Biorepositories for the Public Good, Part II:

Benefits and Ethical Considerations for Access to Specimens for Epidemic Preparedness

December 5, 2024

09:00 EST | 14:00 GMT | 07:00 MST

THE GLOBAL HEALTH NETWORK
Enabling research by sharing knowledge

Colorado School of Public Health
Center for Global Health

CONTAGIO
COHORTS NETWORK TO BE ACTIVATED GLOBALLY IN OUTBREAKS

Register

Housekeeping

- This webinar is being recorded and will be shared on **The Global Health Network platform**.
- To automatically translate the speech to subtitles in your chosen language, navigate to the ***Closed Captions function*** and select your language.
- Due to the number of participants, your video and microphone have been disabled.
- Please use the ***Chat function*** to introduce yourself or to report any technical issues.
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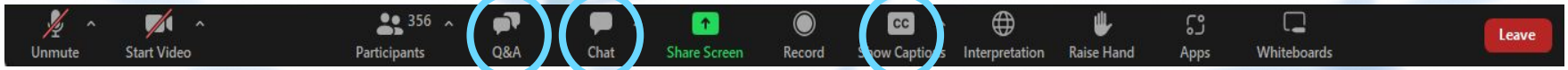


Panel & Agenda

I. Welcome

Opening welcome and webinar goals - **May Chu**, PhD, Colorado School of Public Health

Housekeeping information - **Zoe Steinberg**, MPH, Colorado School of Public Health

II. Presentations: Benefits and Barriers to Access

Chair: María Consuelo Miranda Montoya**,** MD, Universidad Industrial de Santander

Introduction to the VBS and Benefits

Judith Giri, PhD, Colorado School of Public Health

Access and Benefit Sharing

Rebecca Katz, PhD, MPH, Georgetown University

Ethical barriers: broad consent

Lauren Maxwell, PhD, Heidelberg University

The Fiocruz Biobank Network- Infectious Diseases Biobanking: Pitfalls and Solutions

Daiane Franciele Francisco Sertorio, Coordinator, Fiocruz Biobank Network

III. Discussion: Solutions to Barriers and Optimizing Benefits

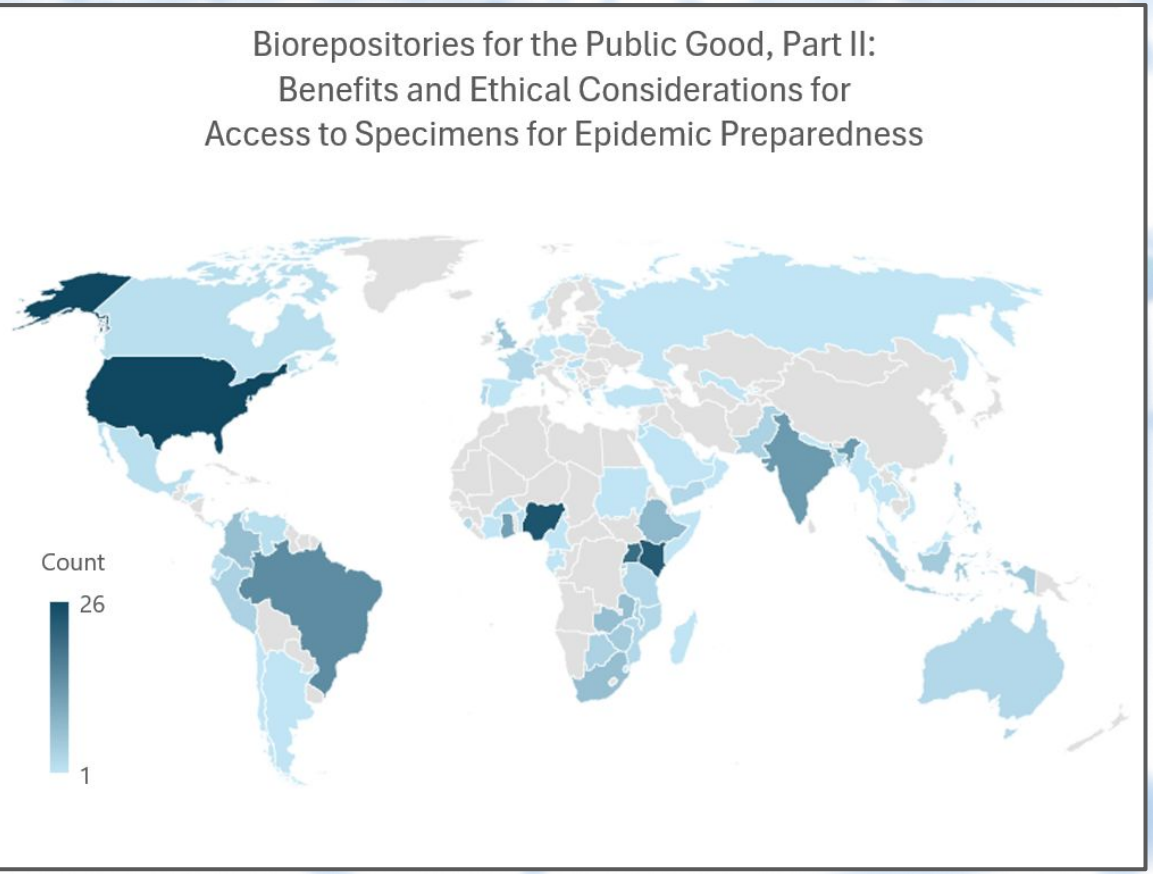
Facilitator: Amy Price, PhD

IV. Closure

Zoe Steinberg

Registered for today's webinar - *Thank you!*

	Country	Count
1	United States	26
2	Nigeria	24
3	Kenya	23
4	Uganda	20
5	Brazil	15
6	India	13
7	Ghana	12
8	Ethiopia	8
9	South Africa	7
10	Colombia	7
11	Zambia	7
12	United Kingdom	6
13	Congo, Democratic I	6
14	Rwanda	5
15	Indonesia	5
16	Zimbabwe	5
17	Pakistan	4
18	Switzerland	4
19	Peru	4
20	Malawi	4
	Total	
	76	300



Introduction to the Virtual Biorepository System and Benefits

Judith Giri, PhD
for the VBS team

The Virtual Biorepository System (VBS)

Concept is to collect specimens for improving preparedness against epidemics by providing an equitable and transparent process to access samples

Specimen sharing for epidemic preparedness: Building a virtual biorepository system from local governance to global partnerships *.PLOS Glob Public Health*. 2023 Oct 11;3(10):e0001568. doi: 10.1371/journal.pgph.0001568. PMID: 37819913; PMCID: PMC10566708.

The Virtual Biorepository System

- The goal is to build a trusted, globally representative source of specimens and associated data for calibration of diagnostics, evaluation of vaccine efficacy, and for research and surveillance.

- The VBS was conceptualized to establish a sustainable and equitable system for sharing specimens for future outbreaks, a need identified during Zika, COVID 19.

- A unique feature of the VBS - it is a distributed system: local management of specimens, maintained at the institution where they were collected, while ensuring common standards of quality and equitable accessibility.

PREMISE

PANDEMIC RESPONSE REPOSITORY

MICROBIAL/IMMUNE SURVEILLANCE AND EPIDEMIOLOGY

Sharing information with:

Operating Principle for the Virtual Biorepository System

Biorepositories must **evolve** to meet the need for transparent, equitable access to samples, and develop trusted, sustainable resources that provide **long term stewardship**; one model may not fit all needs.

- The VBS: a platform that helps connect contributors and end users to meet their needs for characterized, quality samples
- Provide reference material (by the group, or link to existing services)

- Hub for templates, training, skills advancement or links to other resources
- Data and site mapping for easy to find/links
- Align with other similar/parallel efforts to be stronger and more useful

Participatory Approach to VBS Development

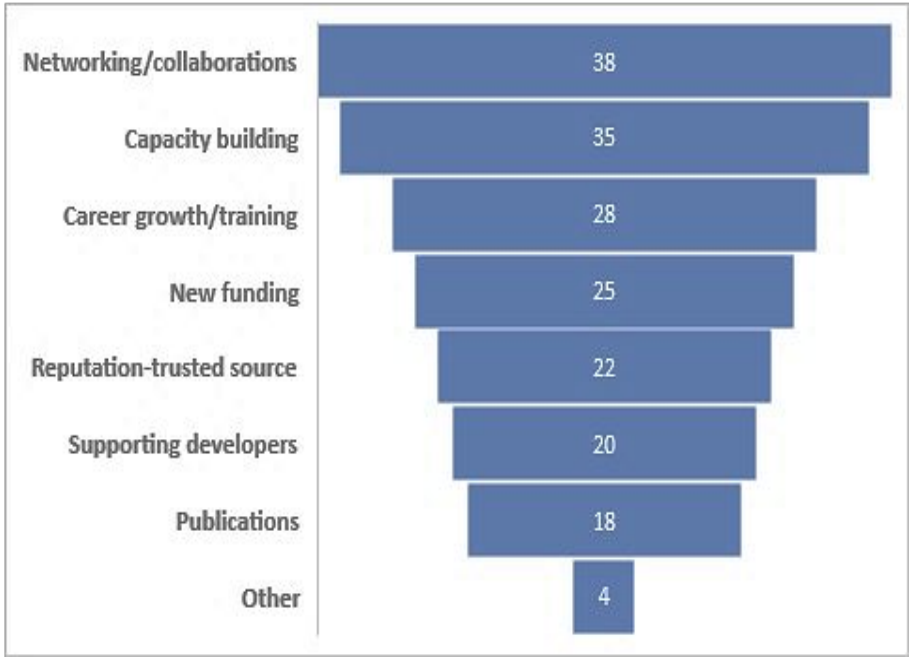
- We have employed surveys, expert interviews, webinars and workshops to understand the needs for specimens, current gaps and barriers to access, and what benefits the VBS could provide for long term sustainability.

- Between 2020-2022 we surveyed and interviewed stakeholders representing both specimen providers and users and diagnostics manufacturers.

