RESEARCH ARTICLE

Comparative analysis of regulatory framework on biobanking to inform policymakers in Central America and the Dominican Republic [version 1; peer review: 2 approved with reservations]

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v1 First published: 06 May 2021, 6:95
<https://doi.org/10.12688/wellcomeopenres.16547.1>
 Latest published: 06 May 2021, 6:95
<https://doi.org/10.12688/wellcomeopenres.16547.1>

Abstract

Background. The clinical and scientific importance of biobanks has been highlighted. Ethical governance and regulatory oversight for biobanks should be in place to preserve and promote ethical and responsible conduct of research.

Methods. This is an analytical documentary study of the regulatory scope concerning biobanks in Central America and the Dominican Republic. From the International Compilation of Human Research Standards 2020 edition of the Office of Human Research Protection Department of Health and Human Services of the United States of America identified the existing guidelines applicable to human research in each of the eight SICA member countries. Regulatory aspects searched for and the analysis was based on the recommendations set forth in Guideline 11 on the collection, storage, and use of biological materials and related data in the International Ethical Guidelines for Research Related to Human Health.

Results. There is a lack of specific guidelines for the collection, use, and storage of human biological materials for research purposes, and the creation of biobanks in the countries been studied. No country in Central America and the Dominican Republic region has specific regulations for the creation of biobanks for research purposes. The term "biobank" was not found in the revised regulations. However, there are good examples of ethical governance of research in general in the region been Costa Rica, Panamá, and Guatemala examples of advances towards this direction.

Conclusions. There is a need to move forward the governance and regulatory framework of biobanks in Central America and the

Open Peer Review

Approval Status ? ?

	1	2
version 1		
06 May 2021	view	view
1. Sergio Litewka , University of Miami, Miami, USA		
2. Nchangwi Syntia Munung , 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.		

Dominican which can be seen as an opportunity for international cooperation and regulatory collaborative agenda within this region.

Keywords

Biobank, Human biomaterials, Regulation, Research, Central America, Dominican Republic

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Author roles: Canario JA: Formal Analysis, Funding Acquisition, Investigation, Project Administration, Writing – Original Draft Preparation

Competing interests: No competing interests were disclosed.

Grant information: This work was supported by Wellcome [216288, <https://doi.org/10.35802/216288>] through a Global Forum on Bioethics in Research (GFBR) fellowship. GFBR funding is provided by the Wellcome Trust, the Bill & Melinda Gates Foundation, the National Institutes of Health and the UK Medical Research Council.

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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How to cite this article: Canario JA. **Comparative analysis of regulatory framework on biobanking to inform policymakers in Central America and the Dominican Republic [version 1; peer review: 2 approved with reservations]** Wellcome Open Research 2021, 6:95 <https://doi.org/10.12688/wellcomeopenres.16547.1>

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Introduction

Health research involving the use of human biological materials and related data is subject to widely recognised ethical considerations. National and institutional policymakers should adopt international ethical standards to ensure respectful and responsible collection, storage, and use of biospecimens to be used in research^{1,2}. The creation and use of biorepositories and biobanks for research purposes is a growing practice around the world. Biorepositories and biobanks offer many advantages to scientific activity, such as resource efficiency, access to biological materials, and the ability to reference related data that enables research that would otherwise not be possible. These advantages, as well as necessities, justify the increasing creation and use of these resource centres. As a result, the number of publications on biobanks has grown steadily over the past two decades. Additionally, the demands of the COVID-19 pandemic has underscored the importance of biobanks³.

A biobank is defined as a non-profit-making establishment that collects, processes, stores, and distributes biological samples of human origin and their associated data for research purposes⁴. There are international regulations and specific technical standards for creating and managing biobanks^{2,4-9}. Biobanks have been seen as a significant opportunity to advance biomedical research because it optimises the use of resources by avoiding collecting biological samples for each of the thousands of studies carried out in the world. It is a way to take advantage of scarce resources by reusing biological samples and associated data¹⁰ to increase the efficiency of research resources.

Conducting secondary analyses minimises unnecessary duplication of sample and data collection and avoids additional risks on participants¹¹. Furthermore, research quality can be improved when various researchers can review and verify the data, thus increasing reliability, reproducibility, and transparency^{12,13}. The donor and the family can also benefit, eventually, with the communication of clinically relevant incidental findings. There are relevant advantages of biobanks for the patients, including earlier and cheaper diagnosis, forecast system, new therapeutic targets, and personalised medicine. Biobanks may be useful at the population level in several instances, such as identifying risk factors, a diagnostic tool for prevention, improvement of public health policies, and equity in health.

