Venezuela  
Gerald Mboowa,  
Makerere University, Uganda

## \*CORRESPONDENCE

Manuela da Silva  
✉ manuela.dasilva@fiocruz.br

RECEIVED 19 April 2024

ACCEPTED 16 May 2024

PUBLISHED 26 June 2024

## CITATION

da Silva M, Stefanoff CG, Eneas PCR,  
Bôas PdCV and Nascimento CRSd (2024)  
Challenges of the new Fiocruz Biodiversity  
and Health Biobank for preparedness and  
response to emerging and re-emerging  
infectious diseases.  
*Front. Trop. Dis* 5:1420326.  
doi: 10.3389/fitd.2024.1420326

## COPYRIGHT

© 2024 da Silva, Stefanoff, Eneas, Bôas and  
Nascimento. This is an open-access article  
distributed under the terms of the [Creative  
Commons Attribution License \(CC BY\)](#). The  
use, distribution or reproduction in other  
forums is permitted, provided the original  
author(s) and the copyright owner(s) are  
credited and that the original publication in  
this journal is cited, in accordance with  
accepted academic practice. No use,  
distribution or reproduction is permitted  
which does not comply with these terms.

# Challenges of the new Fiocruz Biodiversity and Health Biobank for preparedness and response to emerging and re-emerging infectious diseases

Manuela da Silva<sup>1\*</sup>, Claudio Gustavo Stefanoff<sup>1</sup>,  
Paula Cristina Rezende Eneas<sup>1,2</sup>, Paulo de Carvalho Villas Bôas<sup>1</sup>  
and Carlos Roberto Sobrinho do Nascimento<sup>1</sup>

<sup>1</sup>Fiocruz Biodiversity and Health Biobank (BBS-Fiocruz), Oswaldo Cruz Foundation (Fiocruz), Rio de Janeiro, Brazil, <sup>2</sup>Rene Rachou Institute, Oswaldo Cruz Foundation (Fiocruz), Belo Horizonte, Minas Gerais, Brazil

During the COVID-19 pandemic, the Oswaldo Cruz Foundation (Fiocruz), a Brazilian federal research institution supported by the Brazilian Health Ministry, established a biobank. This biobank began by preserving the SARS-CoV-2 virus and human biological material related to COVID-19. This innovative initiative combined human and biodiversity materials within a single infrastructure. Designed for supporting research, development, and innovation in healthcare and preparedness and response to emerging and re-emerging infectious diseases, the biobank's focus has since expanded to include various biological materials, leading to its renaming as the Biodiversity and Health Biobank - Fiocruz-BBS (Portuguese: Biobanco da Biodiversidade e Saúde da Fiocruz - BBS-Fiocruz). This paper outlines the challenges of creating and maintaining an adequate infrastructure in a developing country for promoting and supporting scientific research and biotechnological innovation activities in health through processes of depositing, characterizing, preserving, and supplying human and biodiversity biological materials, alongside associated data, while complying with prevailing legal and ethical rules. These processes adhere to stringent quality, biosafety, and biosecurity standards set forth in ISO 20387:2018. Additionally, the challenges of ensuring the Biobank's long-term sustainability is discussed. This involves a) establishing benchmarks and best practices, b) developing a comprehensive business plan, c) forging partnerships, d) diversifying funding sources, e) ensuring ethical and legal compliance, f) implementing rigorous quality control procedures, and g) investing in human resources and infrastructure. The insights shared in this paper will benefit other biobanks engaged in services related to tropical infectious diseases.

## KEYWORDS

biobanking, standardization, biological resource centers, long-term preservation, health care

## Introduction

Brazil is home to one of the planet's greatest biodiversity, with genetic variability that is increasingly valuable when properly organized, identified, classified, documented, and made accessible through biological collections and biobanks for research, development, and innovation. These infrastructures provide biological materials and associated information, key resources for establishing swift and efficient strategies for scientific and technological advancement, aiding decision-makers and policy-makers (1, 2).

The Oswaldo Cruz Foundation (Fiocruz), a Brazilian federal research institution, coordinates a structured network of epidemiological control and public health and houses various biological collections, whose oldest preserved specimens date back to the early 20<sup>th</sup> century. During scientific expeditions and efforts to combat tropical disease outbreaks in different parts of the country, biological materials were collected, analyzed and deposited in Fiocruz biological collections. Besides the variety of infectious microorganisms, some responsible for severe diseases. Brazilian microbial diversity can also offer solutions for the biological control of disease-causing species and the production of therapeutic bioactive compounds. Fiocruz's biological collections include several culture collections with strains ranging from viruses, bacteria, and fungi to protozoa, along with associated information (3, 4).

