



# Recommendations for Data and Biospecimen Governance in Africa

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Credit: AESA/2020

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## Overview

In 2019, Alliance for Accelerating Excellence in Africa (AESA) convened a team of experts (the Data and Biospecimen Governance Committee) with the aim of reviewing governance issues relevant to Africa around the use and re-use of data and biospecimens originating from African sources, through all stages of the research and translational chain. AESA is an initiative of the African Academy of Sciences (AAS) and the African Union Development Agency (AUDA-NEPAD). Here, we present a summary of guidelines and recommendations for data and biospecimen governance on the continent that can promote a participant-centric approach for research involving human participants, whilst enabling ethical research practices on the Continent and providing governance guidelines. These guidelines aim to facilitate the ethical use and re-use of data and biospecimens for the benefit of Africans by engaging political leadership, institutional leadership, funders and researchers to ensure intersectional accountability, de-colonisation of research attitudes and language, and by encouraging ethical research translation and innovation on the Continent.

## Introduction

Since the completion of the Human Genome Project (HGP) in 2003, advances in technology have led to unprecedented interest and investments in Genomic research. Numerous genomic projects have been established throughout the world, including Africa, promoting the need for international collaboration and associated coordination and sharing - including that of data and biospecimens.

Best ethical practice and standards underscore the need to put participants' interests first, and to

establish a reasonable "social contract" that ensures the rights of the patient, considers the community's best interests, and prioritises social value as a research objective. In order to avoid social injustice and inequalities, African health research must be anchored on these intrinsic values and we must re-examine the concept of data ownership. Ownership is ill-suited to define stakeholders' responsibilities in the use of data and biosources<sup>1</sup>, and can rather be replaced by the broader concept of custodianship – implying caretaking and governance responsibility by the data community, with fair and transparent practices principles based on ethical rather than strictly legal principles to govern data use and protect participants' rights<sup>2</sup> despite significant proliferation in specimen-based research and discoveries during the past decade, research remains challenged by the inequitable access to high-quality biospecimens that are collected under rigorous ethical standards. This is primarily caused by the complex level of control and ownership exerted by the myriad of stakeholders involved in the biospecimen research process. This article discusses the ethical model of custodianship as a framework for biospecimen-based research to promote fair research access and resolve issues of control and potential conflicts between biobanks, investigators, human research participants (human subjects).

AESA convened the Data and Biospecimen Governance Committee to develop guidelines and practical recommendations for data and biospecimen governance on the continent. These inform shall inform a position for the continent for advocacy with varied stakeholders including governments, funding partners, researchers, educators, ethics committees among others.

## Key Domains for Data and Bio-specimen Governance

### 1. Community engagement, participation and involvement: ensuring an equitable social contract

Contemporary approaches for engagement in Africa have reduced the notion of community engagement (CE) into merely sharing of information about research with research participants and communities. There is however a need to ensure CE is made integral to research planning and implementation and is aimed at enabling local communities that are involved in research to be informed and empowered in order to contribute meaningfully in shaping the research agenda.

**Educating and empowering research participants/communities is critical in enabling them to appreciate the value of research, data sharing,**

**models of data sharing and their individual and societal rights.** This must never be an afterthought but must be made an integral part of research planning and implementation for any research conducted in Africa. Doing this will empower communities to rightfully negotiate for more tangible benefits accruing from sharing their data and biospecimens and avoid exploitation that arises due to ignorance, research illiteracy and misinformation.

Tokenistic CE approaches that involve cosmetic involvement of the community only to meet donor or regulatory requirement should be avoided. **Institutions must invest in the selection, training and capacity building of respected community and opinion leaders/representatives, who are able to engage scientists and in science discourse meaningfully and challenge the traditional ways of thinking about and involving the community in research.** We must move away from the notion of doing research on the community, where the community is merely a data and sample mine, and begin to promote the notion of doing research with the com-

## Domains for Data and Biospecimen Governance

01

Community engagement, participation and involvement: ensuring an equitable social contract



02

Ethics



03

Ethics, governance and community engagement in times of crisis



04

Data governance and access





munity, where the community is empowered and is able to contribute in discussion and decision-making processes related to research priorities, design and benefit-sharing.