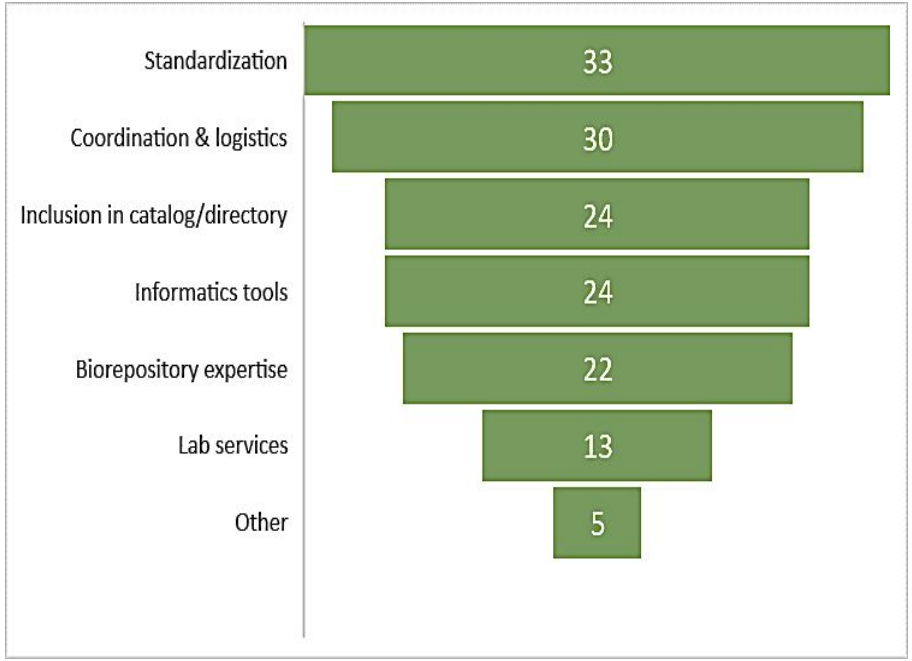
- Participants included a broad group of stakeholders: representing broad geographic distribution and different organizations and roles within organizations.

Virtual Biorepository functions and services of greatest benefit:

For Investigators and their Institutions



For Biorepository Operations



From "Benefits of Contributing to a Virtual Biorepository (VBR) Resource for Coordinated Access to Clinical Specimens" survey

Results of interviews (1)

Common gaps and barriers of high concern:

a) **Timely access** to characterized high quality specimens
b) **Availability of specimen types needed for pathogen detection and test development;** longitudinal collections and specimens collected at different times in an outbreak (before, during and after)
c) **Access to reliable and complete accompanying information** (clinical data, specimen handling conditions)
d) **Need for sample panels and reference materials for quality assessment and validation**

Results of Interviews (2):

Recommended VBS features:

a) **Set criteria for specimen and data quality** for inclusion into the VBS, with potential grading to indicate fit for different uses

b) Access to software as needed to facilitate data sharing and resolve the hurdles created by use of disparate platforms

c) Standardized MTAs and negotiations to facilitate sharing and to enable agile responses in cases of public health emergencies

d) Emphasis on quality including biorepository operations, such as standards for managing and preserving specimens

e) **Facilitation of access with a simplified review process**

f) Building biobanking capacity and trust in LMICs to enable equitable access to specimens and benefits

From Concept to Implementation

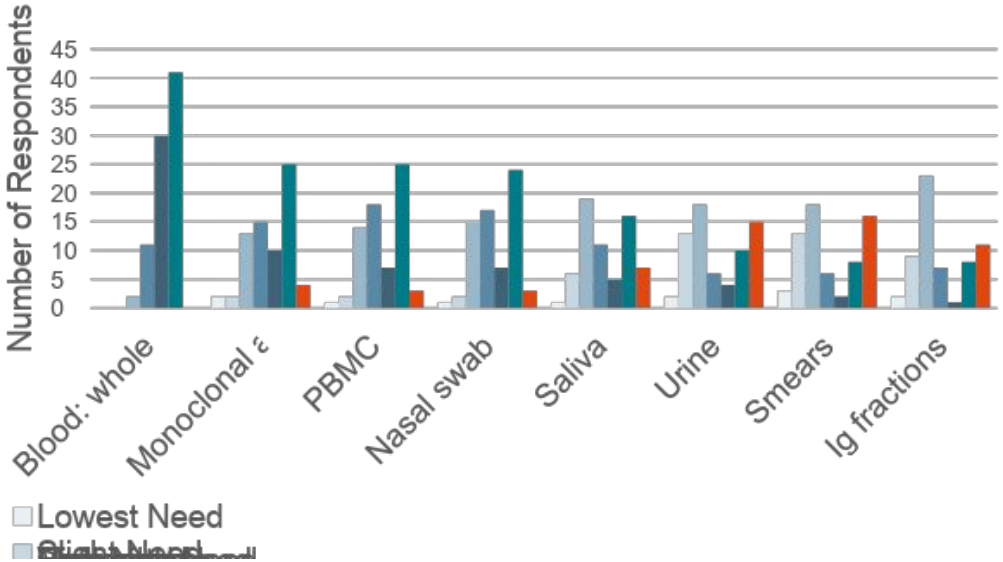
VIRTUAL BIOREPOSITORY

To prioritize actions for implementation of the VBS, we used a Delphi consensus process with inputs from stakeholders with interest in biorepositories and expert advisors.

Delphi Results

In this survey, we narrowed the scope to specimens for immune-based assays. Respondents ranked highly :

- **De-centralized biorepository models**
- **specimen types needed:**
  - **Serum/plasma of highest priority for immunological-based tests and use**
  - **Collection methodologies:**
    - **longitudinal serial samples from confirmed cases, pre-vaccinations and post vaccination**
    - **regionally collected, known endemic diseases**
    - **normal controls**



Respondents were highly supportive of:

- The benefit of providing access to templates for sample and data transfer agreements
- Building trust in quality: minimal standards for specimen inclusion
- A cost recovery plan
- Creating an equitable process, agreed on by VBS members for benefits of membership in the VBS
- Participation in defining VBS policies for access and use of specimens

A demonstration project for VBS implementation was launched in December 2023

- **A proof-of-concept project designated “10x10” has been initiated under the umbrella of the *Cohorts to be Activated Globally in Outbreaks* (CONTAGIO) project, funded by the European Commission.**
- **“10X10” designates 10 participating members, with broad geographical distribution, who have been asked to set aside 10 large volume (at least 10 ml) samples from 10 donors; the first set of samples will be serum or plasma, “healthy control”, for reference material.**
- **These first members are tasked with developing: the governance structure of the VBS; identify barriers and solutions for future growth; and benefits for sustainability.**

10x10 demonstration project:

Main aim is to achieve global representation and equitable benefits sharing for the VBS

Objective 1. To develop a durable virtual biorepository system (VBS) critical to support infectious diseases readiness in alignment with other efforts

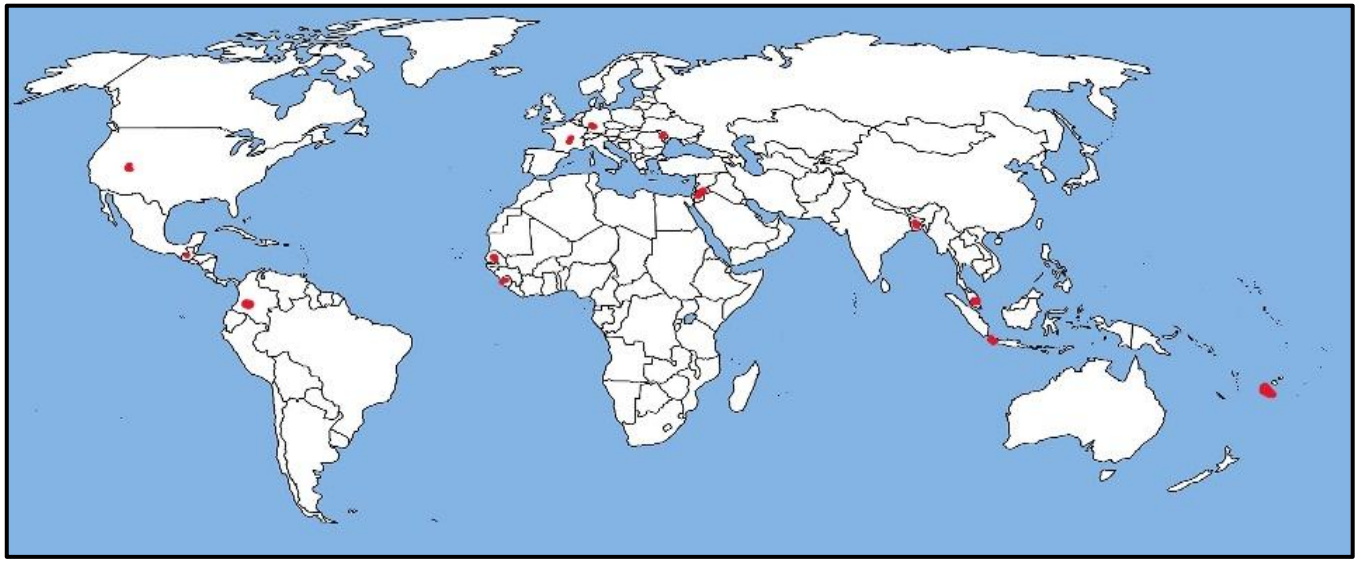
Objective 2. To demonstrate the feasibility of the VBS starting up to 10 LMIC sites that are geographically representative

Demonstrate objectives through action: preparing and validating reference panels

10x10: Broad Geographical Representation

Currently participating partners include organizations from the following countries: ***Colombia, Guatemala, Senegal, Sierra Leone, French Polynesia (Tahiti) Bangladesh, Malaysia, Moldova, Indonesia and Jordan.***

US, France



VBS Working Groups

A. Governance

- Develop the governance framework for VBS

B. Benefits

- Map information needed for access and sharing specimens and identify hurdles and solutions
  - for easy access, map regulatory requirements including benefit sharing (Nagoya protocol); shipping, etc., ethics, etc., for each site
- Identify benefits recommended by the “10X10” for participating in the VBS

C. Sustainability

- Capacity building to characterize of sample, starting with serum/plasma samples
  - PCR (supported by the European Virus Archive (EVAg)
  - Serology (Univ. of Colorado)

Vision for future expansion of the VBS

Force multiplier

- Expansion model by a buddy system- each member helps another and recruit others

- Working groups
  - Governance & best practices
  - Benefits package
  - Sustainable operations

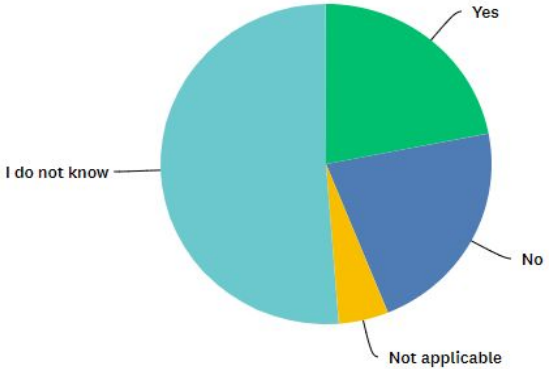
To summarize: some barriers and challenges identified:

- **Locating sources of quality specimens and associated metadata**
  - completeness and quality of diagnostic data
- **Shipping and cold chain**:
  - shipping regulations, importation to US
  - lack of knowledge of local and national regulations
  - cost of shipping and logistics
- **Negotiations- Material Transfer and Data Use Agreements**
- **Restrictions on sharing specimens**
- **Ethics approvals**
- **Infrastructure for storage**; consistent power and back up
- **Funding for operations; Sustainability**

Benefit Sharing (Nagoya Protocol)

The VBR will respect benefit sharing principles and develop transparent, equitable and ethical policies for use of specimens.

Question: Does your country have a specific <u>policy</u> regarding the Nagoya protocol that would prevent you from contributing specimens to the Virtual Biorepository?