Based on its experience with culture collections, since 2005, Fiocruz has been an active participant in building the Brazilian Network of Biological Resources Centers (BRC-Br Network). As a health sector leader within the Network, Fiocruz embarked on establishing a Biological Resource Center for Health (Health-BRC) focusing primarily on microorganisms associated with tropical diseases prevalent in Latin America, including neglected diseases, or with biotechnological potential in the health sector, to support scientific research, epidemiological surveillance, and the development and production of biocompounds for diagnostics, vaccines, and drugs.

Based also on its long experience with collections in the context of human biological materials, in 2015, Fiocruz created the Fiocruz Network of Biobanks (RFBB) in order to establish and maintain institutional biobanks organized in a network, providing the scientific community with high-quality human biological material and associated data. This initiative supports research projects benefiting public health nationwide and safeguards the rights of research participants.

More recently, during the COVID-19 pandemic, a public health emergency of international concern as declared by the World Health Organization (5), Fiocruz undertook significant actions, including building a Hospital Center and two Diagnostic Support Units for COVID-19. In addition, Fiocruz houses several reference laboratories working with SARS-CoV-2, including a WHO reference laboratory for COVID-19 and a Genomic Network for sequencing coronavirus nationwide. These efforts yielded thousands of human clinical samples related to COVID-19 and numerous isolates of SARS-CoV-2 for future research. Consequently, Fiocruz and the Brazilian Health Ministry recognized the need for building an

adequate infrastructure, such as a biobank, to provide safe, reliable, ethical, legal, and traceable storage, complying with national and international regulations.

The main challenge of this initiative was the rapid and efficient conception and construction of this complex biobank infrastructure during the COVID-19 pandemic. This feat was possible thanks to Fiocruz's extensive experience in areas like biological collections, biological resources centers, and human material biobanks, as well as its administrative, technological, and research intellectual capabilities, which led to forming a multidisciplinary working group of professionals from various fields, such as engineering, architecture, quality, biosafety, biosecurity, microbiology, virology, and molecular biology, among others (6).

Following the decision of WHO on May 5, 2023, that COVID-19 no longer constitutes a public health emergency of international concern (7) and the necessity for infrastructure ready for preparedness and response to future pandemics, epidemics, and endemics, the initial scope of the biobank was broadened to encompass a wider range of microorganisms and human biological materials pertaining to various diseases. This scope increase also meets Fiocruz's Health-BRC project and was part of a strategic shift to a much broader mission oriented to reduce the country's dependence on high-quality biological materials, strengthen the national capacity to respond to future health outbreaks with a wider range of specimens, and support a much broader range of strategic R&D activities for the Brazilian public health system. Consequently, at the close of 2023, the Fiocruz COVID-19 Biobank was rebranded as the Fiocruz Biodiversity and Health Biobank (BBS-Fiocruz)<sup>1</sup>.

## Infrastructure

Established in 2021 with the Brazilian Health Ministry's financial support amid the COVID-19 pandemic, the BBS-Fiocruz began by preserving the SARS-CoV-2 virus and human biological samples associated with COVID-19. This infrastructure was designed to support scientific research and technological advancement at Fiocruz as well as at other institutions, and it serves as a resource for addressing future epidemics and pandemics. Constructed under the ISO 20387:2018 standard, the BBS-Fiocruz adheres to the internationally recognized criteria for quality, biosafety, and biosecurity (8).

A modern 1,100 m<sup>2</sup> building was constructed, compartmentalized into sections for the preservation of human and biodiversity biological materials, including laboratories classified as biosafety level 2 (BSL-2) and administrative spaces (Figures 1A, B). Notably, the manipulation of the SARS-CoV-2 virus and other pathogens classified under biosafety level 3 (BSL-3) is conducted within an established network of institutional BSL-3 laboratories.

Biological materials are stored in liquid nitrogen tanks and ultra-low temperature freezers with the capacity for around 1.5 million aliquots (Figures 1C, D). The facility is equipped with a

1 <https://biobanco-bbs.fiocruz.br/en>.