## 2. Ethics

### 2.1. Informed consent and respect for autonomy

Informed consent/respect for persons has often been described as a universal principle, yet research has shown that the application of this principle varies widely from one context to another. Africa has unique values that must be appreciated and considered if persons involved in research in Africa are truly to be respected.

**Informed consent must be preceded by a deliberate effort to understand and appreciate the local values where the research is to be conducted.**

These must be used to inform the appropriate approaches to be used in the informed consent process.

Research participants in Africa often face multiple layers of vulnerability - including but not limited to lack of resources, illiteracy, constrained health systems and high disease burden - which can affect their ability to make informed decisions and maintain autonomy. Potential for exploitation remains high, necessitating informed consent approaches that provide open space for free dialogue and consultation; and that employ interactive approaches to enhance understanding, comprehension and informed decision making without intimidation, fear of discrimination, or favour. Such protection of vulnerable communities reflects the social values of **ubuntu**. Appropriate information for participants can empower them to make an appropriate decision regarding the safeguarding of their confidentiality and privacy. Compensation models for research participation must also take into account the notion of undue inducement - which has often also been used to deny African research participants fair compensation and contributions towards research, inconvenience and the direct and indirect costs involved. Coupled with the appropriate informed consent process, the fear for undue inducement should never arise. **Ethics Review Committees / Institutional Review Boards are responsible for ensuring that informed consent must be sufficiently informed, freely given and genuinely voluntary; and generic guidelines for these committees and review boards in Africa can support their decision-making processes.**

Informed consent from participants is *necessary*, however not *sufficient* for ethical conduct of medical research, and consideration must also be given to potential inducement of African researchers to promulgate unethical consent processes under pressure from funders. **African researchers and institutions must be protected against surrendering their autonomy and authority as stewards of African participants' specimens and data**, which could be

achieved through high-level research institution-funder agreements that ensure the authority to make critical data and biospecimen sharing decisions throughout the research process is retained by African researchers.

There is a push from some stakeholders towards using broad (unlimited) consent from participants for data and biological sample re-use. While aiming to promote open science, this requires participants to cede their autonomy to researchers entirely. Participants would be better served by a dynamic model that incorporates follow up and allows them oversight of how their data and samples are being used - although limited online access and digital literacy in Africa make this currently difficult to implement. Until dynamic consent becomes feasible, tiered consent can allow participants to retain some level of control over re-use of their data/samples<sup>3</sup>. Where researchers are being pressurised by funders to employ broad consent, and lack research capacity without external funding, these calls must be balanced with systems to better empower and engage participants. **To promote respect for the autonomy of African research participants as well as researchers, there is a need to work towards establishing effective systems to follow-up research participants, and to avoid using broad consent for prospective data and biospecimen re-use.**

### 2.2. Research integrity: managing conflicts of interest for funders and researchers

Researchers in Africa work under significant financial restraints, and consequently often remain beholden to foreign research funders. This creates an inequitable relationship where foreign funders hold the upper hand and can unduly influence the ability of African researchers to conduct their research or the way they do so. Foreign funders, especially those disbursing public money, need to return tangible deliverables to the countries they represent, increasingly in the form of samples and data. This creates a conflict of interest for funders, who need participants to donate samples and data and may unduly influence consent procedures accordingly - and more so because they are not operating or accountable in their home country. Similarly, PIs may also be under pressure to meet recruitment targets for funding received or may perceive participant recruitment as a crucial element for building their careers. For these reasons, **a healthy distance should be maintained between funders and ethics and consent protocols; and where possible PIs should also aim to have independent, un-invested oversight of their consent and recruitment practices.**

### 2.3. Upholding privacy and confidentiality

The need to protect the privacy of research participants and the confidentiality of their personal information is