Majority of respondents (more than 55%) did not know if their country had policies in accordance with the benefit sharing aspects of the Nagoya protocol and if, or how, it applied to them

From survey "Benefits of Contributing to a Virtual Biorepository (VBR) Resource for Coordinated Access to Clinical Specimens"

Webinar Series Biorepositories for the Public Good: Access to Specimens for Epidemic Preparedness

Based on the information gathered about barriers for access and solutions needed, focused in this webinar on two key aspects:

- Benefit Sharing (Nagoya Protocol) and impact on specimen sharing
- Ethics approval concerns for sample access and use and the broad consent

For the next webinar in this series, plan to focus on:

- Governance
- Developing a business model for sustainability

Acknowledgements

VBS Team
Colorado School of Public Health, Center for Global Health

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Zoe Steinberg
Julia Poje
Amy Price
Nikaash Pasnoori
Judith Giri
Thomas Jaenisch

CONTAGIO Team

10X 10 Members*:*
Colombia: Anyela Lazano and Gustavo Gómez, Universidad Industrial de Santander
French Polynesia: Van-Mai Cao-Lormeau, Institut Louis Malardé
Bangladesh: MD Moyeen Uddin Chowdhury, International Centre for Diarrhoeal Disease Reserach
Sierra Leone: Ibrahim Swaray, Njala University
Moldova: Ecaterina Noroc, Clinical Hospital of Infectious Diseases and Elena Romancenco, Institute of Clinical Microbiology and Infectious Disease
Senegal: Ines Vigan-Womas, and Ousmane Diallo, Institut Pasteur de Dakar
G*uatemala*: Kareen Arias, Fundaçion para la Salud Integral de los Guatemaltecos
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Indonesia: Jajah Fachiroh, Universitas Gadjah Mada
Jordan: Ruba Alsmadi, Jordan-CDC

France: Laura Pezzi; Aix-Marseille University

Thank you

Questions?

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VIRTUAL BIOREPOSITORY

CONTAGIO
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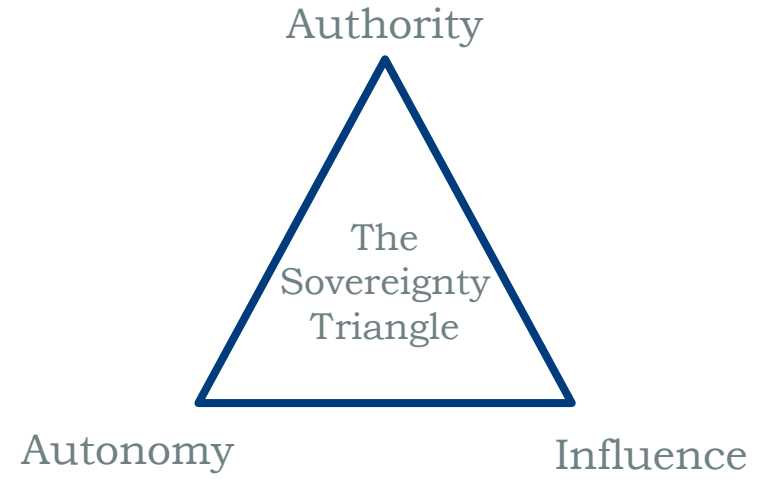
Viral Sovereignty and Access and Benefit Sharing

Rebecca Katz

PhD, MPH, Professor at Georgetown University Medical Center and School of Foreign Service, and Director of the Center for Global Health Science and Security

Sovereignty

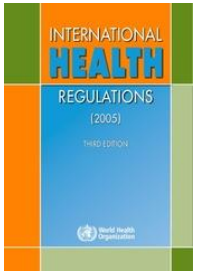
- States may determine laws and policies within their border
- States choose to enter into conventions and treaties (not automatic)
- "**Viral sovereignty**"- application of principle to specific resources within a state's borders (where resources are defined to include viruses)

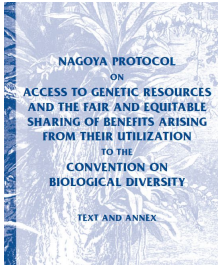


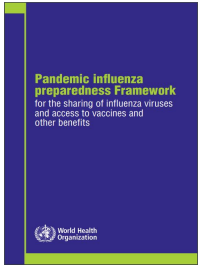
"Sovereignty is among the most frequently invoked, polemical, and vexing concepts in politics—particularly American politics."

Patrick (2017) *The Sovereignty Wars*

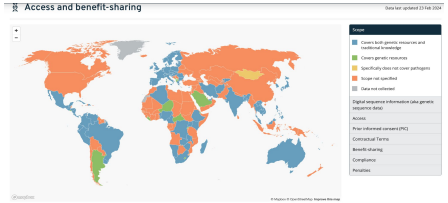
Frameworks for Emerging Infectious Disease Governance

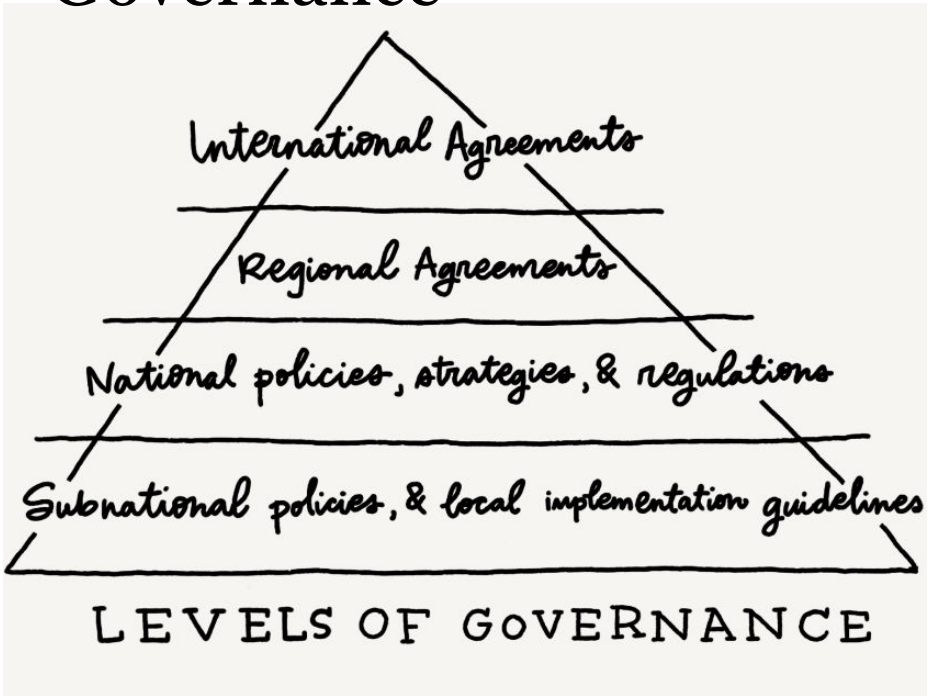






Convention on Biological Diversity





Global legal framework on biodiversity

- Signed in 1992; entered into force in 1993
- Objectives:

(1) "the conservation of biological diversity";

(2) "the sustainable use of its components";

(3) "the fair and equitable sharing of the benefits arising out of the utilization of genetic resources"

Convention on Biological Diversity

Purpose: rights of states to control and make decisions about their genetic resources.

Convention on Biological Diversity

Article 15: Access to Genetic Resources

1. “Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.”

2. “Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.”

3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party […] are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.

Convention on Biological Diversity

Article 15: Access to Genetic Resources

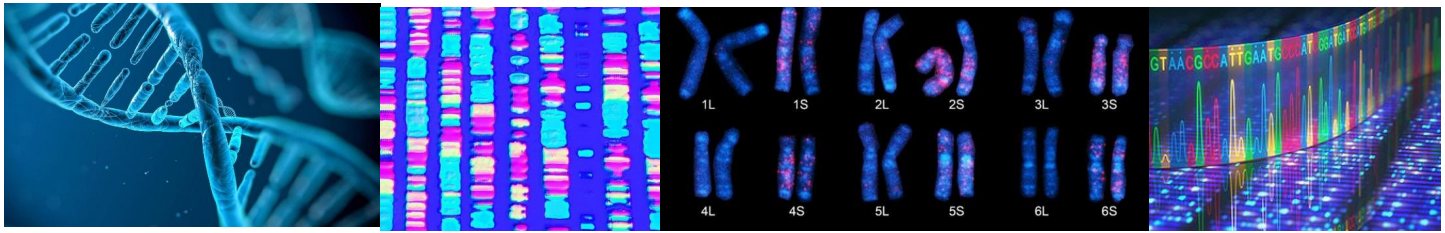
4. “Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.”

5. “Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.”

7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate … with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

ACCESS AND BENEFIT-SHARING (ABS)

Genetic Resources (definition)



CBD, Article 2:

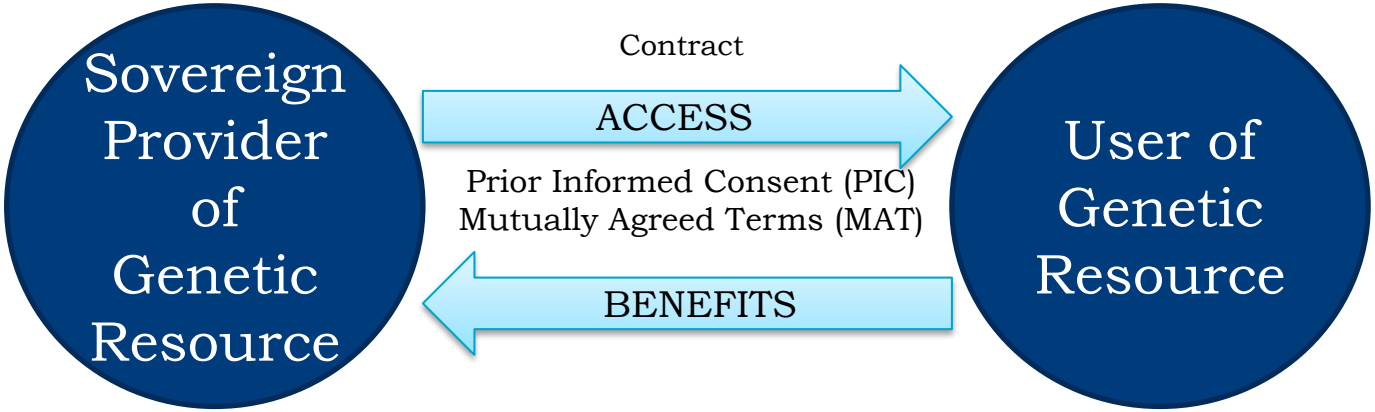
"Genetic resources means genetic material of actual or potential value"

"Genetic material means any material of plant, animal, **microbial** or other origin containing functional units of heredity"

ACCESS AND BENEFIT SHARING

- Access: access to genetic resources
  - Unlimited, non-commercial, commercial
- Benefit Sharing: the sharing of benefits arising from the use of the resources
- Benefits
  - Monetary
    - lump sum, royalties etc
  - Intellectual Property
    - Patents
  - Recognition/acknowledgement in publications, conferences