There are many ethical challenges regarding the establishment of biobanks. Conversely, despite the benefits stated, ethical concerns are diverse¹⁴⁻¹⁶, starting with doubts about getting informed consent (IC). Obtaining the IC is an essential ethical requirement before sharing with third parties the data or material collected. However, IC models require careful consideration before use in biobanks¹⁷⁻¹⁹. The IC may be specific or broad. Specific IC is bound to a particular investigation, while broad IC refers to a donated sample in the context of a study yet to be applied to other unspecified research in the future²⁰⁻²². For the biobanks, the recommendation is that IC should be broad to fulfil the functions and purposes of this kind of biorepository.

Another ethical concern is the loss of privacy and confidentiality, which can occur when individual data associated with biological samples are shared^{23,24}. For analytical purposes, biobanks may require identifiers from the samples to which they have access. Removing case identifiers (de-identification) is a procedure used to protect individual data. However, there is still a risk of re-identification depending on anonymisation standards. Anonymisation refers to a process of hiding sensitive information to protect confidentiality. The lack of consistency in anonymisation is an ongoing problem²⁵, and there is even concern that this is not a sufficient procedure to avoid identifying the donor of the samples.

The challenge of promoting equity is the risk of exploitation. We must explore to what extent biobanks' creation can be useful in promoting justice, building capacity, and sharing benefits. There are fears and distrust given the prevailing view of the harmful results of collaborative research in the past, and there is a perception of protecting local scientists and populations²². Another issue related to justice is the inclusion of populations traditionally underrepresented but who do not benefit from the research results and the technologies resulting from them. Involving the community in the different stages of the research project means making them partners in the discussions where the research problem and the method are selected and during the analysis. Utilising community engagement strategies allow research participants and communities to be active entities, not a mere recipient of research outputs. Likewise, it is meaningful to involve them in conversations that seek to implement responsible, efficient, and fair governance frameworks to support the best ethical practices in biobanks and data exchange with cross-border harmonisation. The ethical governance of scientific research occurs within the framework of a broader system^{26,27} since it involves the various interest groups recognising their knowledge, attitudes, and perceptions regarding biobanks. Also, it should consider various mechanisms to meet the ethical requirements of this scientific activity²⁸. Governance itself has become an object of study²⁹, and its been used as a framework in the analysis of the ethics of data sharing and biobanking in health research³⁰.

Health research in the member states of the Central American Integration System (SICA)

The Central American Integration System (SICA) is the institutional framework for Central American Regional Integration made up of eight countries, including Guatemala, El Salvador, Panama, Honduras, Costa Rica, Nicaragua, Belize, and the Dominican Republic. According to Economic Commission for Latin America and the Caribbean (ECLAC) data (2016), this subregion has more than 57 million inhabitants with an average life expectancy at birth of 75.1 years. It has 63 indigenous peoples. In political terms, the SICA states have had 30 years of peace, democracy, and political stability³¹. While this is true, the last few years have seen reversing trends in the political spheres, and there is a climate of crisis in several SICA countries. In economic terms, Belize's Gross Domestic Product is the lowest (3.22), and the

Dominican Republic is the highest in the region (173). The region's unemployment rate ranges from 2.3 to 9%. There are marked differences in health indicators such as infant mortality rate (range 7.8 - 23.3), the maternal mortality rate (27-198), and health expenditure (6.1-7.8) (Table 1).

Clinical trials conducted in the SICA Member States during the entire data registration period of 2020 are available on the clinicaltrials.gov website (www.clinicaltrials.gov). A total

of 1,119 are reported for SICA Member States; of those 13 in Nicaragua and 308 in Guatemala are reported (Table 2). As most countries in the region do not have the requirement to register all clinical trials, the number of clinical trials conducted in this region may be higher. In Central America and the Caribbean, there is currently no information regarding the status of normative (laws, guidelines, or recommendations) regulation of the creation of biobanks for research purposes. The problem is that, in the absence of a framework that

Table 1. Summary of economic and health indicators in the Central Americas and the Dominican Republic.

Country	Gross Domestic Product ^a	Unemployment rate ^b	Health expenditure ^c	Child mortality rate ^d	Maternal mortality rate ^e
Dominican Republic	173	5.1	6.2	22.7	95
Guatemala	138.1	2.3	5.	23.3	95
Panamá	104.1	6	7	9.6	52
Costa Rica	83.94	8.1	7.6	7.8	27
El Salvador	51.17	7	7	16.3	46
Honduras	46.3	5.6	7.6	16.7	65
Nicaragua	36.4	6.4	7.8	17.7	198
Belize	3.22	9	6.1	12	36

Source: CIA World Factbook

^a<https://www.indexmundi.com/g/r.aspx?t=0&v=65&l=es>

^b<https://www.indexmundi.com/g/r.aspx?t=0&v=74&l=es>

^c<https://www.indexmundi.com/g/r.aspx?t=0&v=2225&l=es>

^d<https://www.indexmundi.com/g/r.aspx?t=0&v=29&l=es>

^e<https://www.indexmundi.com/g/r.aspx?t=0&v=2223&l=es>

Table 2. Clinical trials in SICA countries according to clinicaltrials.gov.