FIGURE 1

BBS-Fiocruz infrastructure. Cell culture room of the Virology Laboratory (A), access area to BSL-2 laboratories (B), ultra-low temperature freezers (C) and liquid nitrogen tanks rooms (D).

stabilized and redundant electricity supply, a dedicated nitrogen center for cryopreservation, an automated monitoring system, and an independent air conditioning system for each environment, among other utilities. The building was designed to accommodate both horizontal and vertical expansions in the future.

In accordance with biosecurity protocols (9) and due to the sensitive nature of the stored biological materials, the facility is encircled by perimeter fencing, featuring two guardhouses—one at the primary entrance and another at the rear. Entry to the Biobank and its restricted zones is regulated through electronically registered key cards with varying access privileges. The premises are under automated surveillance and equipped with fire and panic prevention and emergency response systems, as well as secure storage for biological materials. Additionally, Closed Circuit Television (CCTV) provides comprehensive area monitoring.

## Collections

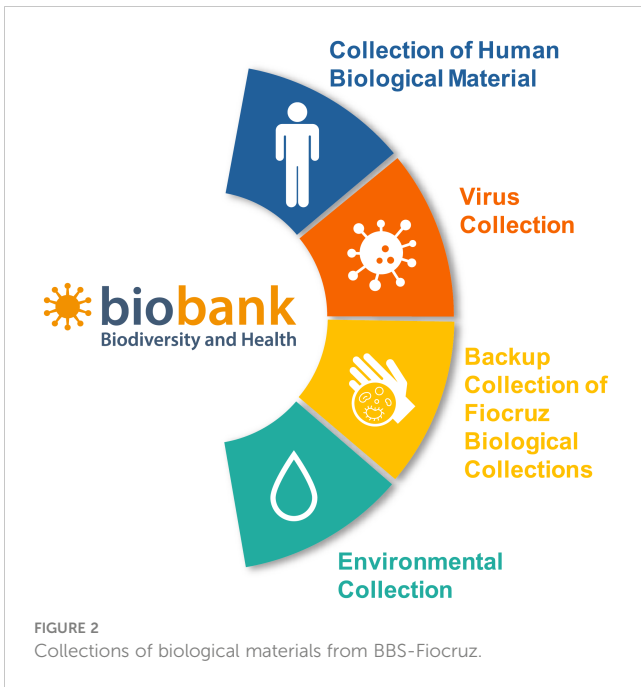
The BBS-Fiocruz serves as an open service platform, offering accessibility to Fiocruz, to other science and technology institutions and for both national and international collaborative initiatives. Presently, it houses a collection of human biological materials and three additional collections pertaining to biodiversity (Figure 2). This integration aligns with the expanded biobank definition according to ISO 20387:2018 (8). Nonetheless bringing together human and biodiversity biological materials in the same

infrastructure introduces significant challenges and complexities regarding technical aspects, legal and ethical compliance, and data management (10).

Human Biological Material Collection comprises human biological materials from healthcare services, health surveillance actions, or research projects. The BBS-Fiocruz is officially recognized as a research biobank of human biological materials, in line with national regulations (11, 12), and certified by the National Research Ethics Commission (Conep/CNS/MS)<sup>2</sup>. To date, it has received oropharyngeal swab samples associated with COVID-19, representative of different epidemiological weeks. Currently, BBS-Fiocruz is in the process of expanding its scope to accommodate human biological materials linked to a broader spectrum of diseases, including emerging and re-emerging infectious diseases, alongside public health emergencies.

Virus Collection houses viruses that are significant from taxonomic, epidemiological, and biotechnological perspectives, sourced from Fiocruz's laboratories as well as other national and international institutions, complying with the requirements established for Biological Resources Centers (9). It adheres to both national and international regulations concerning Access and Benefit Sharing (13–15). Currently, the collection includes 170 strains of the SARS-CoV-2 coronavirus and one strain of *Zika virus*, *Chikungunya virus*, and *Culex flavivirus*.

<sup>2</sup> <https://conselho.saude.gov.br/comissoes-cns/conep>.



Backup Collection is dedicated to biological materials from Fiocruz’s institutionalized Biological Collections, serving as an off-site backup to safeguard the most representative specimens. Given the susceptibility of collections to losses, it is recommended as a best practice to maintain duplicates of key resources at a secure, off-site facility (9).