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*It is important for African Nations to establish and support such national authorities and ensure suitable guidelines are in place to guide the authorities in making decisions*

enshrined in international and regional ethical and legal frameworks, such as the Declaration of Helsinki (2013)<sup>4</sup>. The African Union's Convention on Cybersecurity and Personal Data Protection (2014)<sup>5</sup> Article 10(4) (a) requires the processing of personal data involving genetic information and health research to be undertaken with the authorisation of the national protection authority. **It is important for African Nations to establish and support such national authorities and ensure suitable guidelines are in place to guide the authorities in making decisions.** In the absence of suitable guidelines, varying practices can make it difficult to comply with ethical principles thus leading to ethics dumping<sup>6</sup>.

#### 2.4. Promoting equity

There is a close relationship between equity and compliance with ethical standards in research. Accordingly, **African institutions must make their institutional policies and values explicit in international collaborative research and engage in a process of continuing improvement of the quality, fairness and equity of the research partnerships in which they are engaged**<sup>7</sup> source: "DOI.org (Datacite). A formalised Pan African position on data and bioresource access and governance can ensure African institutions are less prone to inequitable research partnerships.

#### 2.5. Responsible and culturally sensitive reporting and dissemination of findings

Uneducated, insensitive, inappropriate and inaccurate reporting about African populations has been commonplace for decades, and still persists – causing personal, community and population-level harms. **Clear guidelines must be developed in consultation with participant stakeholders to ensure that such community and population harms are kept to a minimum.** These should include the recommendation to avoid non-essential descriptions of race or ancestry in publications, except where it contributes materially to the methods, findings or discussions. For example, participant or study groups can be described as a North/Southern/West/East African, or African population, or by their country of origin - unless specific and demonstrable value is to be gained by reporting with further granularity.

### 3. Ethics, governance and community engagement in times of crisis

#### 3.1. Community engagement during times of crisis

During times of crisis, local communities should be involved in shaping the research agenda and empowered to differentiate between research and treatment.

**Effective measures for community engagement and community participation including use of organized/existing groups, opinion and religious leaders, to identify strategies for addressing the crisis must be put in place,** to build mutual trust and respect. National governments and the region must put in place ongoing surveillance to inform future emergencies; and community engagement processes can contribute to and facilitate the effectiveness of such surveillance.

#### 3.2. Ethics and informed consent in times of crisis

Times of crisis are challenging, and a lot can go wrong: Important standard operating procedures can be overlooked, resources are usually constrained and there is a lot of anxiety. During this time, lines between health care and research become more blurred. The community and research participants become more vulnerable and desperate for any kind of support. In this scenario, **health care and management of victims should be given priority. Informed consent processes should consider the vulnerability of the potential participants and put in place adequate measures to protect them.**

#### 3.3. Outbreak Mode Response

In order to promote best practice during a public health crisis, adequate preparation is essential.

Firstly, **a National or regional multidisciplinary team to advise and manage public emergency should be in place.** African governments must put in place a public health emergency framework that stipulates what must be done and procedures to be followed during a public health crisis, including to develop a code of conduct to facilitate respectful collaboration and cooperation between stakeholders during a crisis, and to develop a framework for priority-setting at a local level.

We can try to understand how deferential ethics may apply to routine medical research compared to research during outbreaks caused by high consequence pathogens. During outbreak scenarios which are characterized by chaos and multiple international agency interventions, ethics is usually relaxed to allow for multiple opportunities for introduction of potential treatment options. During the West African Ebola outbreak which typified the scenario, opportunism was rife. We propose that during such scenarios Ethics needs to be heightened. More ethicists and Data and Safety Monitoring Boards (DSMB) need to be available to ensure that the participants are not taken advantage of by virtue of the circumstances pervasive during an outbreak in a community which lacks adequate human and infrastructural resources to cope, and where outbreak victims are extremely vulnerable due to life-threatening circumstances.