Country	Number of clinical trials registered in clinicaltrials.gov December 2020
Guatemala	308
Panamá	292
Costa Rica	191
Dominican Republic	184
Honduras	67
El Salvador	43
Belize	21
Nicaragua	13

Source: www.clinicaltrials.gov

encompasses ethics, regulations, and governance at the national level, there is an increased risk of exploitation to vulnerable populations. Simultaneously, there are ethical doubts about applying IC, the proper handling of data, policies to ensure access to data, the return of research results, the democratisation of knowledge, shared benefits, and social justice³².

The 2018 Global Forum on Bioethics in Research (GFBR) had the theme “data sharing and biobanks.” The discussion focused on the main challenges around ensuring participants’ rights and the need to increase efficiency in scientific efforts. Key

governance issues were identified as a result of discussions among 95 participants from 35 countries³³. The status of biobank regulations in Central America and the Dominican Republic is currently unknown. The following study aims to analyse the current regulatory framework by identifying deficiencies and gaps in biobanking governance.

Methods

Design

This study is an analytical documentary study of the regulatory scope concerning biobanks in SICA member States. [Table 3](#) presents regulatory aspects set out in the guideline

Table 3. Regulatory aspects of the collection, use and storage of human biological materials and research-related data as set out in CIOMS Guideline 11.

Regulatory element
Legal status of the biological sample. It is a regime analogous to the donation of organs and tissues of the human body (res extracommercium)
Samples as a medium for personal information
Data from sample analysis (protection of genetic data)
Collection and use of living donor biological samples / use of tissues or body parts
Biobank definition
Scope of application. The standard refers to cases in which the collection of biological samples of human origin and associated data is applicable for research purposes or when these materials are collected for other purposes but there are expectations of a possible use in research
Origin of biological samples. Declaration of origin of samples, collected for the specific purpose of research or for another purpose. A remnant remains with the expectation of future use in research.
Conditions of consent. Specific IC: specific informed consent for a particular use, broad IC: for an unspecified future use, Children and adolescents: they are asked to consent once they are adults, Results and unsolicited findings, Decisions on aspects not foreseen in the IC, Historical collections of biological samples.
Organization, Responsible institution, Institutional support
Procedures, Standardized Operations. Data storage, security and confidentiality. Link between donor materials and personal identifiers. To inform donors or participants in scientific research about revocation rights and processes. For data access and sample availability. Quality management with documentation, records, biosafety and training
Human Resources. Director, scientific-technological responsible
Research Ethics Committee
Community Involvement. Guideline 7, Community Involvement
Infrastructure and operation Prepared areas, Qualified personnel, Quality assurance plan, Equipment, Confidentiality - Information protection system, Biosafety plan, Preventive maintenance plan, Disaster contingency plan, Internal audit
Distribution of samples and data (ATM) Guidelines and mechanisms for the transfer or submission of samples and related data.
Destination of samples and/or biobank data. Social Value, Access to Benefits: Provide for the return of data to the original environment and share possible results and benefits, if data is stored outside the original environment, Disclosure of results, Data Sharing and Guidelines 8, Research partnerships and capacity-building and research review, On intellectual property derived from research with samples from a BB
Sustainability plan. Plans to maintain biological and biobank samples with the appropriate resources over time and safely
Closure. Guidelines describing procedures for the final closure of a biobank

11 of the International Ethical Guidelines for Health-related Research Involving Humans applicable to the collection, use, and storage of human biological samples and the creation of biobanks, including topics such as a) the protection of human beings (b) the technical aspects of the organisation, operation, sustainability, closing of biobanks); and (c) the forms and conditions for sharing data, results, and dissemination shared benefits and the involvement of the community and interest groups in research.

Data sources

The [International Compilation of Human Research Standards](#) 2020 edition of the Office of Human Research Protection Department of Health and Human Services of the United States

of America was used to identify existing guidelines applicable to human research in each of the eight SICA member countries ([Table 4](#)). Of the eight countries located in Central America and the Dominican Republic, only Belize have no reported regulations. Nicaragua, which was previously absent at the beginning of this study in 2018, was included in 2020.