Bilateral Access & Benefit-Sharing

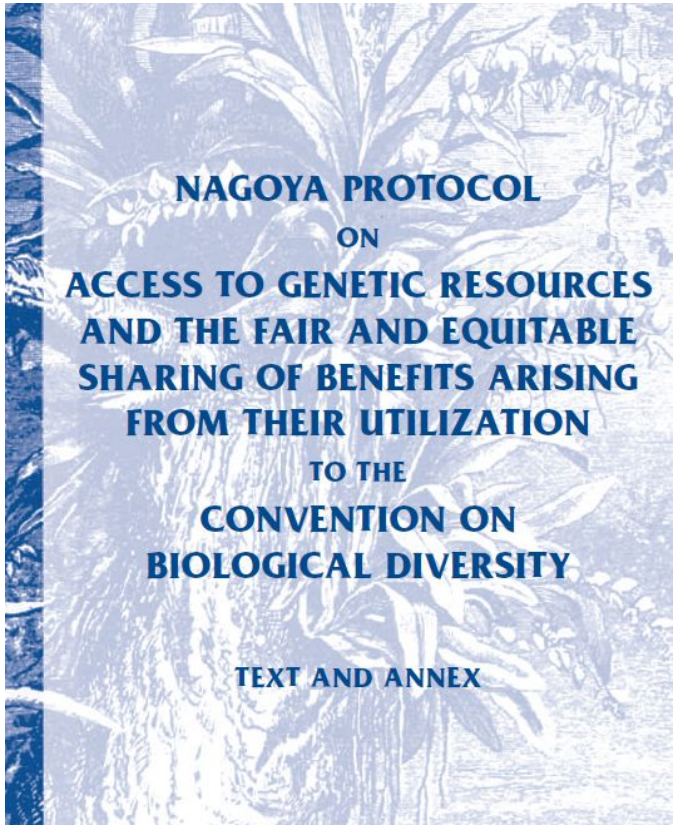


- The principle of resource sovereignty creates an economic mechanism (ABS) to address the “market failure” of environmental conservation

Multilateral Access & Benefit-Sharing

- Multiple providers —> Intermediary —> Multiple users
- *International Treaty on Plant Genetic Resources for Food and Agriculture* (ITPGRFA) "Multilateral System" for Annex 1 Plants

More Info: Charles Lawson (2012) *Regulating Genetic Resources*



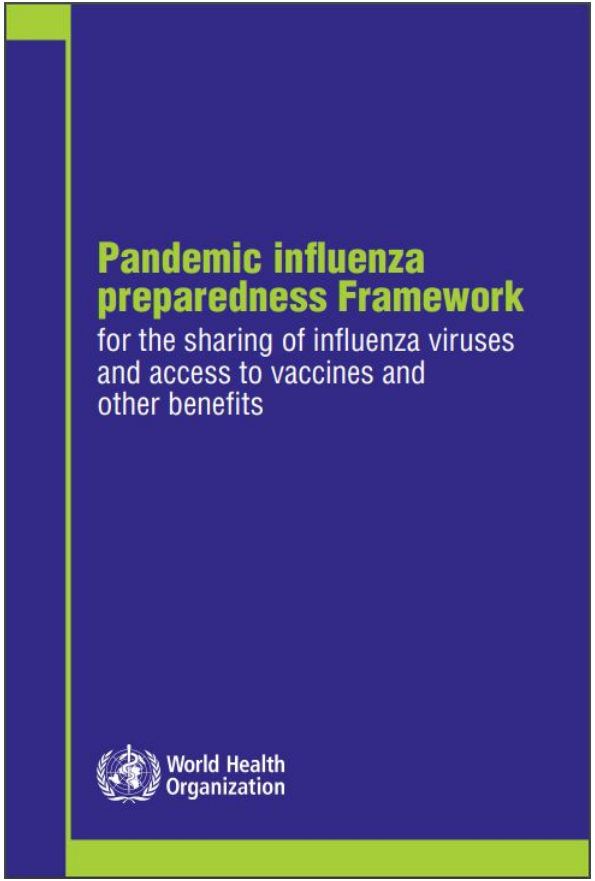
- Adopted by the Conference of the Parties to the CBD in 2010
- Entered into force on 12 October 2014
- Clarifies Article 15 of the CBD

Good and Bad of Nagoya

POTENTIAL POSITIVE IMPACTS FOR PUBLIC HEALTH

- Risk of slowing or limiting the global sharing of pathogens:
  - Uncertainty regarding scope and implementation of the Nagoya Protocol
  - Unclear national authorities (Minister for Health, Minister for Environment?) and complex different domestic regimes
  - Drafting, negotiation, and signing of MTAs for every pathogen transfer
  - Researchers won't want to deal with administrative burden, will change research focus

- May promote increased sharing from a wider number of countries
  - Address through clear guidance from WHO/CBD on model laws or key requirements for implementation
  - Establish National Focal Point and clear authority in laws
  - Template MTAs
  - Researchers who previously did not have the ad hoc contacts can now work with countries for access

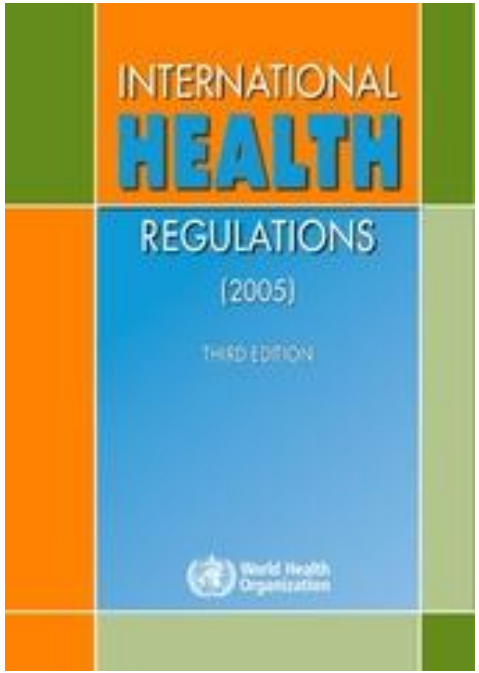


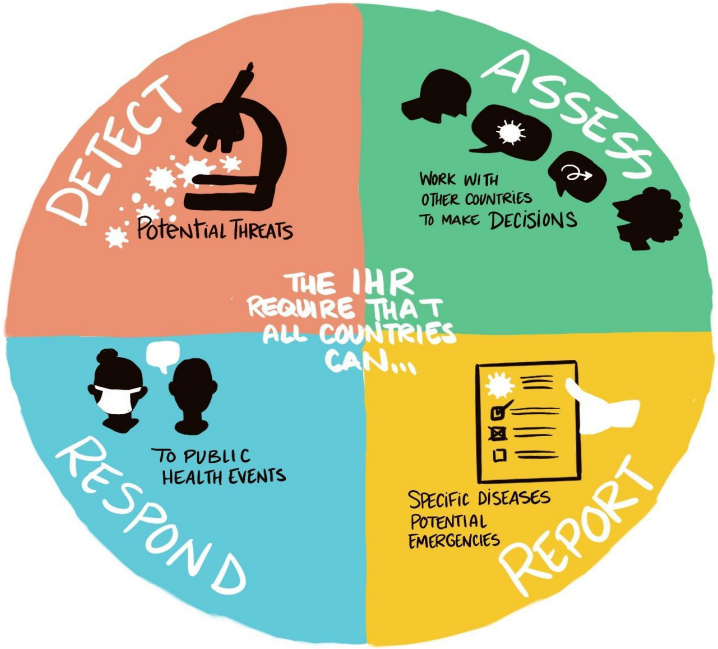
Art 1 (11): WHO Member States “recognize the sovereign right of States over their biological resources”

Art 3 (1): This Framework applies to the sharing of H5N1 and other influenza viruses with human pandemic potential and the sharing of benefits.

Art 3 (2): This Framework does not apply to seasonal influenza viruses or other non-influenza pathogens or biological substances that may be contained in clinical specimens shared under this Framework.

Updating Norms: Reforming the IHR





World Health Organization

“The World Together”: the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response

Issues at stake- Pandemic Access and Benefit Sharing (PABS) system

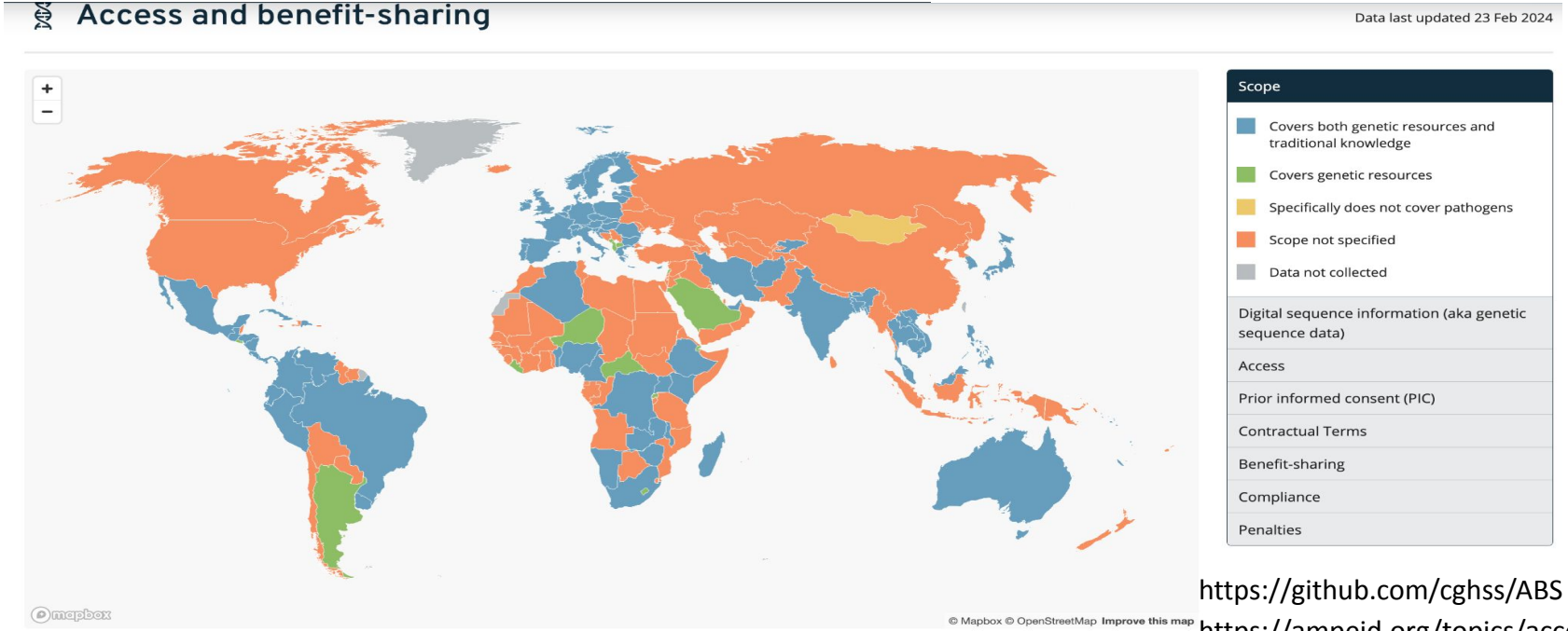
- Some advocate for ‘decoupling’ access and benefit
- Sharing PABS biological materials with or without SMTAs. Are terms of reference legally enforceable?
- GSD platforms, and who the users are/who is subject to agreements (how do you enforce benefits if can’t track access?)
- How to enforce benefit sharing?
- Are samples shared outside of the proposed PABS system? (ex of PIP)
- Intellectual property and GSD (can researchers still try to patent a virus if they are recipients of GSD?)
- Non monetary benefits: MCM. Who gets what?
- What has obligations? (commercial versus non commercial)
- Links with PIP, Nagoya, and IHR