Environmental Collection is dedicated to environmental samples from the FioAntar Project. This project is part of the Brazilian Antarctic Program (Proantar), led by the Interministerial Commission for Sea Resources (CIRM) of the Brazilian Navy. It aims to study microorganisms found on the Antarctic continent to uncover potential threats to human health and discover opportunities for biotechnological advancements (16).

## Services provided

BBS-Fiocruz offers a diverse range of services designed to fulfill both internal institutional requirements and the needs of external partners and clients. It plays a crucial strategic role (17) in fostering Brazilian biotechnological independence by (i) decreasing national reliance on imported high-quality biological materials, (ii) bolstering capabilities for preparedness and response to emerging and re-emerging infectious diseases, and (iii) facilitating a wider spectrum of research and development(R&D) endeavors.

All services offered by BBS-Fiocruz adhere to international standards (8, 9) and encompass a comprehensive range of activities: collecting, preserving, identifying, processing, sequencing, and supplying high-quality biological materials, along with associated information. These services support cutting-edge studies across a vast spectrum of fields, from genomics and infectious diseases to ecology and biodiversity conservation. In the near future, the BBS-Fiocruz aims to expand its offerings to include consulting and training programs. This initiative will enable researchers and collaborators from both public and private laboratories to access and benefit from the expertise of BBS-Fiocruz (Figure 3).

## Sustainability

As an infrastructure of the Oswaldo Cruz Foundation, a centennial Brazilian public institution, the BBS-Fiocruz primarily relies on government funding for its operations. However, a sustainability plan (18) is currently being developed to ensure ongoing operations, planned expansion, and Biobank’s strategic role for the nation.

As expected, facing the development of a sustainability plan for BBS-Fiocruz is a considerable challenge, mainly due to two factors. First, the concept of a “*sustainability plan*” for a biobank is a



relatively new approach, as biobanks are typically funded by public sources, a common scenario in developing countries. This new approach presents numerous complexities, particularly due to the stringent Brazilian laws governing public funding. These laws pose challenges in establishing financial models for the Biobank that are legally compliant, resilient, and sufficiently adaptable to meet the changing demands of this specialized field.

Second, the critical mission of the BBS-Fiocruz in enhancing Brazilian biotechnology autonomy and its capacity to respond effectively to health crises necessitates more than just reliance on federal budget allocations. This financial constraint underscores the need to investigate alternative funding sources and establish strategic partnerships to broaden the range of income streams.

Acknowledging this, the BBS-Fiocruz is developing its sustainability plan focused on the diversification of funding sources (19, 20) and based on the following guidelines:

1. **Public Funding Programs:** Brazil offers a wide range of public funding programs to support R&D activities, including grants, loans, and subsidies provided by government agencies such as the Brazilian Development Bank (BNDES), the Brazilian Innovation Agency (FINEP), the National Council for Scientific and Technological Development (CNPq), and state-level research funding bodies (21).
2. **Fee-for-Service Model:** Revenue generated from fee-for-service arrangements, wherein users pay to utilize BBS-Fiocruz resources and services, will aid in sustaining the Biobank's operations and contribute to ensuring its financial sustainability.
3. **Legal Incentives and Public-Private Partnerships:** Brazil offers a variety of legal incentive programs to encourage technological innovation, including tax incentives for companies that invest in innovative projects. Companies engaged in R&D activities can benefit from tax exemptions, reductions, and incentives, enabling them to deduct a portion of their R&D expenditures from their corporate income tax. These incentives are pivotal in attracting private partners and are a key element of BBS-Fiocruz's sustainability plan. The Brazilian Science and Technology legal framework, established in 2016, has also reduced bureaucratic barriers for public institutions like BBS-Fiocruz in delivering scientific services. This framework has also introduced a variety of new legal mechanisms to enhance resource utilization in collaborative R&D projects (22).
4. **International Collaborations:** BBS-Fiocruz is committed to forming various agreements with international organizations, research consortia, and funding agencies. These partnerships aim to provide access to additional resources, expertise, and research opportunities.
5. **Contributions:** BBS-Fiocruz pursues strategic partnerships with philanthropic entities, foundations, and private donors interested in supporting biodiversity, health, and scientific research initiatives. Contributions to these

initiatives are potentially eligible for tax incentives, a key aspect of the sustainability plan for BBS-Fiocruz.

