



OPEN LETTER

**REVISED** **Role of a regulatory and governance framework in human biological materials and data sharing in National Biobanks: Case studies from Biobank Integrating Platform, Taiwan and the National Biorepository, Uganda [version 2; peer review: 2 approved]**

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### Abstract

**Background:** In the last decade, Low- and Middle-Income Countries (LMICs) have set up Biobanks to collect human biological materials and associated data for genomic research and public health purposes. Biobanking gives rise to ethical challenges, such as informed consent, benefit sharing, confidentiality, ownership, commercialization and public participation which are harder to navigate in LMIC settings due to disparities in research infrastructure and capacity. This paper summarizes presentations on Biobank related case studies from two countries, with a focus on challenges in the regulatory and governance framework and suggestions on how to mitigate them.

**Methods:** Two case studies of Biobanks from LMICs have been used. The case studies were presented at the 2018 Global Forum on Bioethics in Research (GFBR) meeting on the “Ethics of data sharing and Biobanking in health research”.

**Results:** The case studies show that an integrated, well-regulated platform for human biological materials and data ensures good quality of human biological materials, saves resources and promotes mutual collaboration of work among researchers. National regulatory bodies are required to generate Biobanking guidelines and policies to facilitate guidance to the rapidly changing landscape of science.

**Discussion:** In general, LMICs have weaker research regulatory infrastructure and governance mechanisms for Biobanks than high-income countries. This has increased the fear of exploitation i.e. unfair

### Open Peer Review

**Reviewer Status**

	Invited Reviewers	
	1	2
<b>version 2</b> (revision) 01 Sep 2020		
<b>version 1</b> 12 Nov 2019	 report	 report


1. **Nirmal Kumar Ganguly**, Translational Health Science and Technology Institute, Faridabad, India  
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distribution of risks and benefits. Establishment of Biobanks and producing effective scientific outcomes based on the Biobanking resources is difficult without a proper legislative, regulatory and governance framework.

**Conclusion:** These two case studies from different LMICs settings show that although in both settings there is strong awareness of the scientific and population health value of Biobanks and strong commitment to their establishment, regulatory and ethical guidance show gaps that need to be addressed.

### Keywords

Governance, Biobanking, Data sharing, Biobanks, Biological materials, LMICs

2. **Jantina de Vries** , University of Cape Town, Cape Town, South Africa

Any reports and responses or comments on the article can be found at the end of the article.

This article is included in the [GFBR: The ethics of data sharing and biobanking in health research](#) collection.



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**Author roles:** **Nansumba H:** Conceptualization, Investigation, Methodology, Writing – Original Draft Preparation; **Ssewanyana I:** Conceptualization, Visualization; **Tai M:** Conceptualization, Investigation, Methodology, Writing – Original Draft Preparation, Writing – Review & Editing; **Wassenaar D:** Supervision, Writing – Review & Editing

**Competing interests:** No competing interests were disclosed.

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**REVISED Amendments from Version 1**

The establishment of Biobanks is an important step towards establishing national genomics research programmes. Maintaining these Biobanks and producing effective scientific outcomes based on Biobanking resources are not easy without a proper legislative, regulatory and governance framework.

The findings from the Taiwan case study indicate that substantial financial monetary and personnel resources have been invested but the results are not as promising as hoped for, because: 1) all Biobanks operate on their own without sharing information with others. Thus, if any researcher needs certain tissue for research, she/he will have to check all bio-banks till the data is found, 2) some Biobanks have never received any requests for data 3) the cost of maintaining the Biobanks increases with accumulated tissues 4) some question the value of setting up too many Biobanks for lack of research that ended up wasting much of valuable resources.

This review has a limitation of comparison of informed consent processes between the Taiwan case study and National Biorepository, Uganda. Future studies are recommended to compare the two categories.