Access & Benefits Sharing

Global Patterns in Access and Benefit-Sharing:A Comprehensive Review of National Policies

Gunnar V. Ljungqvist, Ciara M. Weets, Tess Stevens, Hailey Robertson, Ryan Zimmerman, Ellie Graeden, Rebecca Katz

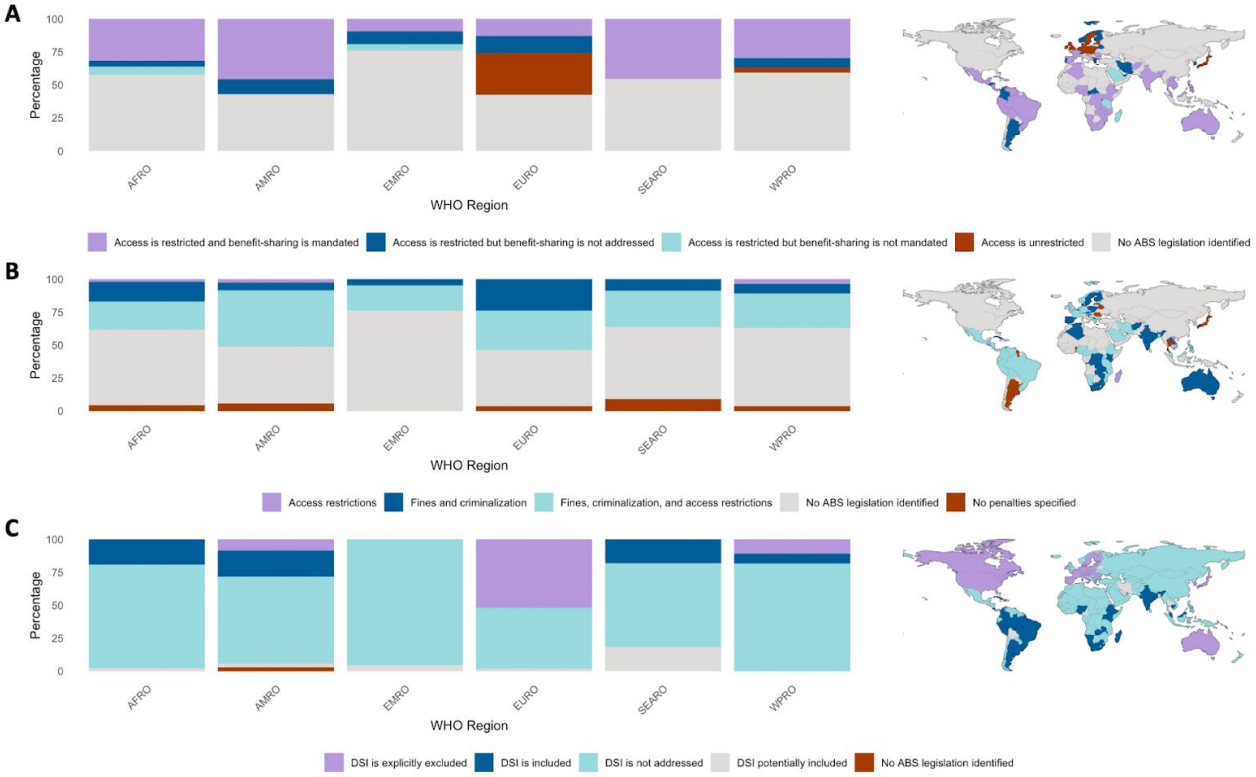
doi: https://doi.org/10.1101/2024.07.12.24310347



https://github.com/cghss/ABS

https://ampeid.org/topics/access-and-benefit-sharing/

National level policies around Access and Benefit Sharing

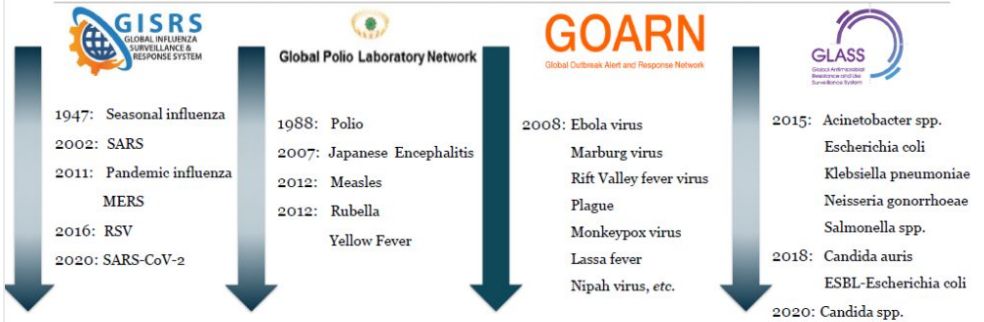


(A) legally-enforceable policy pertaining to genetic resource access

(B) sanctions included in legally-enforceable ABS policy

(C) legally-enforceable policy that covers Digital Sequence Information (DSI)

Selected Surveillance Networks



Take-away: (1) More than a dozen global initiatives; (2) highly diverse due to *e.g.* underlying pathogen, surveillance needs, public health objectives, funding, capacity, geography…; (3) takes years to build up; (4) trust.

Sharing through Surveillance Networks

	GISRS	Global Polio Laboratory Network	GOARN	GLASS
Sharing of samples **within** Network	Yes, **under Terms of Reference**, and as a matter of **practice**	Yes, as a matter of **practice**	Does not appear regulated, but happens in **practice**	Does not appear regulated, but happens in **practice**
Sharing of samples **outside** of network	Seasonal: under **terms of reference** and practice Pandemic: **SMTA**	**Restricted**, terms of reference not public	Happens in **practice**, but not regulated	Happens in **practice**, but not regulated
Genetic Sequence Data Sharing?	**Outside** of Network: GISAID and GenBank	**Within** the Network: Internal database	**Outside** of Network: GenBank, some GISAID	**Outside** of Network: GenBank

Take-away: some sharing through networks, mostly for surveillance.
However, more pathogen and data sharing – e.g. for R&D – occurs through:
(1) non-surveillance networks of biobanks, and external databases;
(2) bilateral institutional and personal relationships.

https://healthpolicy-watch.news/pathogen-sharing-pandemic-accord/

National Institute of Allergy and Infectious Diseases

The Changing Relevance of Material Transfer Agreements for Infectious Disease Research: Enhancing the Role of Investigators

May 4, 2018

Ethical barriers: broad consent

Lauren Maxwell

PhD, MPH, Research Group Leader at Heidelberger Institut für Global Health, Universitätsklinikum Heidelberg, Heidelberg, DE

Broad consent for future use

The reuse of data and/or samples collected by researchers who may not be affiliated with the original study team for purposes that may differ from the objectives of the original study.

	Study Consent	Broad Consent for Future Use	Blanket Consent for Future Use
Definition	Consent limited to participation in a specific study.	Consent allowing data and samples to be used for future research within specified boundaries.	Consent allowing unrestricted future use of data and samples without additional oversight.
Scope	Narrow, study-specific.	Moderate, future use within predefined conditions (e.g., health research).	Broadest, future use across any purpose without constraints.
Ethical Oversight	High, limited to the approved study protocol.	Moderate, typically governed by ethics committees for future uses.	Low, minimal or no oversight over future uses.
Participant Control	Full control over how data/samples are used in the study.	Partial control, as specific boundaries are outlined but future use decisions rest with the researchers/ethics boards.	Minimal control, as participants relinquish oversight of future use.
Transparency	High, study details fully disclosed.	Moderate, general future use outlined but not specific studies.	Low, lacks detailed information on how data/samples will be used.
Regulatory Frameworks	Often required by ethics boards for each study.	Supported under frameworks like CIOMS and national guidelines, with conditions.	Rarely recommended or endorsed due to ethical concerns.
Flexibility for Researchers	Low, restricted to the study's original objectives.	High, allows for diverse future research within boundaries.	Very high, unrestricted future use across domains.

Guidance Document	Provisions on Broad Consent
CIOMS (Council for International Organizations of Medical Sciences), 2016	Recommends broad consent for future research if: (1) participants are informed about the scope of future use, (2) governance mechanisms are in place, and (3) participants can opt out if desired.
Declaration of Helsinki (2013)	Allows for the use of identifiable data and samples with participant consent if future use aligns with the original consent parameters.
OECD Guidelines on Human Biobanks and Genetic Research Databases (2009)	Supports broad consent if governance mechanisms ensure ethical oversight, transparency, and accountability for future uses.
EU General Data Protection Regulation (GDPR), 2018	Permits broad consent for secondary use of data, provided safeguards like data minimization, anonymization, and participant rights are upheld.
UNESCO Universal Declaration on Bioethics and Human Rights (2005)	Encourages ethical use of biological samples under broad consent, emphasizing the importance of protecting participant autonomy and privacy.

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UNESCO Universal Declaration on Bioethics and Human Rights (2005)	Encourages ethical use of biological samples under broad consent, emphasizing the importance of protecting participant autonomy and privacy.

How do we know if we got broad consent right?

Current work

1. Scoping review to identify status of current recommendations for Broad Consent for Future Use

2. Qualitative study to understand ERC members' concerns about Broad Consent for Future Use & Waivers of Consent in Colombia

3. Cognitive interview study in Nicaragua and Colombia to explore how research participants understand recommended language related to broad consent for future use

4. Quantitative survey of ID cohort participants' attitudes related to sample reuse in Nicaragua and Colombia

Scoping review on broad consent for future use

Findings (N=48 articles)

Most studies recommended some type of community engagement, but community engagement was almost never done

Not all future uses created equally

- Lack of support for sharing data or samples with commercial entities
- Governance concerns related to sample sharing are less pronounces if samples are used locally
- Need for transparent & clear governance to retain research participant and community trust in context of data and sample sharing by researchers in LMIC

Scoping review on broad consent for future use

Findings (N=48 articles)

Lack of understanding of broad consent for future use

- Biobank participants may believe that sample reuse can related to direct gains for their health

Age related differences

- Older participants expressed stronger trust in the research enterprise, greater interest in serving the common good than did younger participants
- Younger participants had a more sophisticated understanding of the potential benefits of genomic research, they described greater privacy concerns and desire for control of study data

Limitations of research

- Highly selected populations with very low response rates
- In some cases, participants had difficulty understanding the questionnaires, which involve difficult to understand concepts

Colombian ERC members concerns about future use (N=24; 10 ERCs)

Objective

Understand ERC members' concerns when evaluating research protocols that include broad consent for future use.