Procedures for identifying data

The regulatory aspects in [Table 3](#) were used, as a checklist, to review the presence or absence of the regulatory in each country. To facilitate the identification of relevant data, in each regulatory document we conduct a search utilizing the following keywords: “biological material”, “biological sample”, “biorepository”, and “biobank”. Also, the content

Table 4. Normative documents of health research by countries of the Central American region and the Dominican Republic.

Country	Organization	Legislation	Regulation	Guidelines
Costa Rica	Ministry of Health: http://www.misalud.go.cr National Health Research Council: http://www.ministeriodesalud.go.cr/index.php/consejos/conis	Regulatory Law of Biomedical Research No. 9234 (2014): http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=77070&nValor3=96424&strTipM=TC	1. Regulatory Decree N° 39061-S (2016) on the Regulatory Law of Biomedical Research N° 39533-S: http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=81213&nValor3=103450&strTipM=TC 2. Reforms to the Regulatory Decree No. 39533-S (2016) Regulatory Law of Biomedical Research No. 9234: http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=81213&nValor3=103450&strTipM=TC	Various: https://www.ministeriodesalud.go.cr/index.php/consejos/conis
El Salvador	National Health Research Ethics Committee: http://www.cneis.org.sv/			1. Standard Operating Procedures for the Ethical Evaluation of Health Research (2015): http://cssp.gob.sv/wp-content/uploads/2016/06/MANUAL-CNEIS-2017-03-15.pdf 2. Manual on the Functioning of the National Health Research Ethics Committee (2017): http://cssp.gob.sv/wp-content/uploads/2016/06/manual_funcionamiento_comite_nacional_etica_investigacion_en_salud.pdf User's Guide for the Application of Clinical Investigation Protocols: https://www.medicamentos.gob.sv/index.php/es/servicios-m/descargables/ensayos-clinicos

Country	Organization	Legislation	Regulation	Guidelines
Guatemala	Ministry of Public Health and Social Assistance: http://www.mspas.gob.gt/		1. Governmental Agreement 712-99, Articles 91-94 (1999): http://asisehace.gt/media/ag_712_99.pdf 2. Rules for the Regulation of Human Clinical Trials. Ministerial Accord 82-2019: https://medicamentos.mspas.gob.gt/phocadownload/Acuerdo%20Ministerial%2082-2019.pdf	Drug Surveillance -- Clinical Trials: http://www.mspas.gob.gt/index.php/servicios/farmacovigilancia
Honduras	Secretariat of Health: http://www.salud.gob.hn/	Law of Donation and Transplantation of Anatomical Organs in Human Beings (2014): http://www.tsc.gob.hn/leyes/Ley_donacion_transp_organos_2014.pdf%20n.%20329-2013	Health Code, Decree No. 65-91, Articles 175 and 176: https://www.acnur.org/fileadmin/Documentos/BDL/2016/10636.pdf	
Panamá	Ministry of Health (MINSA): http://www.minsa.gob.pa/ ICGES Bioethics Research Committee (CBI): http://www.gorgas.gob.pa/index.php?option=com_content&view=article&id=54&Itemid=103&lang=es	Law 1 of 2001, Official Gazette 24,218 (Drugs, Biologics, and Devices): http://www.perezcarrera.com/leyes/ley-registro-sanitario-panama.pdf Law 68 of 2003, Official Gazette 24,935 (Privacy/Data Protection) Law 3 of 2010, Official Gazette 26,468-B on Transplant of Organs and Tissues (human biological materials): https://www.gacetaoficial.gob.pa/pdfTemp/26468_B/GacetaNo_26468b_20100210.pdf	Executive Decree No. 2 on Stem Cells (2013),) Embryos, Stem Cells, and Cloning): http://www.gacetaoficial.gob.pa/pdfTemp/27207/40367.pdf Executive Decree No. 2 on Stem Cells (2013): http://www.gacetaoficial.gob.pa/pdfTemp/27207/40367.pdf	CBI: Various: http://www.gorgas.gob.pa/index.php?option=com_content&view=article&id=54&Itemid=103&lang=es https://www.gacetaoficial.gob.pa/Busqueda
Dominican Republic	National Council on Health Bioethics: http://conabios.gob.do/	National Health Law 42-01, Chapter VI (general): https://repositorio.msp.gob.do/bitstream/handle/123456789/793/LeyNo.%2042-01.PDF?sequence=1&isAllowed=y National Health Law 42-01, Book Five (Materiales biológicos): https://repositorio.msp.gob.do/bitstream/handle/123456789/793/LeyNo.%2042-01.PDF?sequence=1&isAllowed=y	Regulation for Evaluation Request for a Clinical Investigation Project: http://conabios.gob.do/wp-content/uploads/2018/07/Formulario-para-Someter-Proyectos-de-Investigaci%C3%B3n-al-CONABIOS-2014.doc-Documentos-de-Google.pdf	
Nicaragua	Ministry of Health (MINSA) Nicaragua: http://www.minsa.gob.ni Institutional Ethical Review Committee (CIRE)	Ley General de Salud, No 423 Republica de Nicaragua: http://www.vertic.org/media/National%20Legislation/Nicaragua/NI_Le_y_423_General_de_Salud_2002.pdf		

There is no data for Belize.