**Any further responses from the reviewers can be found at the end of the article**

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The views expressed in this article are those of the author(s). Publication in Wellcome Open Research does not imply endorsement by Wellcome.

**Background**

Biobanks have been set up in Low- and Middle-Income Countries (LMICs) in support of research studies on genetic diversity in health and disease in LMIC populations<sup>1</sup>. The Biobanks have been established to address various research gaps such as National Biobanks, disease specific Biobanks, Biobanking networks etc.<sup>2-4</sup>. However, establishment and use of biological materials and data in a Biobank has ethical and legal requirements. The Declaration of Helsinki highlights the ethical principles and governance of Biobanks. It is important to protect the dignity, autonomy and confidentiality of research participants<sup>5</sup>. Ethical, legal and social issues such as informed consent, benefit sharing, ownership, public engagement and commercialization associated with Biobanks are still complex issues in LMICs. Compared with many high-income countries, where the ethical, legal and social issues of Biobanks have been debated, researchers in LIMCs are less experienced in addressing these issues<sup>3,6</sup>.

Data sharing is a key component in Biobanking as they are increasingly being used to support global health research<sup>7</sup>. Greater data sharing maximizes the value and utility of datasets and minimizes the costs of unnecessary duplication of research<sup>8</sup>. A study by de Vries *et al.* (2017) on content analysis of ethics guidelines, policies and procedures of 22 African countries indicates that African regulation is either absent, outdated, conservative or difficult to navigate<sup>9</sup>. Additionally, Research

Ethics Committees (RECs) lack guidance on how to review genomics and Biobanking proposals. This paper presents case studies from two LMICs on the regulatory and governance framework for Biobanking, including challenges and suggestions on how to mitigate them.

**Case study 1: Taiwanese experience in Biobanking Introduction**

The first Biobank in Taiwan was officially established in 2005 in Academia Sinica (AS), the largest and most prestigious research institute of Taiwan<sup>10</sup>. The purpose of this Biobank is to discover the hidden genetic diseases of Taiwanese people and promote their health. The project aimed to recruit two hundred thousand residents. So far, more than that number of people has taken part in the project by providing their personal information and details of their living habits. About half of the participants have also donated human biological materials that are deposited in the AS Biobank for study. Beginning from one Biobank, the number of Biobanks in Taiwan has increased to 31 in the last 13 years. Among these, three are population based and the rest are disease oriented.

The team at AS Biobank has published many scholarly papers<sup>11-13</sup>, mostly in the area of public health and statistical determinations of the nation's health status. However, discoveries of genetic causes of disease and possible cures are still below expectation. The Ministry of Health and Welfare, under which these Biobanks are registered, started evaluation visits to all Biobanks two years ago to assess whether or not these Biobanks have functioned and produced results as originally expected.

The findings of these visits are that substantial financial monetary and personnel resources have been invested but the results are not as promising as hoped for, because: 1) all biobanks operate on their own without sharing information with others thus if any researcher needs certain tissue for research, they will have to check all biobanks till the data is found, 2) some biobanks have never received any requests for data 3) the cost of maintaining a biobank increases with accumulated tissues 4) some question the value of setting up too many biobanks for lack of research that ended up in wasting valuable resources. As a result, a new initiative has been introduced to integrate all Biobanks through data-sharing while each Biobank maintains its own uniqueness.

**Biobank Structural Innovation Project**

The Ministry of Health and Welfare of Taiwan has initiated a structural innovation project to integrate all Biobanks in the areas of stored data. This project is called the Biobank Integrating Platform. The purpose is to promote data sharing and shorten the time of scientific and ethical review so that researchers can start their studies with a minimum of delay.

The first step is to create an intranet to gather detailed information on all Biobanks' data and make it available to all other Biobanks. In this way, each Biobank no longer works on its

own and is integrated in a coordinated structure and service. Each Biobank still functions as originally established but the bio-data is sent to the integrated platform for circulation to researchers. However, there is only one window or portal that researchers need to contact when seeking to access research data. Additionally, this platform ensures that donors' personal identifiable information will not be available to any researcher in order to ensure their protection. However, doubt has been raised within the Ethics Governance Council (EGC) of the Taiwan Biobank about whether individuals' privacy can be absolutely safeguarded.