As a strategic public infrastructure, the BBS-Fiocruz will play a key role in facilitating groundbreaking research and conservation endeavors by offering an array of services, diversifying its funding, and focusing on enduring sustainability.

With its broad array of services, multiple funding avenues, and a firm commitment to excellence, the Biobank's mission focuses on enhancing scientific advances, promoting health equity, and safeguarding biodiversity for future generations (23).

## Quality management

Another important contribution to the BBS-Fiocruz project has been the adoption of the new ISO standard for biobanking. ISO 20387:2018 outlines general requirements for biobanks, focusing on competence, impartiality, and consistent operation, including quality control requirements to ensure the appropriate quality of biological material and data collections. This document applies to all organizations performing biobanking, including storage of biological material from multicellular organisms (e.g., human, animal, fungus and plant) and microorganisms for research and development. The new ISO defines a biobank as a legal entity, or part of it, that performs the process of acquisition and storing, together with some or all of the activities related to the collection, preparation, preservation, testing, analysis, and distribution of defined biological materials as well as related information and data (8).

With ISO 20387:2018's publication, the significance of governance and managerial aspects has become increasingly apparent, in addition to strictly operational actions. Governance and management aspects include procedures, policies for confidentiality and impartiality, the verification of Quality Management System (QMS) performance, and the assessment of personnel qualification and competency (24).

The primary challenge in implementing ISO requirements stems from the intricate nature of biobank operations. This requires thoroughly mapping technical, managerial, and quality processes and procedures. Accordingly, at BBS-Fiocruz a checklist has been established to track the progress of ISO implementation. This checklist outlines an action plan, assigns responsibilities, and sets deadlines, which are overseen by the Quality Management team. Work processes are developed based on the team's expertise, adherence to standard operating procedures, and compliance with technical, scientific, and legal standards. Additionally, the BBS-Fiocruz team consistently undergoes training and qualification in technical, biosafety, biosecurity, and quality aspects to fulfill the intended objectives.

The adoption of the biobank standard brings benefits such as ensuring the confidentiality and quality of the samples and improving the efficiency of research resources. These improvements lead to more reliable data, increased experimental reproducibility, and reduced costs related to reagents, equipment, and personnel (25).

BBS-Fiocruz is continually striving to comply with the requirements of ISO 20387:2018. This encompasses managing the entire lifecycle of samples, including their receipt, processing, storage, quality control, distribution, and disposal, as well as associated data. It is also committed to upholding ethical and legal standards in all its national and international activities and projects.

## Governance

An organizational structure was established to manage, plan, and monitor BBS-Fiocruz’s strategic policy (Figure 4).

At the forefront of BBS-Fiocruz is the General Management. To ensure expertise across all facets of biobanking operations, three distinct management divisions have been formed: Quality Management, Biological Materials and Technological Services Management, and External Relations Management, along with a Planning and Management Advisory.

Furthermore, the organizational framework includes both a Steering Committee and a Technical-Scientific Committee, each comprised of experts from the institution.