Source: Office for Human Research Protections, U.S. Department of Health and Human Services, International Compilation of Human Research Standards, 2020

was reviewed thoroughly to make sure that no relevant data was excluded or not identified.

Analysis plan

The analysis plan presents a synthesis of the information found in the review of the regulatory documents in each country. We will focus on [Guideline 11 on the collection, storage, and use of biological materials and related data](#) of the International

Ethical Guidelines for Research Related to Human Health³⁴, in addition to Guideline 7 on community involvement.

Results

The study's first finding was a pervasive lack of specific guidelines for the collection, use and storage of human biological materials for research purposes, and the creation of biobanks in the countries studied. No country in SICA has specific

regulations for the creation of biobanks for research purposes. The term “biobank” was not found in the revised regulations. The Costa Rican regulation appropriately covers various protection elements for participants and minimal requirements for laboratories participating in clinical research. Guatemala and Panama also consider several fundamental aspects of the regulation of research involving human beings. However, the necessary provisions for the proper governance and monitoring of the collection and use and storage of human biological materials are meagre.

It is important to note that the current regulatory framework in Central America and the Dominican Republic demonstrates a duty to submit to ethical review when the research requires collecting human biological samples. While the ethical regulation of research in the various countries include the ethics review by Research Ethics Committees and National Council on Bioethics/Research Ethics depending on the country formal institutional organisation, other ethical considerations have been left out or not addressed in sufficient depth. There is no reference of conditions for conducting studies under the comprehensive IC; the IC for children and adolescents; the communication of unsolicited results and findings; and decisions on aspects not provided for in the IC. Additionally, no considerations regarding community involvement or shared benefits were found.

The following is a summary of the findings for each of the countries with identified regulations (see also [Table 4](#)).

Costa Rica

The Regulation of the Biomedical Research Act N° 39061-S in Chapter III on Biological Samples of Human Material, Article 10 sets out the minimum requirements for clinical research laboratories. Article 11 guides the management of biological laboratories. The ethical regulatory framework of research with human biological samples must consider this case since it includes principal issues.

This standard defines the research site as the “place where research activities are carried out or where samples of biological material or research products are stored, stored or dispensed, which must have the health clearance corresponding to their category of the establishment”. The Regulation Reform to the Biomedical Research Regulatory Law N° 39533 -S establishes that: “Laboratories shall be responsible for verifying that the transport agency complies with the requirements established by the United Nations Committee of Experts for the Transport of Samples, and any other national or international binding standards.” Besides, it requires specifying the last purpose of the participant’s medical records and biological samples (Article 16). Concerning the future of the samples, the regulation establishes the protocol: “destroy the biological samples obtained when the research is completed and, if not, details their storage (where, how, for how long and their final disposal). The participant may refuse storage (Article 17).”

Guatemala

Guatemala has rules for the regulation of clinical trials in humans published in the Ministerial Agreement number Law 299-219 of December 12, 2019, by the Directorate General of Regulation, Health Surveillance and Control of the Department for the Regulation and Control of Pharmaceutical and Related Products of the Ministry of Public Health and Social Welfare. The rules frame the regulations and essential characteristics of governance in the use of biological samples of human origin for research purposes in a pragmatic way. Specifically, these regulations deal with the processing of samples obtained in clinical trials, which must have adequate equipment and material for the processing and proper preservation of the specimens. If the unit carries out analytical determinations of investigational medicinal products or any of its metabolites, its operation must comply with Good Laboratory Practice requirements established by the Department of Regulation and Control of Health Establishments (DRACES).

Panamá

Law 84 of May 14, 2019, regulates and promotes research for health, establishes its direction and governance, and dictates other provisions. Article 11, of Chapter 1 on the exercise of the Leadership of Title II Governance, indicates that the Ministry of Health, through the National Committee on Bioethics of Research, will monitor compliance with the ethical review of research with human participants and responsible conduct of research for health. Decree No. 2 of 2013 establishes guidelines for stem cells in the Republic of Panama, addresses stem cell therapies but not their use for research purposes. Although the document is outside the scope of this analysis, this rule seeks to regulate the operations related to stem cell laboratories. Panamanian law names a “Director of Research” within laboratory staff, assuming research will take place.