Several challenges still need to be resolved. First, there is no bargaining forum for researchers who pay large fees for data. Each Biobank has a different scale of fees and some are expensive. Secondly, there is a lack of clarity about the intellectual property rights of the original institution versus the researcher and his/her institution in cases where novel research findings are discovered. Third, directors and or managers of Biobanks use large volumes of human biological materials from their own Biobanks, hence depriving the other researchers from accessing these limited resources Biobank. This has been criticized as a conflict of interest.

#### Establishment of a scientific review committee

A scientific review committee has been set up to perform an initial review of all research protocols and then the Biobank's Institutional Review Board (IRB) and EGC need only to do an expedited review to facilitate the review process. The bio-data fees are payable to the institutional Biobank that provides the data.

#### Reflection

The establishment of the Biobank Integrating Platform facilitates researchers' access to data, ensures the quality of human biological materials, saves resources and enhances the quality of research and promotes collaboration among researchers. This sample and data-sharing platform is new, and its effectiveness has already been demonstrated by an increase in applications for data. The integration is not to force all Biobanks into one; rather, each Biobank maintains its own strength, vision and uniqueness while opening up to all researchers through a common portal so that the goal of promoting health and curing diseases can be realized, and public health benefits can be maximized.

### **Case study 2: Establishing the National Biorepository in Uganda: some regulatory and ethical uncertainties**

#### Introduction

In 2006, Uganda adopted a centralized model to scale-up its national HIV Early Infant Diagnosis (EID) programme. A HIV viral load monitoring (VL) programme was implemented in July 2014. Human biological materials such as dried blood spots (DBS) and plasma are collected from all health facilities in Uganda and delivered to HUBS. A HUB is a coordination center of the sub-district network serving approximately

20–40 health facilities where several referral tests are done, including: CD4+ counts, liver function test, renal function tests, complete blood counts etc. To date, there are 100 functional HUBS bringing together a network of over 2500 health facilities. EID and VL human biological materials are transported from the HUBS to the Central Public Health Laboratory for testing<sup>14</sup>. The total national coverage of both EID and VL for over 150,000 HIV exposed infants and 1,100,000 HIV patients on ART has resulted in the collection of over 1,000,000 remnant DBS and plasma human biological materials in a National Biorepository for future research. Approximately, 1,600 microbiological isolates are received from surveillance and epidemic investigations across various regions in Uganda. In September 2016, the National Biorepository proposed to set up a biorepository for appropriate storage of human biological materials in a retrievable manner for future research purposes and to foster both local and international research collaborations. The National Biorepository is owned by the Government of Uganda under the custodianship of Central Public Health Laboratories (CPHL). During 2017–2018, the National Biorepository has sought prior informed consent for long term storage and use of remnant clinical human biological materials, mainly from the centralized reference HIV early infant diagnosis (EID) and viral load programmes, as well as isolates of antimicrobial drug resistance surveillance and disease outbreak investigations. An informed consent statement has been added to the laboratory request forms. A Biorepository Governance Committee has been appointed to oversee the activities of the National Biorepository, provide direction on priority human biological materials and to store and regulate access to the repository resources. Plans are underway to create collaborations with universities and research institutions to promote human biological materials access. In addition, the National Biorepository will provide training in biorepository science to medical students and health workers.