Methods

WhatsApp-based, semi-structured IDIs

Thematic analysis using deductive & inductive codes

Data analyzed in MAXQDA

Population

24 interviews with ERC members (9 local, 1 national ERC)

Colombian ERC members concerns about future use (N=24; 10 ERCs)

“(...) the consent forms are not sufficiently clear, so that a person with the level of education that the patient is expected to be, can read it and know what is happening (...) The rights of people must be respected, society must respect the individual and to respect it, consents must be well formulated." (CEI 10)

"Something that I would not approve is to leave the broad informed consent like a blank check." (CEI 004)

"... because sometimes it gives the impression with some things that I have heard and I have also seen, (...) that biorepositories are used as a backdoor to do certain things." (CEI-010)

(...) who safeguards the information ... Who is in charge of defining that this sample leaves or does not leave for investigation, and (...) the direct sufferer, then, administer and safeguard their information. Another is a defined area of ... a boundary, so to speak, to that expanded consent, yes? At least a subject area, or at least a defined disease, or at least a defined context, not that something remains open (...). (CEI-004)

Colombian ERC members concerned about benefit sharing & community involvement

“.. we also want to avoid this use of samples in Latin America to do extractive research. That is, Latin America as a sample dispenser only ” (CEI 017)

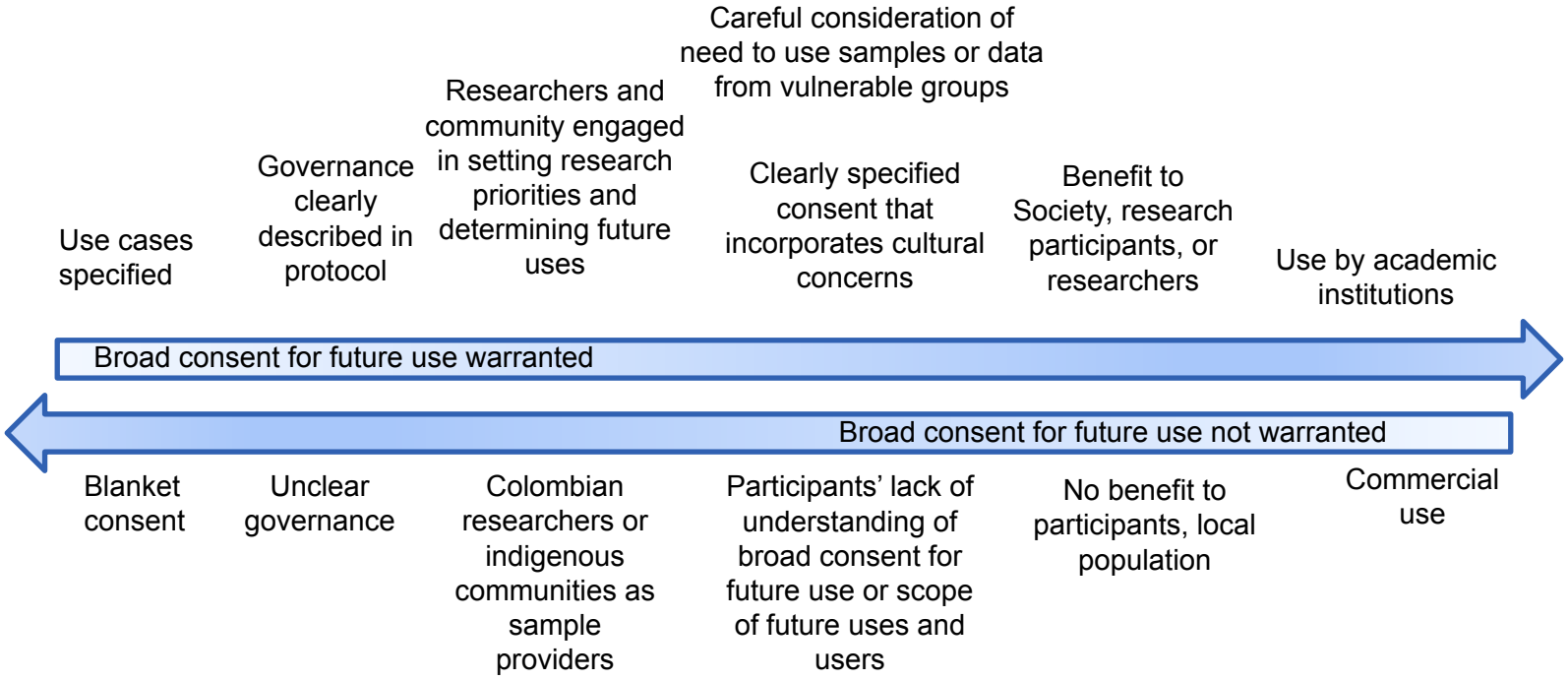
“What if they manage to identify any identified clinical alteration in those samples? (...) ah well ... allow broad consent but (...) but if any inherent condition is found in the samples, ask the patient if they want to know that inherent information of their samples, that is, it is a total dissociation of the relationship of samples versus research, which (...) from at least my point of view, is that the patient ends up as an input, another provider of information, there is no interaction or benefit (...) that can derive for him ”. “(…) I think that it is very well marked, how to be honest with the volunteers about where the focus is going, and that the volunteer also has the ability to define if he wants that benefit or I do not want that benefit.” (CEI-Privado -004)

“This pandemic has exposed the need to do research, has shown the little knowledge (..) that people should be involved in an educational process that allows them to participate in decision-making in regards to ... the generation of knowledge precisely through what they are, live, the problems they have. , of what ... of the resources they provide, such as their samples. (CEI 01)

Colombian ERC members see samples/data as a public good

The pandemic has put in our face that this is not local or regional or mine, the knowledge is not mine, rather this belongs to everyone, we all have to put this together. I believe one of the things we have learned from the pandemic [related to broad consent for future use] is the connotation that I am going to export the samples from my people, my data, my sample, our [samples], from our area, from our country, from our region. (CE-01)

"y creo que esta pandemia nos lo ha puesto en la cara, no es local, ni regional, ni mía, ni el conocimiento es mío, sino que justamente es de todos, todos tenemos que construirlo, todos tenemos que poner, a todos nos va a costar, ¿sí? Creo que, de las enseñanzas de la pandemia, justamente en este campo es esa, pero… cuando lo analizamos individualmente en un comité, siempre esta… la connotación de… voy a exportar las muestras de mi gente, de mi información, de mi… nuestra, la de nuestro territorio, la de nuestro país, la de nuestra región."



Colombian ERC members suggestions on when to use or not use broad consent for future use

Cognitive interview study with ID cohort participants in Nicaragua and Colombia (N=52))

Objective

Explore ID cohort participants and their parents' understanding of and agreement with broad consent for future use language

Methods

Cognitive interviews
Semi-structured interviews
Thematic analysis in MAXQDA

Population

52 interviews with DENV and ZIKV cohort participants in Nicaragua and Colombia

Cognitive interview study with ID cohort participants in Nicaragua and Colombia (N=52)

Broad consent-related language in University-mandated ICFs (including Moore Clause for reuse of specimens) is not well understood

Participants did not understand that they would not be informed about the future uses or users

In some cases, genetic data, as described using standard ICF language is taken to mean cloning

Belief/expectation that sharing data or samples will benefit their specific case - that the results will be returned to them

Lack of comfort with broad consent for future use where the types of uses and the end users are not specified

Trust in the research team and the belief that sharing data and samples could lead to new vaccines or treatments were drivers behind participants support for data & sample sharing.

Biobanking attitudes survey with ID cohort participants in Nicaragua and Colombia (N=120)

Objective

Explore ID cohort participants and their parents' understanding of and agreement with broad consent for future use language

Methods

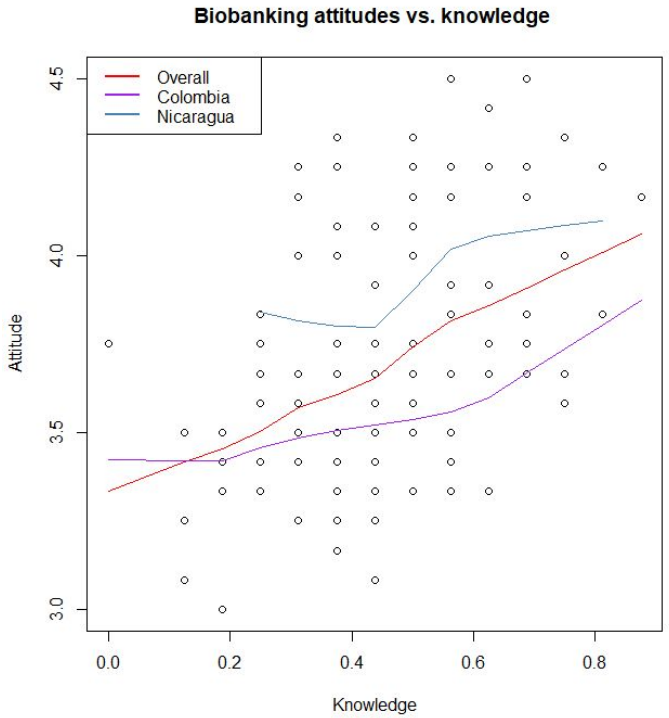
Piloted and modified the BANKS-SP, a quantitative survey of biobanking attitudes services available in Spanish

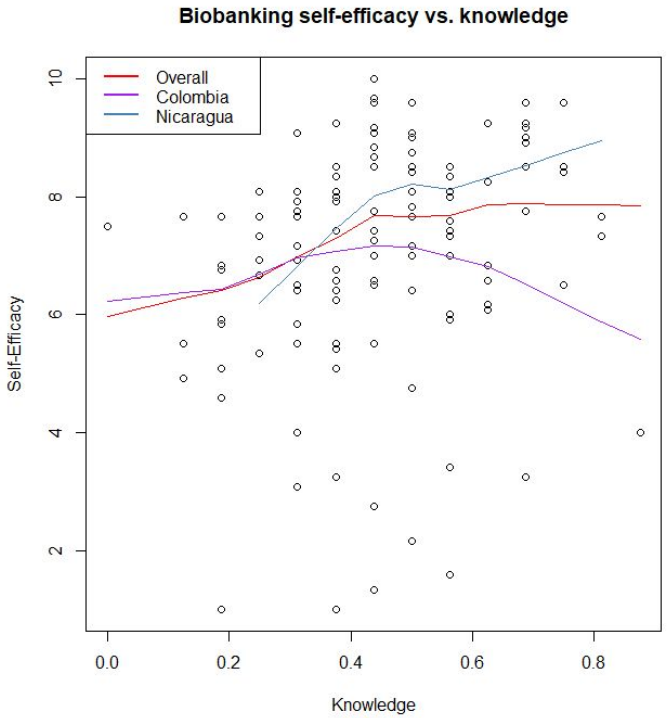
Population

120 quantitative surveys with DENV and ZIKV cohort participants in Nicaragua and Colombia

Arevalo, Mariana, et al. "Development and validation of the biobanking attitudes and knowledge survey-Spanish (BANKS-SP)." *Journal of community genetics* 7 (2016): 303-314.