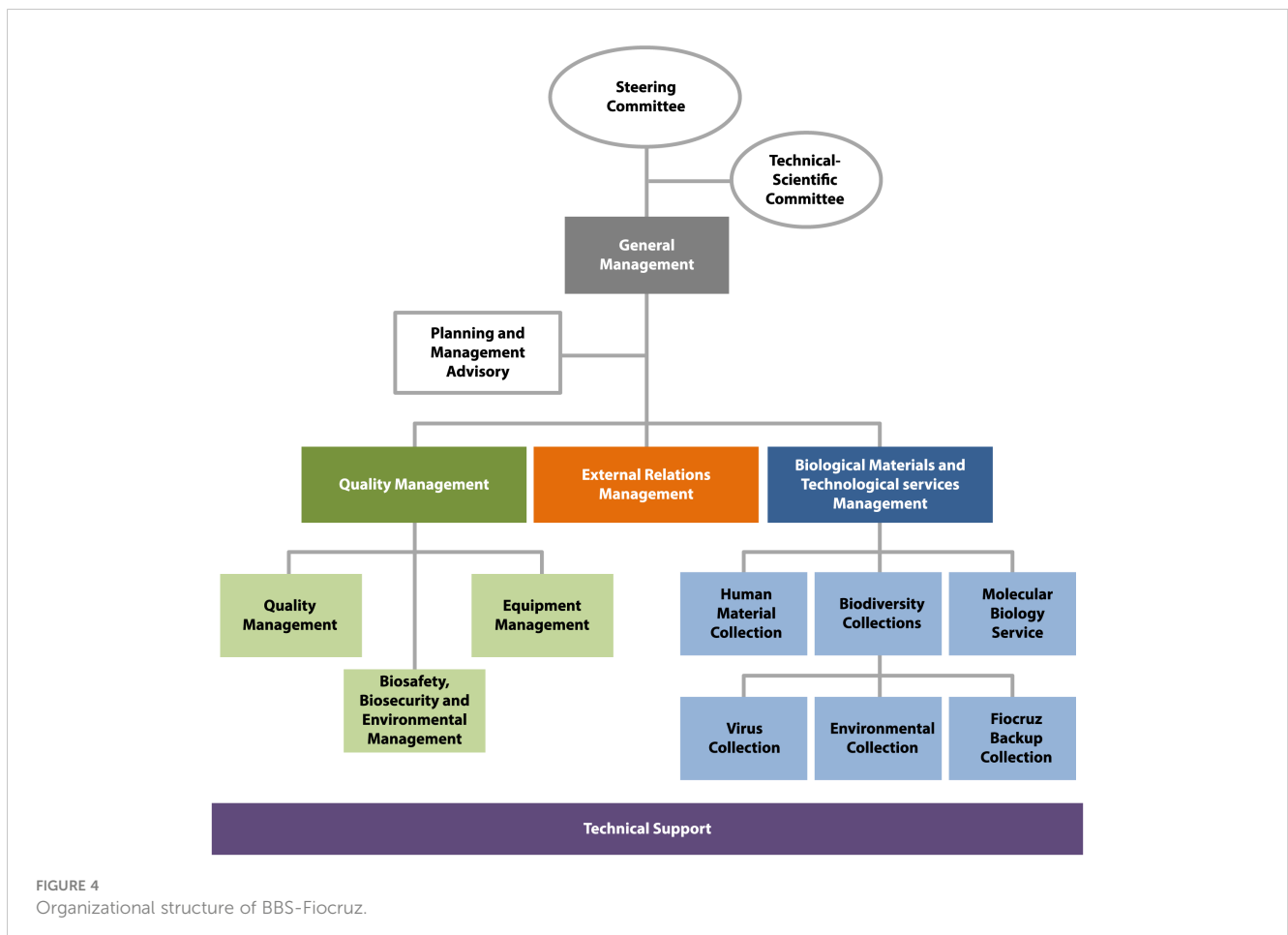
Additionally, Fiocruz has institutional instances related to ethical, legal and social policies with strict rules regarding these matters. These bodies include the Research Ethics Committee

(CEP), which analyze and evaluate research projects involving human beings, in order to ensure that the research meets ethical and scientific foundations and compliance with Brazilian Resolutions, and the Technological Management Coordination (Gestec) responsible for the Fiocruz System of Technological and Innovation Management in matters related to the protection of the institution’s scientific and technological heritage, and for the commercialization of its results, as well as for providing support for compliance with legal and regulatory matters regarding R&D activities.

## Perspectives

BBS-Fiocruz is prepared to embark on several initiatives to improve its operations and broaden its impact in the short to medium term.

For the full operationalization of its collections, these include completing institutional recognition of the Virus Collection, requesting Conep/CNS/MS authorization to deposit human biological materials related to other diseases of interest, implementing the deposit process for the Environmental Collection and for the Backup Collection of Fiocruz Biological Collections, establishing Biological Materials Deposit and Supply Policies, and providing a catalog of biological materials.



Concerning the services BBS-Fiocruz offers, future directions involve defining the legal framework for service delivery, benchmarking with other public institutions for best practices, setting pricing strategies for services; identification of new opportunities for resource mobilization and partnerships for service provision and project development, and assessing spontaneous requests for the incorporation of new services.

From a quality management perspective, BBS-Fiocruz plans to perform situational assessments related to ISO 20387:2018 compliance, define specific action plans for each responsible area and monitor their execution, continue process mapping and documentation, provide training in Quality, Biosafety, and Biosecurity to its team, and develop and implement contingency plans for its activities.