#### Planning and development

CPHL has set up a task force to develop a proposal to store remnant human biological materials<sup>15</sup>. The proposal was submitted to an accredited Research Ethics Committee (REC) in Uganda. The protocol was reviewed and the feedback was that establishment of Biorepositories was outside the scope of ethics review by the REC. The REC advised that it would only be within its scope if a researcher intending to use the stored human biological materials applied for ethics review. Additionally, we were advised to submit the protocol to the Uganda National Council of Science and Technology (UNCST). The protocol was submitted to UNCST early in 2017, but no formal feedback was received until December 2018. Oversight of research involving humans as research participants in Uganda is done first at the organization level by RECs and second at national level by UNCST in collaboration with Uganda National Research Organization (UNHRO)<sup>16</sup>. Unfortunately, UNCST currently has no regulations governing the establishment and operation of Biobanks/biorepositories. This has resulted in an unregulated proliferation of independent research Biobanks and/or biorepositories

established to serve specific research interests in Uganda. Additionally, the regulatory body has apparently not yet mapped existing biorepositories/Biobanks in Uganda. As a consequence, the National Biorepository proposal and Standard Operating Procedures remain unapproved by UNCST.

### Informed consent

Implementation of informed consent in a setting with no regulations on Biobanking is challenging. National guidelines for research involving humans as research participants state that a specific informed consent form shall be used for human biological materials that are collected with the intention of being stored and used for future studies<sup>16</sup>. This model offers the best protection for autonomy but has several limitations. It is difficult or impossible to gain specific consent, as future uses of the human biological materials and data are unknown at the time of diagnostic testing. Broad consent in cases where several possible future research uses are provided to research participants would be a good strategy to increase utilization of human biological materials and associated data and could foster international collaboration<sup>17</sup>. Currently, UNCST is reviewing the Guidelines to offer guidance on the type of informed consent applicable to Biobanking institutions, especially for remnant human biological materials of clinical origin. Currently, the National Biorepository allows access of stored human biological materials to researchers who seek approval through an accredited REC to waive informed consent for the use of human biological materials for minimal risk research. This type of consent is however limited by the lack of national regulations. This also hinders collaborations.

### Community engagement

A stakeholder consultation meeting was conducted in 2018. The stakeholders comprised UNCST, civil society, lawyers from the Ministry of Justice and Constitutional Affairs, REC, district health officers, hospital directors, university lecturers and students and development partners. Information was shared about the National Biorepository such as Current Status and future prospects; its governance and legal and ethical issues. Resolutions from this meeting included: (a) Clinical and laboratory request forms should be modified to include a broad consent for storage and future use for research. (b) UNCST was tasked to write biorepository guidelines based on international standards. (c) For remnant human biological materials already in storage without consent, the National Biorepository should seek government advice through the attorney general. (d) UNCST was tasked to fast-track the compilation of Biobanking specific policies and guidelines.

### Reflection

National Regulatory Bodies are required to generate Biobanking Guidelines and Policies. Inadequate specialized ethics and regulatory knowledge seems to be the major cause of the lack of regulations or policies to guide Biobanking science in Uganda. Hence, education on Biobanking science and ethics in LMICs is required.

### Discussion

LMICs generally have weaker research capacity and governance mechanisms for Biobanks than high-income countries<sup>6,18</sup>. Human biological materials and data sharing from Biobanks are increasingly being used to support collaborative national and international health research. These approaches have the potential to increase scientific efficiency by maximizing the utility of human biological materials and data for researchers and funders<sup>8</sup>. Managing data flows into and out of Biobanks gives rise to various ethical challenges which are exacerbated in some LMIC settings due to disparities in infrastructure, resources and capacity<sup>7</sup>. National and or local regulatory authorities are required to develop Biobanking Guidelines<sup>17,19</sup>. In 2010, the Government of Western Australia through its Department of Health issued an operational directive that launched Guidelines for human Biobanks, genetic research databases and associated data that provides a set of principles and best practices to guide researchers and clinicians involved with Biobanks<sup>20</sup>. Requesting appropriate informed consent in Biobanks has become a cornerstone for the collection of human biological materials and data for use in research, but this needs to be supported by relevant guidelines and legislation. For research involving Biobanking, government regulations and guidelines should identify key categories of information to be communicated to prospective participants during the consent process<sup>21,22</sup>. Various consent types<sup>12,17</sup> have been recommended such as Consent waiver, Opt out, Opt in (Specific consent, Specific and broad consent), Broad consent and Dynamic consent. The establishment of Biobanks is an important step towards establishing national genomics research programmes. Maintaining these Biobanks and producing effective scientific outcomes based on Biobanking resources are not easy without a proper legislative, regulatory and governance framework. Good governance of a Biobank includes engaging with the public during the establishment of a Biobank and throughout the lifecycle of the Biobank<sup>23</sup>.