Biobanking attitudes survey with ID cohort participants in Nicaragua and Colombia (N=120)





Key takeaways

A one size fits all approach to broad consent for future use doesn’t work

ERC members & research participants are concerned about broad consent for future use & benefit sharing

Better recommendations around community engagement, benefit sharing, & evaluating understanding of broad consent for future use-related language are needed

ERC members & research participants are concerned about broad consent for future use & benefit sharing

They suggested the following to help address their concerns

- Pre-specification of reuse purposes
- Clarify the data and sample governance framework/processes
- Ensure participants understand broad consent for future use-related language
- Engage the community in setting public health priorities for data reuse

How do we know if we got broad consent right?

How to do broad consent for future use of data & samples

Minimal

- Pilot test broad consent language
- Provide opt-out
- Consider benefit sharing and address risk of extractive/parachute research
- Ensure clauses on incidental findings and expectation of direct benefit are clarified during consent process
- Pathway for withdrawing consent
- Describe basic aspects of governance (e.g., studies must have ethical review)
- Use DUO

Better

- Describe governance process in consent
- Conduct a cognitive interview study to assess understanding of broad consent
- Consult the community about broad consent and benefit sharing
- Include source community or research participants in governance

Further reading

[Scoping review to identify status of current recommendations for Broad Consent for Future Use]

Miranda Montoya MC, Bravo Chamorro J, Leegstra LM, Duque Ortiz D, Maxwell L (2022) **A blank check or a global public good? A qualitative study of how ethics review committee members in Colombia weigh the risks and benefits of broad consent for data and sample sharing during a pandemic. PLOS Global Public Health** 2(6): e0000364. https://doi.org/10.1371/journal.pgph.0000364

Maxwell L, Chamorro JB, Leegstra LM, Laguna HS, Miranda Montoya MC. "How about me giving blood for the COVID vaccine and not being able to get vaccinated?" **A cognitive interview study on understanding of and agreement with broad consent for future use of data and samples in Colombia and Nicaragua.** PLOS Glob Public Health. 2023 May 17;3(5):e0001253. doi: 10.1371/journal.pgph.0001253. PMID: 37195974; PMCID: PMC10191364.

Quantitative survey of ID cohort participants' attitudes related to sample reuse in Nicaragua and Colombia

Thank you!

TDR For research on diseases of poverty
UNICEF • UNDP • World Bank • WHO

COVID-19 Clinical Research Coalition

ReCoDID

European Commission

CIHR IRSC
Canadian Institutes of Health Research / Instituts de recherche en santé du Canada
Institute of Genetics / L'Institut de génétique

CONTAGIO
COHORTS NETWORK TO BE ACTIVATED GLOBALLY IN OUTBREAKS

SR & Scoping Review

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Priya Shreedhar
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Shaila Akter
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Joy Mauti

Qual & Quant Studies

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Lauren Maxwell
Luz Leegstra
Jacqueline Bravo
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CONTAGIO, EU Horizon Europe [GA 101137283]
TDR, the Special Programme for Research and Training in Tropical Diseases [GA P20-00007]

Infectious Diseases: Biobanking in a Network

Daiane Sertorio

Coordinator of the Fiocruz Biobank Network

REDE FIOCRUZ DE BIOBANCOS

FIOCRUZ

SUS

MINISTÉRIO DA SAÚDE

GOVERNO FEDERAL

BRASIL

UNIÃO E RECONSTRUÇÃO

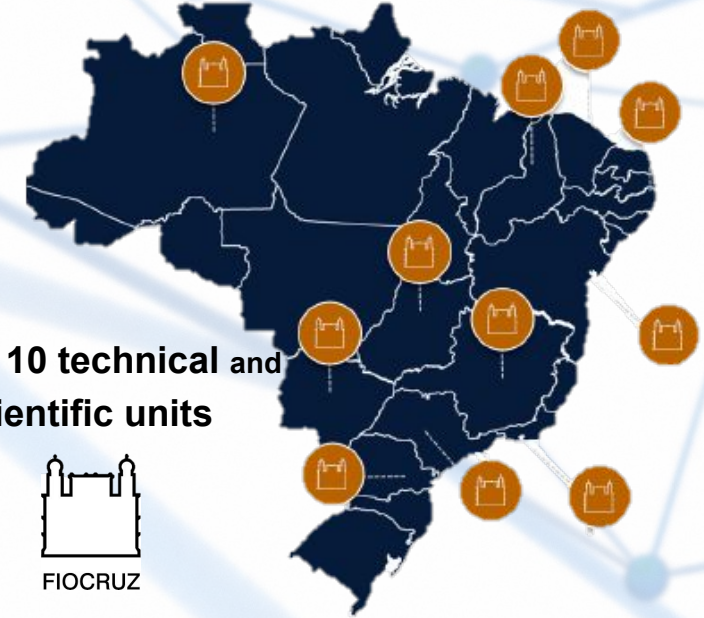
Summary

1. Fiocruz
2. Fiocruz Biobank Network
3. Brazilian Regulatory Landscape
4. Barriers and solutions

FIOCRUZ IN NUMBERS

OSWALDO CRUZ FOUNDATION – PUBLIC HEALTH INSTITUTION (193 YEARS)

+ 15.000



+ 10 technical and scientific units

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Environment & Health

Health Care
Reference hospitals and Community outpatients

Production
Health Economic-Industrial Complex

Education
Academic & professional

Surveillance, Compliance & Regulatory bodies
Reference Labs, Quality Control, Ethical Committees, Biosafety/ Bioprotection

History of Science Historical and Biological heritage

Information & communication
Production of innovative knowledge for implementation of public health policies and decision-making processes

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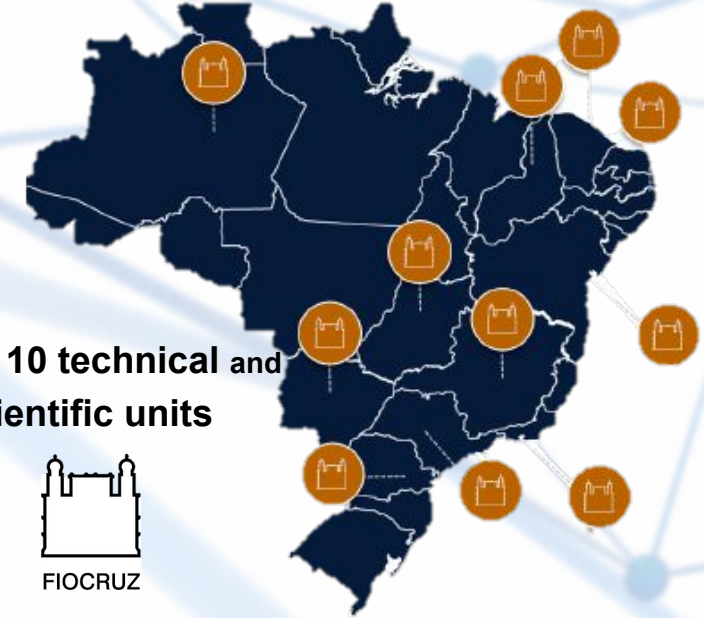

+ 10 technical and scientific units

FIOCRUZ

National and International Cooperation

Science, Technology and Innovation for the Unified Health System (SUS)

Main non-non-university institution on training and qualification of human resources for SUS and for science and technology in Brazil.

Reducing inequalities in health, education and science

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FIOCRUZ BIOBANK NETWORK

RFBB

Key Goals:

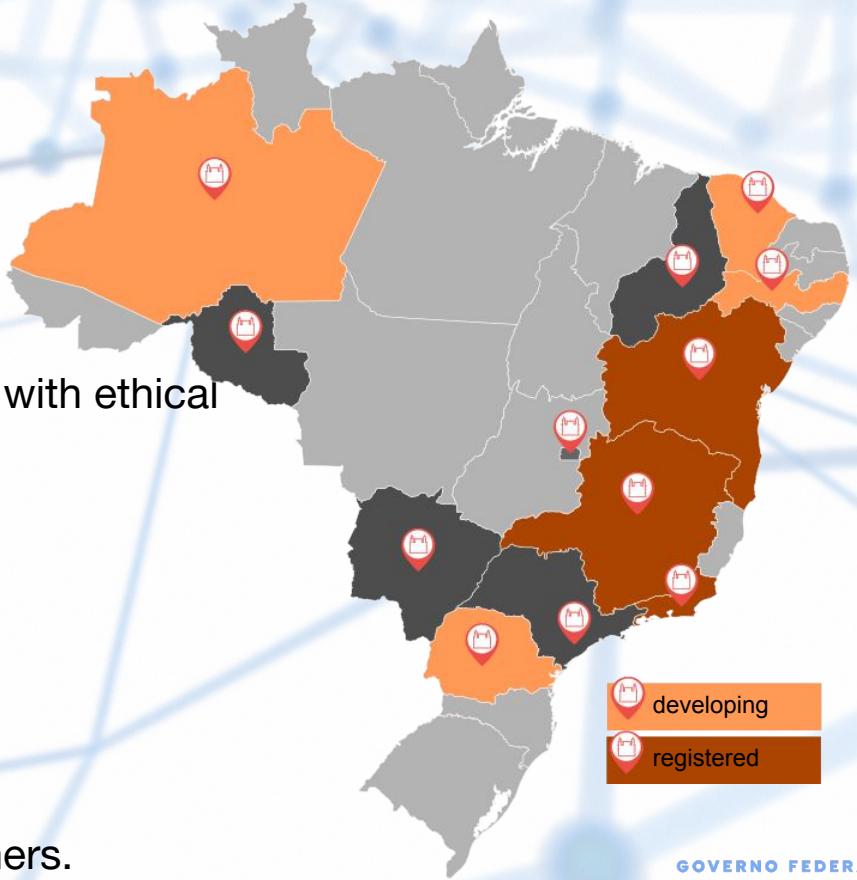
- Provide quality samples for research in public health
- Harmonize practices and protocols
- Foster collaborations and ensure compliance with ethical and legal standards

Decentralized Biobank strategy:

- 5 registered Biobanks
- 5 developing Biobanks

Sources:

- Research projects for reuse
- Outpatient health care from Fiocruz and Partners.