Credit: AESA

Melissa Kapulu, an AAS Affiliate working at the KEMRI-Wellcome Trust Programme

## 4. Data governance and access

### 4.1. Protecting bioresources: biobanking samples and data provenance

Data and biospecimen provenance is poor globally, with very limited tracking of samples and data, the consents and use agreements under which they were collected or generated, or how they are re-used elsewhere. **Within Africa, new technologies must be explored to ensure that sample and data consents, use and re-use can be traced back to origin and validated, as well as followed forward** to ensure appropriate, consented re-use as well as equitable benefit sharing from future use. Distributed ledger technology (DLT) is a technology established to govern digital currency or the bitcoin exchange. Developments in the field of cryptography leading to records linked through chains of computer network has created a system that seemingly has transparency and immutability built into the exchange of data, records, files or contracts. This popularly now known as blockchain. The blockchain networks rely on multiple computational nodes to simultaneously store information allowing the verification of the transactions entrenched by a timestamp mechanism making centralization redundant and imputing digital trust.

This blockchain DLT system holds great potential for the field of biological resource management and governance<sup>3</sup>. As transactions and information and subsequent updates are added to the decentralized dis-

tributed ledger, it is impossible to alter such records because they are embedded in multiple copies of cryptographically linked records. In principle, records of the chain of custody of biological records can be created in this digital trust network protecting the chain of custody on its route through an innovation pipeline leading to commercialization which is an immutable value chain proposition of provenance.

This improves accountability and the ability to attribute ownership of data even as value add occurs along its route, keeping ascribable records of intellectual property rights (IPRs). The sharing of data can be regulated and managed using DLT avoiding mismanagement and inappropriate/unethical use of data. All relevant interactions between the data provider/patient and subsequent permissible users can be locked into the blockchain ensuring transparency and correct management of data.

**Smart contracts can provide the ability to ensure that research and innovation pipeline activity are occurring as prescribed by the agreed governance and financial compensations can be appropriately distributed based on prior informed consent and benefit-sharing agreements allowing for the possibilities of the original data provider or their community to share in benefits resulting from innovation.** Similarly, with the development of single nucleotide polymorphism (SNP) genotyping technology, we are able to fingerprint samples based on variation in genetic alleles ascribing individuality to each sample. A short string of known SNPs common to a particular ethnic group, can pro-



vide an irrefutable origin of individual samples and their donors. Biobanks can utilize this already available fingerprinting technology not only for quality assurance but also for establishing source and traceability.

#### 4.2. Governance structures, responsibilities and oversights

Whilst it is commendable that a number of organisations are establishing Data and Biospecimen Access Committees, their ability to function efficiently requires clear policy guidance and normative frameworks. This can be facilitated through **a pan-African normative framework that reconciles competing societal, individual and industries' interests in data and bioresources, ensuring fair access while minimising legal and ethical risks.** Such a framework should provide documents that provide recommendations, support and guidelines for drawing up regional or National policies, as well as generic templates for ensuring best practice, appropriate governance and oversight of data<sup>9</sup> and biospecimen use, sharing, re-use and return of benefits. **Guidelines and policy can also be written to inform funders and external researchers of policy for data and biospecimen governance within Africa, and how they will be held accountable for observing these guidelines.**

#### 4.3. Engaging funders and institutes to uphold African data and biospecimen governance policy

Governance of data and bioresources access must also include governance at the research contracting and collaboration stage where African institutions tend to sign unconscionable terms. Reliance on freedom of contract can trump governance structures and policies. Consequently, **research institutions and research regulators must be sensitised on the need to negotiate data and benefit sharing terms based on African needs and policies, and to ensure that researchers are not forced into unethical or inequitable agreements with funders** in order to be able to continue with their research.