### Conclusion

These two cases studies from different LMIC settings show that although in both settings there is strong awareness of the scientific and population health value of biorepositories, and strong commitment to their establishment, regulatory and ethical guidance show gaps that need to be addressed. Unfortunately, exact comparative categories of data could not be collected for each data bank and this should be remedied in future comparative studies. These gaps concern both the ethical acquisition of new human biological materials and the management of ethical access and use of such national resources in a way that is respectful of the donor communities, local regulations and legislation, and international best practices. Efforts need to be made nationally and internationally to create suitable enabling ethical governance of these valuable national and international resources.

### Data availability

#### Underlying data

No data are associated with this article.

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# Open Peer Review

Current Peer Review Status:  

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## Version 2

Reviewer Report 08 September 2020

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**Jantina de Vries** 

Department of Medicine, Faculty of Health Sciences, University of Cape Town, Cape Town, South Africa

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Bioethics, ethics of genomics, qualitative research methods

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

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## Version 1

Reviewer Report 29 January 2020

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**Jantina de Vries** 

Department of Medicine, Faculty of Health Sciences, University of Cape Town, Cape Town, South Africa

**Substantive issues**

*Taiwan case study*

In the Taiwan case study you say that “substantial financial monetary and personnel resources

have been invested but the results are not as promising as hoped for, *implying wastage of valuable resources.*” Do you mean to suggest that if there had been less wastage and more efficiency, the biobanks would have been more successful? Or do you mean to say that perhaps the entire idea of biobanking is a bit of a waste? It would be good if you could clarify this – not in the least because there are also other authors who have warned that the promises of biobanking may have been overplayed and that the expectations are unrealistic.

For the Uganda case study, information is provided about the informed consent process, the regulatory approval process and community engagement. In order for these two case studies to be comparable for the reader, it would be good if they could both present similar types of information. Can the Taiwan case study perhaps be enriched with a description of those same items?

#### *Uganda case study*

W.r.t. the Ugandan case study, the article describes that the biobank application was ‘not approved’. Wouldn’t it be more correct to say that it was ‘not reviewed’? From your explanation, it looks like the HREC determined that reviewing the establishment of a biobank fell outside of its mandate and so the suggestion is that they didn’t review it. (please note that your use of ‘we’ in that paragraph is different in style from the rest of the descriptions you give and you may want to change this). W.r.t. that case study – have you got any idea what is causing the delays in review by UNCST? It would be helpful for the article if you could spend a few more words describing the nature of your discussions with UNCST and what you attribute this delay to.

In the Ugandan case study, there is some confusion about HIV DBS repository, the ‘proposal’ developed by CPHL the ‘national biorepository’ and what you refer to as ‘The Biorepository’. Please can you streamline this. Are these all one and the same repository or are these different ones? Do they exist already or are they still in development?

#### *Discussion*

As it stands, the paper Discussion is more a summary of published literature than a discussion of the findings from both case studies. The Discussion should be enriched with a discussion of the observations and lessons learnt from the two case studies. For instance, I would have liked to learn more about how your understanding of the particular contexts enriches the international literature. What did you find or experience that is different from what others have published? Also, what is common and what is different in the two cases you present? Taiwan and Uganda are obviously two very different countries, on different continents with different languages, GDPs, cultures and scientific traditions. Are there any common lessons learnt?