BIOBANKS in the NETWORK

RFBB

Decentralized Biobank strategy:

- 5 registered Biobanks

- 5 developing Biobanks

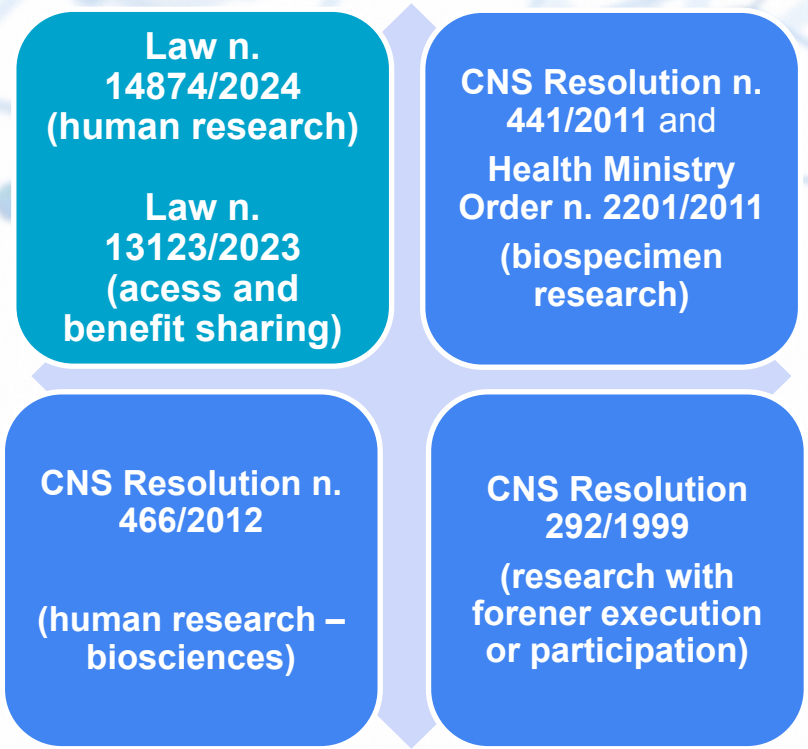
Scope: Public health

CHALLENGES IN SHARING SPECIMENS

- **Barriers:**
  - Complexities in benefit-sharing laws
  - Navigating international shipping regulations
  - Ethical concerns and governance issues
- **Solutions:**
  - Establishment of partnerships and alliances
  - Development of streamlined legal frameworks
  - Digital systems for sample tracking and consent management

SHARING BIOLOGICAL SAMPLES

THE BRAZILIAN REGULATORY LANDSCAPE

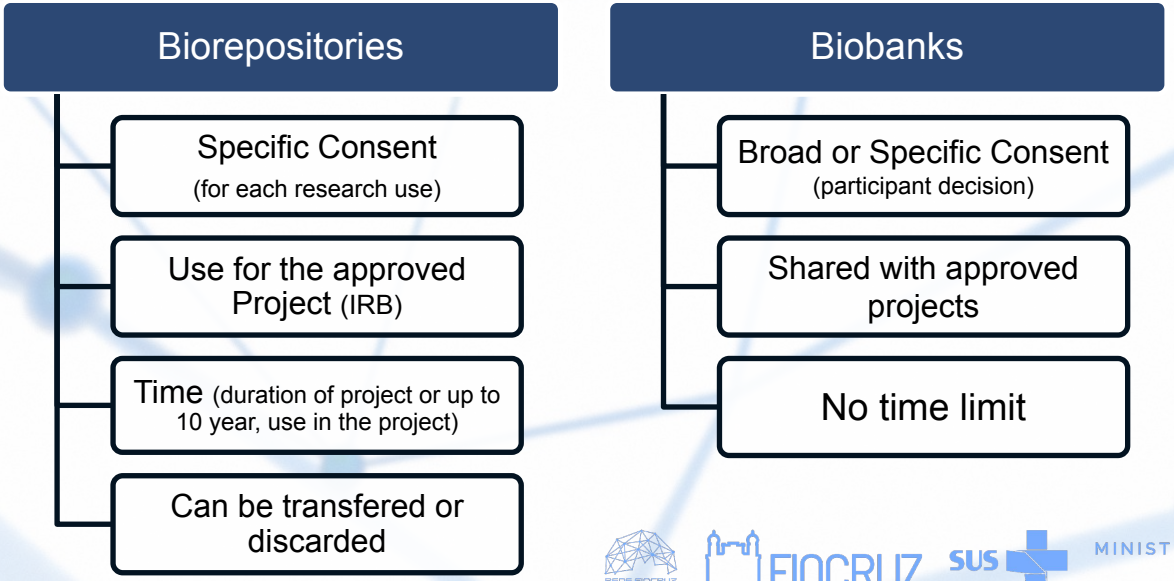


SHARING BIOLOGICAL SAMPLES

THE BRAZILIAN REGULATORY LANDSCAPE

Overview:

- Law n. 14874/2024
  - Biorepositories and Biobanks (differences)
  - Need for complementar regulation about biological samples



Research with brazilian specimens and data

in other countries

- Ethical appproval
- Submission of the protocol (documents needed)
  - IRB origin
  - local IRB BR (CEP)
  - local researcher partnership as co-responsible
    - Agreement with partnership
    - Budget Sources
  - Declaration of compliance with Brazilian law and regulations
    - Ownership of the participant
    - Forbid to patent BR human specimens
    - Benefit sharing
    - Declaration of use exclusive to the approved project

Research with brazilian specimens and data

in Brazil with external collaborations

Ethical approval

Submission of the protocol (documents needed)

local IRB BR (CEP)

local researcher partnership as co-responsible

Declaration of compliance with Brazilian law and regulations

Agreement with partnership

Budget Sources

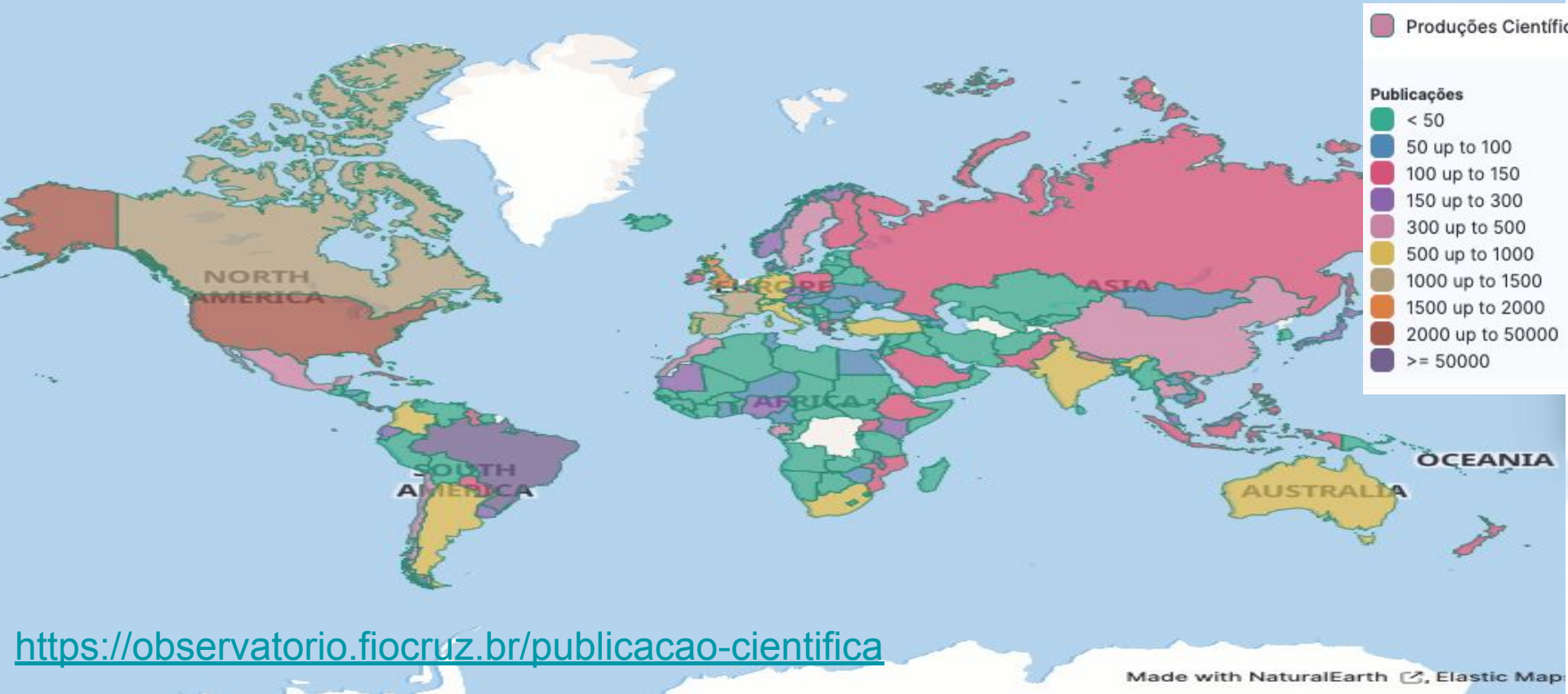
Ownership of the participant

Forbid to patent BR human specimens

Benefit sharing

FIOCRUZ IN NUMBERS

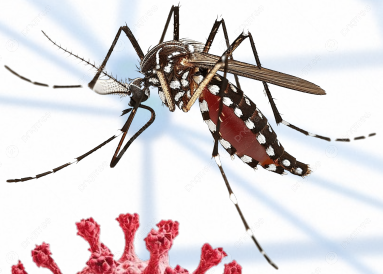
PARTNERSHIPS AND SCIENTIFIC PRODUCTION

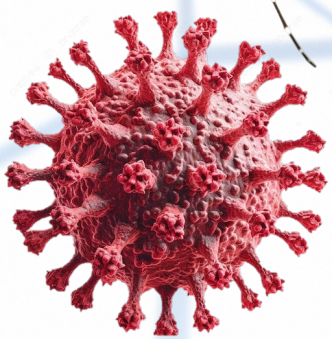


https://observatorio.fiocruz.br/publicacao-cientifica

EXAMPLES OF COLLABORATIONS

- Development of vaccines and diagnostic tests for infectious diseases
- Drug testing with international research institutions





  - **Example 1:** Collaboration for Zika virus research (2015-2016)
    Shared specimens to understand the disease, support diagnostics and (Lebov et al. BMC Pregnancy and Childbirth (2019) 19:282 https://doi.org/10.1186/s12884-019-2430-4)

  - **Example 2:** COVID-19 vaccine partnership
    - Joint efforts in testing and implementing innovation

  - **Takeaways:**
    - Importance of the reuse of biospecimens and data
    - The importance of ethical and regulatory frameworks in global partnerships

FIOCRUZ BIOBANK NETWORK

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Thank you

Questions?

THE GLOBAL HEALTH NETWORK
Enabling research by sharing knowledge

colorado school of public health
Center for Global Health

VIRTUAL BIOREPOSITORY

CONTAGIO
COHORTS NETWORK TO BE ACTIVATED GLOBALLY IN OUTBREAKS

Become a member of the Virtual Biorepository hub!

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