#### 4.4 Guidelines and templates for enabling pan-African data and biospecimen governance.

Guidelines can be provided to assist and inform the development of National and Regional policy for data and biospecimen governance. These can address some of the following issues:

- **Standard Operating Procedures for appropriate collection and storage processes and practices for bio-specimens and data** can ensure an appropriate standard of data and biospecimen handling, storage and oversight across Africa.
- **Informed consent, governance and benefit-sharing guidelines for Institutions and Funders** can assist with negotiations with ex-

ternal funders about consent models, benefit sharing and Intellectual property agreements. Institutional approaches to governance principles to which funders must adhere can also assist with reducing pressure on researchers and the inherent conflict of interest they face.

- **Developing standard operating procedures, protocols and frameworks for emergency response in advance**, for example with respect to data-sharing, can narrow the requirements for development and review during an emergency, and can ensure participant beneficence by including requirements for developing sustainable capacity such as infrastructure and expertise across various domains of research, and to support countries in taking control of preventive measures, and of emergency response in the future.
- Generic template documents should be developed, to ensure appropriate content and implementation for the following types of agreements and documents:
  - **Material Transfer Agreements template** for movement of samples and/or data across borders
  - **Mutually Agreed Terms template** for benefit-sharing agreements.
  - **Key components for participant information and consent processes** can be described.

#### 4.5 Standardisation to ensure maximal data benefits

Different types of data are collected under different research and service delivery domains (e.g. clinical data or genomic data). Within each specialised domain, **the standardised collection and coding of data should be undertaken** to ensure that data are meaningful, re-usable where the appropriate consent is in place, and comparable across different sources of the same type of data. This requires engaging with or developing standardised data capture techniques, data coding, standardised data vocabularies and ontologies. This can ensure maximal data benefits from existing data and ensure sustainability of evidence-based research<sup>9</sup>.

The richer the phenotypic data that accompanies a biological resource, the more useful it will be to the broader scientific community. Harmonising phenotype data between research projects will create opportunities for performing research on larger sample sizes across regions and ethnicities improving statistical power and deduction, increase the usefulness of the entire resource. For example, anonymized subjects from one study might serve as controls for another study. Such cross-studies analyses will be facilitated if the data can be harmonized or is collected in a uniform manner from the very start.



## Guidelines and templates for enabling pan-African data and biospecimen governance

### Standard Operating Procedures for appropriate collection and storage processes and practices for bio-specimens and data

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### Developing standard operating procedures, protocols and frameworks for emergency response in advance

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### Informed consent, governance and benefit-sharing guidelines for Institutions and Funders

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### Generic template documents

should be developed, to ensure appropriate content and implementation for the following types of agreements and documents:

**Material Transfer Agreements template** for movement of samples and/or data across borders

**Mutually Agreed Terms template** for benefit-sharing agreements.

**Key components for participant information and consent processes** can be described.

### 4.6 Supporting custodians to safeguard data and African interests

Particularly with increasing data protection under data privacy legislation such as the Protection of Personal Information Act (POPI Act, South Africa<sup>10</sup>), similar to the General Data Protection Regulation<sup>11</sup> in the European Union, the role of data custodians who safeguard data is becoming more prevalent. In order to ensure there are skilled data custodians

available, **training and career support for new data custodians must be developed and provided on the Continent**, as well as workshops and ongoing learning opportunities for established researchers to ensure capacity for appropriate data management and governance going forward. A unified curriculum for training in data and biospecimen governance and ethical practices can ensure a high standard of practitioners working within Africa in the future.

## 5. Ethical and Regulatory Oversight of Benefit Sharing Agreements

All access to Africa's biological resource has the potential to result in innovation and commercialization in the knowledge economy. Be it academic currency, copyright, patents or innovative pipeline products the end result of which is financial benefit and improved human and environmental welfare. The paradigm shift to liberal access to resources on an altruistic philosophical basis, is not tenable in Africa and Access Benefit Sharing and Compliance with Reparative Justice of (ABC-RJ) is evolving as a more practical paradigm; with Reparative Justice being the operative governance framework that attempts to reverse the vestiges of historical extraction and introduces global social restitution.