#### **Issues of style and form**

Throughout the manuscript, there is a shifting between different units of analysis that is not justified or explained. For instance, whilst the abstract concludes that “In general, LMICs have weaker research regulatory infrastructure and governance mechanisms for Biobanks than high-income Countries”, the work in the paper only focused on case studies in two countries (Uganda and Thailand) and one cannot use evidence from those two countries to make generalised statements of the regulations in all LMICs. The authors need to revise their manuscript to make sure that their observations and conclusions are pertinent to their observations in those two countries, and not extrapolate too broadly.



Finally, there are many typographical and syntax errors in the document that need to be corrected by the authors. The authors particularly need to streamline their use of tenses – in some instances, both past and present tenses are used in the same paragraphs.

**Is the rationale for the Open Letter provided in sufficient detail?**

Yes

**Does the article adequately reference differing views and opinions?**

Yes

**Are all factual statements correct, and are statements and arguments made adequately supported by citations?**

Yes

**Is the Open Letter written in accessible language?**

Partly

**Where applicable, are recommendations and next steps explained clearly for others to follow?**

Partly

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Bioethics, ethics of genomics, qualitative research methods

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.**

Author Response 02 Sep 2020

**Hellen Nansumba**, Ministry of Health of Uganda, Kampala, Uganda

### **A Summary of responses to reviewers' comments**

#### **1. Reviewers' comment**

**In the Taiwan case study you say that “substantial financial monetary and personnel resources have been invested but the results are not as promising as hoped for, implying wastage of valuable resources.” Do you mean to suggest that if there had been less wastage and more efficiency, the bio-banks would have been more successful? Or do you mean to say that perhaps the entire idea of biobanking is a bit of a waste? It would be good if you could clarify this – not in the least because there are also other authors who have warned that the promises of biobanking may have been overplayed and that the expectations are unrealistic.**

#### **Response to Reviewers' comment**

Thank you for this comment. The section has been changed to read: The findings of these

visits are that substantial financial monetary and personnel resources have been invested but the results are not as promising as hoped for, because: 1) all bio-banks operate on their own without sharing information with others. Thus, if any researcher needs certain tissue for research, she/he will have to check all bio-banks till the data is found, 2) some bio-banks have never received any requests for data 3) the cost of maintaining the bio-bank increases with accumulated tissues 4) some question the value of setting up too many bio-banks for lack of research that ended up wasting much of valuable resources.

## **2. Reviewers' comment**

**For the Uganda case study, information is provided about the informed consent process, the regulatory approval process and community engagement. In order for these two case studies to be comparable for the reader, it would be good if they could both present similar types of information. Can the Taiwan case study perhaps be enriched with a description of those same items?**

### Response to Reviewers' comment

Thank you for this comment. This paper a summary of the presentation made at the 2018 GFBR and the Taiwan Case study did not highlight the informed consent process procedures and this information is unfortunately not available to us. We have acknowledged this as a limitation added a line to this effect, with a recommendation for future studies to use comparable data categories.

## **3. Reviewers' comment**

**W.r.t. the Ugandan case study, the article describes that the biobank application was 'not approved'. Wouldn't it be more correct to say that it was 'not reviewed'? From your explanation, it looks like the HREC determined that reviewing the establishment of a biobank fell outside of its mandate and so the suggestion is that they didn't review it. (please note that your use of 'we' in that paragraph is different in style from the rest of the descriptions you give and you may want to change this). W.r.t. that case study - have you got any idea what is causing the delays in review by UNCST? It would be helpful for the article if you could spend a few more words describing the nature of your discussions with UNCST and what you attribute this delay to.**

### Response to Reviewers' comment

Thanks for this comment. This section has been revised to read: The protocol was reviewed and the feedback was that establishment of Biorepositories was outside the scope of ethics review by the REC. The REC advised that it would only be within its scope if a researcher intending to use the stored human biological materials applied for ethics review.