Article 16 indicates that the CNBI will review stem cell studies, and article 17 in paragraph 4 establishes requirements and standards for clinical trials with stem cells. The main objectives are to define who can start a clinical trial and how to minimise risks by presenting safety studies.

Law 3 of February 8, 2010 on the transplantation of anatomical components establishes that the Ministry of Health will regulate all stages related to the anatomical components of living or dead donors, including their storage. Art. 18 only allows the exchange of anatomical components of deceased donors with countries that have signed agreements for this purpose.

On the other hand, Executive Decree 179 of June 2018 that regulates research with tissues and cells of human origin in the Republic of Panama, establishes that the use of tissues and cells of human origin for clinical research in humans will be evaluated by the National Research Bioethics Committee

(CNBI) in accordance with the national regulations that regulate clinical research, the CIOMS international ethical guidelines for health-related research in human beings in collaboration with the WHO, the principles set forth in the declaration of Helsinki of the World Medical Association the standards of Good Clinical Practice (GCP) derived from the International Conference on Harmonization (ICH) and other agreed international guidelines on the matter.

El Salvador

There is a Manual of Standard Operating Procedures for Health Research Ethics Committees drafted by the National Committee on Health Research Ethics. This document serves as a standard for ethical review. The following citation appears in this document: “For research already initiated with molecules, invasive clinical procedures, management of blood samples or collection of biological tissues for genetic analysis, which have not received an initial audit, the CNEIS shall indicate an audit of studies already initiated.” Additionally, Procedure 3 on “Determining the Type of Project Evaluation” stipulates that expedited evaluation as a possible mechanism for evaluating studies involving materials already collected, which may be data or samples. In El Salvador, there are no specific regulations in this area of biobanking.

Honduras

In Honduras, the Health Code (GACETA NO.26509 DEL 06/08/1991) issued by Decree No. 65-91 of 28/05/1991, in Title III on health professionals in Article 0175 provides the following instruction: “All scientific research involving human subjects must be carried out by professionals specialised in the field and establishments with the appropriate facilities, equipment and materials for each case, following special regulations approved by the Ministry Furthermore, Article 0176 states: “No one may be subjected to the investigations indicated in the previous article, without being previously informed of the risks to which he will be subjected to and without obtaining his written consent or that of his representative in case of incapacity.” In this case, the Honduran regulation on organ transplantation alludes to biological samples in educational and research practices.

Dominican Republic

The General Health Law refers to research activity as an essential function of public health. It mentions certain considerations for establishing research priorities, such as the socio-sanitary reality, the causes and mechanisms that determine the modes and means of preventive and curative intervention and the evaluation rigorous of the effectiveness and efficiency of the interventions. Specifically, paragraph 11 refers that the Ministry of Health will prepare the regulations that are required for the application of the listed actions and that investigations should adhere to scientific principles and nationally and internationally approved bioethics. There is no specific regulation in research, and no content is provided for the collection of biological samples and associated data or biobanks in the revised documents.

Nicaragua

The General Health Law 423 states the role of the Ministry of Health to regulate and promote scientific research in health and biomedical and development and transfer of technology within the Health Sector, also promote the education and training of health researchers. No specific element exists referring to the collection, storage and use of biological materials, and related data and analysis regarding the creation of biobanks for research purposes. Also, in the Ministry of Health there will open a Program and a Committee National Research Council in charge of promoting and prioritizing, issues that contribute to improving the health of the population. The Research must refer to scientific and ethical principles internationally approved. For the application of the indicated actions, will develop a regulation.

Discussion

The present study aimed to analyse the guidelines for collection, storage and use of biological materials, and related data and analysis regarding the creation of biobanks for research purposes in the Member States of the Central American Integration System and the Dominican Republic (SICA). We have sought to identify gaps in existing regulations that hinder proper governance and adequate protection for people who donate biological material with this analysis. The findings indicate that SICA states have not developed technical, legal, and ethical guidelines or regulations on biobanks. Costa Rica is the only country in the SICA region that displays guidelines for collecting, storing, and using biological materials and related data for research purposes. The Guatemalan regulation has taken steps in that direction but these are not currently sufficient for biobank use.

In other countries, regulatory ethics provisions are much smaller and practically non-existent. Even the fundamental elements concerning the legal status of the biological sample, samples as a medium of personal information, data obtained from the analysis of samples (protection of genetic data), and the collection and use of living donor biological samples, or the use of tissues or body parts have not been addressed from a research point of view. The provisions on organ donation in these countries are not necessarily sufficient or applicable to the research context.