Benefit sharing is a cardinal principle of collaborative research in Africa, referring to the profits, advantages, gains and royalties that should accrue to participants, communities and countries that host collaborative research <sup>12</sup>gaining prominence in international law, research ethics and political philosophy. In spite of this prominence, the concept of benefit sharing is not devoid of controversies related to its definition and justification. This article examines the discourses and justifications of benefit sharing concept. We examine the discourse on benefit sharing within three main spheres; namely: common heritage of humankind, access and use of genetic resources according to the Convention on Biological Diversity (CBD). The importance of benefit sharing in Africa is to ensure that host communities and countries are not used merely as a means but also as an end in research. In other words, the concept of benefit sharing seeks to avoid exploitative practices whereby the host community that provide data and specimens are excluded from enjoying the benefits that emanate from them — a phenomenon commonly referred to as “parachute research” <sup>13</sup>, “helicopter research” or predatory research. In the era of genomic revolution in Africa <sup>14</sup>, exploitative practices present through the acquisition of data and bio-specimen mining without an appropriate agreement, community engagement and benefit sharing with host countries.

To protect against this exploitation, stakeholders must establish substantial benefit-sharing terms to foster fairer gains from research for host communities. Although accepted in principle, what is the right, appropriate or fair benefit for host communities and countries remains vague <sup>15</sup>. **Guidelines and policy provided at National, regional or Continental level can empower researchers and IRBs to insist on appropriate benefits, and Community Advisory Boards, Researchers and IRBs must negotiate with research sponsors accordingly** <sup>16</sup>, recognising all contributions such as access to local biodiversity and genetic resources, data, networks and local knowledge. Key components for benefit sharing agreements include:

### 5.1. Equal partnerships between researchers or/and Institutions

Research partners that exercise the same degree of equality in driving research agenda are likely to have equal power to negotiate for fairer and appropriate benefit sharing. Research funders set the research agenda and exert control over the researchers they fund. This is usually exacerbated in settings where there are no/limited framework that promote healthy and equitable research partnerships such as the Africa region. In order to promote fair, respectful and equitable partnership, there is a need to develop institutional and regional partnership frameworks that will give African researchers, institutions and national governments the power and voice to negotiate for equitable partnership when applying for/negotiating on research grants, partnerships and collaborations. This can promote respect in partnerships and foster equal benefit sharing negotiation.

### 5.2. A strong African negotiating position

Achieving equity in partnership between African researcher and their counterparts in the North is important if it is translated into a stronger negotiating position. The main reason African researchers assume a weak negotiating stance arises from the fear of losing funding and grants opportunities, which usually comes from the big funders outside Africa. African researchers must develop mechanisms to forestall this fear and assume a stronger negotiating standpoint in order to accrue better benefit-sharing deals for the continent, and National, regional and Continental policy and guidelines about key components to include when setting up research agreements can support researchers to do so. In doing so, African researchers must value partnership not only from the foci of research grants gains from the rich countries but also through the value of data, specimen, value chain they possess and the ultimate contribution to science, humanity and possible commercial value that will be generated from the use of data and biospecimen.

Lobbying Governments for increased African-origin research funding will also empower African researchers and increasing national budgets for health research can reduce Africa's over-reliance on external funding. Most African countries have a requirement to commit 5% of their budget into R&D, but not one has achieved this to date. Most R&D budgets are not ring-fenced for health research, making accountability for health research impossible. The AU could enforce this requirement, as well as develop a regional R&D fund aimed at building a research fund for Africa by Africa. These are key advantages that should fortify stronger negotiations.

.....  
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 .....



### 5.3. Stringent ethical and regulatory oversight

One of the key enablers of parachute research in Africa is weak ethical and regulatory oversight. Although this problem is improving in most African countries as a result of proliferation in size and quality of Ethics Review Boards, there is still a need to strengthen ethical oversight and harmonize ethics frameworks across the continent. Ethics guidelines must spell out in clear terms the requirement of benefit sharing when collaborating in research involving the use of data and biospecimen in Africa. There should be a dedicated session in research protocols for benefit-sharing wherein the research sponsors clearly state the form(s) of benefit sharing that should accrue host communities for the use of data and biospecimen. Research host through the IRBs, research investigators and CABs should be able to negotiate with research sponsors on the appropriateness and fairness of the benefits

### 5.4. Legal frameworks

At the National level, most countries have health acts, data privacy acts, acts that protect minors or vulnerable populations and acts that protect 'Indigenous knowledge' and biodiversity resources. Biopiracy is the act of directly or indirectly taking undue advantage of research participants and communities in global health research and bioprospecting. This is the current state of affairs operating in multiple disguises across the continent.