## Discussion

In this article, we have outlined the challenges encountered in the design and construction of a complex biobank infrastructure within a developing country, particularly during the urgent circumstances of the recent COVID-19 pandemic. Our focus has been on facilitating and supporting health sector science and technology through the deposit, characterization, preservation, and supply of human biological materials and biodiversity within a single infrastructure. This endeavor adheres to existing legal and ethical standards and meets the stringent quality, biosafety, and biosecurity requirements set by ISO 20387:2018, in addition to aligning with national and international legislations. Moreover, we have discussed the challenges and strategies to ensure the long-term sustainability of a public biobank, particularly through the diversification of funding sources. The information provided in this paper will benefit other biobanks engaged in tropical infectious disease services in developing countries.

## Author contributions

MdS: Conceptualization, Methodology, Project administration, Writing – original draft, Writing – review & editing. CGS: Conceptualization, Methodology, Project administration, Writing – original draft, Writing – review & editing. PCRE: Writing – review

& editing. PCVB: Writing – review & editing. CRSN: Conceptualization, Methodology, Project administration, Writing – original draft, Writing – review & editing.

## Funding

The author(s) declare that no financial support was received for the research, authorship, and/or publication of this article.

## Acknowledgments

The authors would like to thank the Presidency of the Oswaldo Cruz Foundation (Fiocruz) for proposing the Biobank project and for the strong institutional support, Renata Almeida de Souza (Coordination of Quality/Fiocruz) for the competent coordination of the project, the General Coordination of Campus Infrastructure (Cogic/Fiocruz) team for planning and supervising the construction, and the Health Environment Surveillance Secretariat of the Brazilian Ministry of Health (SVSA/MS) for financing the construction and equipping the BBS-Fiocruz. We especially thank Rodrigo Corrêa-Oliveira (in memoriam) for his tireless leadership in the process of idealizing and building the BBS-Fiocruz.

## Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

## Publisher's note

All claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organizations, or those of the publisher, the editors and the reviewers. Any product that may be evaluated in this article, or claim that may be made by its manufacturer, is not guaranteed or endorsed by the publisher.

## References

- Moratelli R. Wildlife biologists are on the right track: A mammalogist's view of specimen collection. *Zool.* (2014) 31:413–7. doi: 10.1590/S1984-46702014000500001
- da Silva M, Chame M, Moratelli R. Fiocruz Biological Collections: strengthening Brazil's biodiversity knowledge and scientific applications opportunities. *Biodivers Data J.* (2020) 8:e53607. doi: 10.3897/BDJ.8.e53607
- da Silva M, Cupolillo E, Pirmez C. Fiocruz microbial collections: the impact of biodiversity to public health. *WFCC Newsletter.* (2011) 51:78. doi: 10.3897/BDJ.8.e53607
- da Silva M, Sá MR. Coleções vivas: as coleções microbiológicas da Fundação Oswaldo Cruz. *Rev Museol. Interdiscip.* (2017) 5:175–87. doi: 10.26512/museologia.v5i9.17290
- World Health Organization. *COVID-19 Public Health Emergency of International Concern (PHEIC). Global research and innovation forum: towards a research roadmap.* Geneva: WHO (2020). Available at: [https://www.who.int/publications/m/item/covid-19-public-health-emergency-of-international-concern-\(pheic\)-global-research-and-innovation-forum](https://www.who.int/publications/m/item/covid-19-public-health-emergency-of-international-concern-(pheic)-global-research-and-innovation-forum)
- Turco CS, Stefanoff G, Nascimento C, Brum R, da Silva M. The new fiocruz covid-19 biobank will bring together human and non-human biological materials for research and development. *Biopreserv. Biobank.* (2023) 21:A–1-A-72. doi: 10.1089/bio.2023.29118.abstracts
- World Health Organization. *Statement on the fifteenth meeting of the IHR (2005). Emergency Committee on the COVID-19 pandemic* (2023). Available online at: [https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic)