At the same time, the lack of definition creates legal loopholes: what a biobank consists of, its scope of application, the origin of biological samples, standard operating procedures, human resources, infrastructure and operation, distribution of samples and data in transfer agreements, destination of specimens or data, sustainability plan and closure of activities. The existence of national regulations governing biobanks for research purposes in African, Asian, and South American countries indicates a global movement to adopt norms at the local level.

In times of COVID-19, it is relevant to mention the lack of collaboration and the waste of limited resources^{34,35}. Many countries have conducted international clinical trials involving

the storage of genetic material often shipping those materials outside the country to other facilities and laboratories with the capacity to analyse those samples, without an agreement to transfer biological material. We have found that there are still countries in the Central American region that have not yet established comprehensive and adequate normative frameworks for research involving human beings. This systemic problem must be addressed in a comprehensive way to cover more specific issues such as biobanks, collection, and storage and use of human biological samples.

The current regulations are limited to a subset of ethical matters and leave out important issues. The assertion that in low and middle-income countries, there are no appropriate regulations or governance mechanisms in biobanks is confirmed^{36,37}. For example, as De Vries *et al.* observed in regulations on genetic research in Africa, these are virtually non-existent, outdated, conservative, inefficient or difficult to navigate²³.

As a document review, this analysis has a limitation: it cannot identify the practices regarding the application of international ethical standards in the collection, storage and use of biological materials, and related data. In this sense, the lack of knowledge of actual practices can only be observed in another type of research design. The deficiency of regulations and their supervision may lead to practices that increase the vulnerability of people who donate biological material and fail to uphold their fundamental rights and human dignity. This study does not capture this incidence. Additionally, in order to provide a full picture of all relevant regulatory aspects concerning collection, storage and use of human biological material it would be necessary to review regulations applicable to the general use of samples, personal data protection laws, human genome (anti-discrimination), and donation of human tissue for research purposes which were not revised in this study.

Conclusions

This review of the regulatory framework of biobanks of the states that make up the SICA region shows the absence of national regulations in this area. The legislation in place is based on

fundamental principles of research ethics with human beings and does not incorporate elements contained in current international ethical norms. It is essential to note the interest of SICA authorities in building scientific exchanges in the region, according to a recent call to form research and scientific exchange networks. It is hoped that such initiatives will impact the Central American and the Dominican Republic region. However, under a poorly developed regulatory framework, these initiatives may face many problems accomplishing their goals and meeting international ethical standards when collecting, storing and using human biological samples.

It is highly recommended to launch an initiative based on regional scientific exchange mechanisms and, simultaneously, within the framework of the Council of Ministers of Health of Central America (COMISCA), to advance in the development of a framework of ethical governance in health research relevant to the collection, storage and use of biological materials, and related data covering the creation of biobanks for research purposes as well. Small biorepositories maintained by individual researchers or in research centres may benefit from this kind of regulation. They may scale their biorepositories to a formal biobank as a national and regional biobank that may significantly impact their work. Following this direction avoids the duplication of efforts, the lack of collaboration and formalisation of research that still is a weakness in Latin America³⁸. In the midst of difficult times, it is also an opportunity to work together towards a regional mechanism that advance collaboration through international cooperation such as those recently implemented by SICA Executive Secretariat to advance research networks within the region. A similar effort to advance research ethics governance and regulation in biobanking and research, in general, is urgently needed and forthcoming.

Data availability

Underlying data

Data pertaining to the regulations discussed in this work are available in [Table 4](#).

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Current Peer Review Status: ? ?

Version 1

Reviewer Report 27 May 2021

<https://doi.org/10.21956/wellcomeopenres.18233.r43799>

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? **Nchangwi Syntia Munung**

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This manuscript presents the results of a thematic analysis of biobanking guidelines in the Member States of the Central American Integration System and the Dominican Republic. It is a very comprehensive review and the guidelines for each country are mapped to that of the CIOMS guideline 11. The paper will be a good resource for stakeholders interested in biobanking in the SICA region.

Major Comments:

Introduction

Paragraph 4: The sentenceconversely, despite the benefits stated, ethical concerns are diverse, starting with doubts about getting informed consent.... may need to be explained further for clarity. I do not think there has been any/much doubt about getting informed consent for sample storage. The main issue seems to be the type of consent (specific, broad, etc.) that may be more appropriate.