## **4. Reviewers' comment**

**In the Ugandan case study, there is some confusion about HIV DBS repository, the 'proposal' developed by CPHL the 'national biorepository' and what you refer to as 'The Biorepository'. Please can you streamline this. Are these all one and the same repository or are these different ones? Do they exist already or are they still in development?**

Response to Reviewers' comment

Thank you. We have harmonized the word "Biorepository" in the document

**5. Reviewers' comment**

**As it stands, the paper Discussion is more a summary of published literature than a discussion of the findings from both case studies. The Discussion should be enriched with a discussion of the observations and lessons learnt from the two case studies. For instance, I would have liked to learn more about how your understanding of the particular contexts enriches the international literature. What did you find or experience that is different from what others have published? Also, what is common and what is different in the two cases you present? Taiwan and Uganda are obviously two very different countries, on different continents with different languages, GDPs, cultures and scientific traditions. Are there any common lessons learnt?**

Response to Reviewers' comment

Thank you. The Discussion has been expanded to read:

LMICs generally have weaker research capacity and governance mechanisms for Biobanks than high-income countries [6](#) [18](#) . Human biological materials and data sharing from Biobanks are increasingly being used to support collaborative national and international health research. These approaches have the potential to increase scientific efficiency by maximizing the utility of human biological materials and data for researchers and funders [8](#) . Managing data flows into and out of Biobanks gives rise to various ethical challenges which are exacerbated in some LMIC settings due to disparities in infrastructure, resources and capacity [7](#) . National and or local regulatory authorities are required to develop Biobanking Guidelines [17](#) [19](#) . In 2010, the Government of Western Australia through its Department of Health issued an operational directive that launched Guidelines for human Biobanks, genetic research databases and associated data that provides a set of principles and best practices to guide researchers and clinicians involved with Biobanks [20](#) . Requesting appropriate informed consent in Biobanks has become a cornerstone for the collection of human biological materials and data for use in research, but this needs to be supported by relevant guidelines and legislation. For research involving Biobanking, government regulations and guidelines should identify key categories of information to be communicated to prospective participants during the consent process [21](#) [22](#) . Various consent types [12](#) [17](#) have been recommended such as Consent waiver, Opt out, Opt in (Specific consent, Specific and broad consent), Broad consent and Dynamic consent. The establishment of Biobanks is an important step towards establishing national genomics research programmes. Maintaining these Biobanks and producing effective scientific outcomes based on Biobanking resources are not easy without a proper legislative, regulatory and governance framework. Good governance of a Biobank includes engaging with the public during the establishment of a Biobank and throughout the lifecycle of the Biobank [23](#)

**Competing Interests:** No competing interests

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National Biobanks are essential for health system research. New biomedical technology is accelerating research in the discovery of new biomarkers which are subsequently used in predicting and the treatment protocols. Here biobanks play a pivotal role in identifying and validating such markers. The paper analyses how in the various countries that are emerging economies, like Taiwan and Uganda, are effectively using their biobank to further their health research. The paper is a good scientific read and points out the challenges like how patient data confidentiality have to be maintained as well sharing of the same have to be streamlined to gain maximum benefits. The article also mentions that this can be achieved through robust health research policy guidelines. The paper brings into light various aspects of biobanking and hence should be indexed.

#### **Is the rationale for the Open Letter provided in sufficient detail?**

Yes

#### **Does the article adequately reference differing views and opinions?**

Yes

#### **Are all factual statements correct, and are statements and arguments made adequately supported by citations?**

Yes

#### **Is the Open Letter written in accessible language?**

Yes

#### **Where applicable, are recommendations and next steps explained clearly for others to follow?**

Yes

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Public Health, Microbiology, Biotechnology, Cardiovascular and Infectious Diseases

**We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

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