8. International Organization for Standardization. ISO 20387:2018. In: *Biotechnology - Biobanking - General requirements for biobanking*. ISO, Geneva (2018). Available at: <https://www.iso.org/standard/67888.html>
9. OECD. *OECD Best Practice Guidelines for Biological Resource Centres*. Paris: OECD Publishing (2007). p. 115. Available at: <https://www.oecd-ilibrary.org/content/publication/9789264128767-en>
10. Rivera-Alcántara JA, Esparza-Hurtado N, Galán-Ramírez GA, Cruz-Bautista I, Mehta R, Aguilar-Salinas CA, et al. A systematic review of biobanks in Latin America: Strengths and limitations for biomedical research. *Int J Biol Markers*. (2024) 39(2):91–106. doi: 10.1177/03936155241239672
11. Brazil. National Health Council (CNS). *Resolution n° 441– Guidelines for ethical review of research projects involving human biological material storage or use of material stored in previous research* (2011). Available online at: <https://conselho.saude.gov.br/resolucoes/2011/Reso441.pdf>
12. Brazil. Ministry of Health. *Ordinance n° 2.201 - National guidelines for biorepository and biobank of human biological material for research purposes* (2011). Available online at: [https://bvms.saude.gov.br/bvs/saudelegis/gm/2011/prt2201\\_14\\_09\\_2011.html](https://bvms.saude.gov.br/bvs/saudelegis/gm/2011/prt2201_14_09_2011.html)
13. Convention on Biological Diversity. *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity: text and annex*. Montreal: United Nations (2011). Available at: <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>
14. Brazil. *Law n° 13.123 of May 20, 2015 (Access and Benefits Sharing of Genetic Resources and Associated Traditional Knowledge)*. Available online at: [http://www.planalto.gov.br/ccivil\\_03/\\_Ato20152018/2015/Lei/L13123.html](http://www.planalto.gov.br/ccivil_03/_Ato20152018/2015/Lei/L13123.html)
15. Brazil. *Decree n° 8.772 of May 11, 2016, on the Implementation of Law n° 13.123 of May 20, 2015*. Available online at: [https://www.planalto.gov.br/ccivil\\_03/\\_ato2015-2018/2016/decreto/d8772.htm](https://www.planalto.gov.br/ccivil_03/_ato2015-2018/2016/decreto/d8772.htm)
16. Prado T, Brandão ML, Fumian TM, Freitas L, Chame M, Leomil L, et al. Virome analysis in lakes of the South Shetland Islands, Antarctica - 2020. *Sci Total Environ*. (2022) . 852:158537. doi: 10.1016/j.scitotenv.2022.158537
17. Gee S, Oliver R, Corfield J, Georghiou L, Yuille M. Biobank finances: A socio-economic analysis and review. *Biopreserv Biobank*. (2015) 13:435–51. doi: 10.1089/bio.2015.0030
18. Henderson M, Simeon-Dubach D, Albert M. Finding the path to biobank sustainability through sound business planning. *Biopreserv Biobank*. (2015) 13:385–6. doi: 10.1089/bio.2015.29039.mh
19. Seiler CY, Eschbacher J, Bowser R, LaBaer J. Sustainability in a hospital-based biobank and university-based DNA biorepository: strategic roadmaps. *Biopreserv Biobank*. (2015) 13:401–9. doi: 10.1089/bio.2015.0076
20. Uzarski D, Burke J, Turner B, Vroom J, Short N. A plan for academic biobank solvency-leveraging resources and applying business processes to improve sustainability. *J Clin Transl Res*. (2015) 8:553–7. doi: 10.1111/cts.12287
21. Cirani CBS, Kono CM, dos Santos AM, Cassia AR. The role of public institutions for innovation support in Brazil. *Braz Bus. Rev*. (2016) 13:210–30. doi: 10.15728/bbr.1808-2386
22. Reis DL, Albuquerque de Oliveira M, de Melo Barreto SRG, de Mattos Veroneze G, dos Santos de Oliveira AN. The new Brazilian legal framework of science & technology: Barriers, borders and opportunities for innovation. *Int J Innov Educ Res*. (2020) 8:39–50. doi: 10.31686/ijer.vol8.iss6.2366
23. Watson PH, Nussbeck SY, Carter C, O'Donoghue S, Cheah S, Matzke LAM, et al. A framework for biobank sustainability. *Biopreserv Biobank*. (2014) 12:60–8. doi: 10.1089/bio.2013.0064
24. Blasio PD, Biunno I. New challenges for biobanks: accreditation to the new ISO 20387:2018 standard specific for biobanks. *BioTech*. (2021) 10:13. doi: 10.3390/biotech10030013
25. Dagher G. Quality matters: International standards for biobanking. *Cell Prolif*. (2022) 55:e13282. doi: 10.1111/cpr.13282