In the last paragraph of the introduction, there is an underlying assumption that biobanks are often set up between local and international collaborators and that local sites often do not have the capacity to establish, maintain and use the biobanks. This is not always true. Many countries have set up national and institutional biobanks without international collaborators. If the author is specifically referring to the case in SICA, then this needs to be made clear in the introduction, and information on biobanks in the region should be provided, including why issues of justice, capacity building and benefit sharing should be a major concern. Another example provided by the author on justice-related issues relates to the inclusion of populations traditionally underrepresented but who do not benefit from the research results and the technologies resulting from the use of biobanks. However, a potential reader is left with little information on the nature and types of biobanks in the study region, and if some populations are currently underrepresented or if there are concerns around the exploitation of populations. The paragraph (and the introduction) as a

whole needs to provide context to the biobanking situation in the study region

Based on the above, I also suggest that the author considers trimming the information on clinical trials, GDP and health indicators and rather include more information about biobanking activities in SICA, including how they compare to each other and why it was necessary to undertake the analysis of national guidelines.

Methods

The manuscript includes information on the CIOMS guidelines (Table 3) and it is stated that the CIOMS guidelines were used as a checklist, to review the presence or absence of specific biobanking regulation in countries in SICA. More information is needed in the methods section on why the CIOMS guidelines selected as a standard for mapping the content of the different national guidelines, and not for example other international guidelines like the Declaration of Helsinki or the OECD guidelines on Human Biobanks and Genetic Research Databases.

Results

The results should also include information on how each country's guidelines compare to the CIOMS e.g. country X met 50% of the CIOMS requirements etc. This is important as it will give the reader an idea of how each country is fairing with respect to the CIOMS. The author may consider including a table that shows each CIOM guideline on biobanking and whether not it is covered in the respective SICA countries.

The title of the paper suggests that this was a comparative analysis of the regulatory framework on biobanking to inform policymakers in Central America and the Dominican Republic. However, in presenting the results, the author gives a narrative description of the guidelines in each country and no major comparison is made. I will suggest that the author considers either 1) revising the title or 2) include a table or text on how the guidelines compare to each other. If the author agrees with the suggestion above, then the table could address this concern.

Minor comments:

Page 1: Please provide a reference for the statement on ethical considerations as your potential readers may not be familiar with the range of ethical issues.

The statement "As a result, the number of publications on biobanks has grown steadily over the past two decades" also needs to be referenced.

Introduction could be shortened- some text repeated in paragraphs one and three on the uses/importance of a biobank.

Paragraph 4- First sentence can be dropped- it is repetitive.

Is the work clearly and accurately presented and does it cite the current literature?

Yes

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?

Yes

If applicable, is the statistical analysis and its interpretation appropriate?

Not applicable

Are all the source data underlying the results available to ensure full reproducibility?

Yes

Are the conclusions drawn adequately supported by the results?

Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Research ethics- genomics, infectious disease control

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.

Reviewer Report 18 May 2021

<https://doi.org/10.21956/wellcomeopenres.18233.r43802>

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Sergio Litewka

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The author did exhaustive research about biomedical research and health-related personal information regulatory framework in 8 Central American and Caribbean countries. He defines “biobanks” as “non-profit-making establishments that collect, process and distributes biological samples of human origin and their associated data for research purposes.” However, being non for profit is not a sine qua non-condition for being considered a biobank. Shanghai Zhagjiang Biobank, one of the biggest biobanks globally, is a for-profit initiative (see <https://www.biobanking.com/the-shanghai-zhangjiang-biobank/>). Probably the author was referring to those repositories in place in Central American and Caribbean countries,

Importantly, the author expresses his concern about the protection of personal data, as well as whether “biobanks’ creation can be useful in promoting justice, building capacity and sharing benefits’, therefore it would be helpful to consider those situations in which biobanks are not physically present in any of the researched countries, and yet, personal genomic information (as well as any other biological information) may be used for research with or without the subjects’ consent.

In this Big Data and Artificial Intelligence era, the traffic for personal information, particularly

biomedical and genomic data, is global. Just an example: BGI, a Chinese genome-sequencing company, is receiving information from most than 50 laboratories worldwide to create China's national library of genomic data. (see <https://www.foreignaffairs.com/articles/united-states/2021-02-10/technology-innovation-wars>) (<https://en.genomics.cn/>)

In sum: I think that this article offers a valuable opportunity for analyzing the current shortcomings existent in Central American and Caribbean biobanking regulations and, as such, it deserves to be published.

However, the article would gain interest if the author would elaborate a little more on the laws on the use of personal information related to biomedical research considering the novel aspects generated by globalization, the use of Big Data, and existing biotechnological advances.

Is the work clearly and accurately presented and does it cite the current literature?

Yes

Is the study design appropriate and is the work technically sound?

Partly

Are sufficient details of methods and analysis provided to allow replication by others?

Yes

If applicable, is the statistical analysis and its interpretation appropriate?

Not applicable

Are all the source data underlying the results available to ensure full reproducibility?

Yes

Are the conclusions drawn adequately supported by the results?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Research ethics, research integrity

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.