The Nagoya protocol that regulates access to biological resources emanating from biodiversity is now a legally binding document mandating beneficiation to originating communities who provide sample, data and Indigenous Knowledge (IKS). Benefit sharing within the regulation of the Convention on Biological Diversity (CBD) is obligatory and enshrined in law.

Unlike environmental samples which are considered to be jurisdictional and sovereign and profits generated by bioprospecting is shared with the derivative community, human samples are considered to be owned by the community of humanity and therefore, not governed by any binding legal agreements, hence open to interpretation or exploitation as to the degrees of beneficitation that should be negotiated before research commences.

As it stands, the Nagoya Protocol governs the use of physical collected sample as well as associated traditional knowledge. Digital sequence information derived from the sample, however, was excluded due to perceived legal and technical difficulties around its inclusion. Accordingly, where mutually agreed terms may permit sequencing of samples, it may not restrict use of those data once generated. A unified African stance that provides guidelines on benefit sharing for data as an extended use case of the Nagoya Protocol may help to ensure equitable beneficitation for participants.

## 6. Translation, innovation and intellectual property: consolidating an African negotiating position

The exclusion of African researchers from the IP development and innovation stages is a great concern mostly because the unconscionable contractual terms, which govern their international collaborations tend to limit their roles to the provision of data and bioresources or the development of conceptual frameworks. For African countries to contribute to the knowledge-based economy and benefit from it, they must collaborate in the proof of concept stage where the IP creation and subsequent translation and innovation take place.



### 6.1. Promote African localisation of value chains

Research and development (R&D) activities carried out using African-sourced biospecimens and biore-sources in general, have the potential to generate commercially valuable data and inventions.

There is, therefore, the need to develop and implement appropriate data governance policies and processes that adequately safeguard these potentially valuable source-samples and related data generated and protect any resulting intellectual property. The policies should ensure the fulfilment of the following strategic goals: First, they must ensure the ethical acquisition and management of bioresource-samples, from appropriate informed consent, through to benefit sharing, before any approval for sharing and access should be considered. Secondly, they must facilitate







the inclusion of African researchers, upfront, as key IP creators and/or equal co-creators and/or enablers that fully share in the ownership and benefits of any resultant commercial outcomes for an ultimately win-win outcome for all parties.

### 6.2. Ensuring agreements have key clauses

Other activities to promote localised value chains can include raising institutional awareness and ensuring that institutional policies, processes and templates are available. These should be researcher-friendly, whilst including enforceable protective clauses for the providers of bioresource samples, research data and findings. Examples include Intellectual Property Agreements and Material Transfer Agreements.

## Key Action Items

These guidelines may assist those in positions of political and institutional leadership, funders and researchers to:

|           |   |   |
|-----------|---|---|
| <b>01</b> | <b>Educate and empower research participants through investing in locally relevant, inclusive, institution-driven community engagement programs.</b>  |  |
| <b>02</b> | <b>Encourage locally relevant consent processes that provide sufficient information, respect individual autonomy and address community-level concerns by providing support, guidelines and training for institutional Ethics Review Boards.</b> |  |
| <b>03</b> | <b>Explore new technologies to track sample- and data-use permissions and oversight.</b>  |  |
| <b>04</b> | <b>Develop pan-African guidelines for data and biospecimen governance, to inform national policies as well as international funders and researchers operating in Africa.</b>  |  |
| <b>05</b> | <b>Provide guidelines and policy for benefit sharing to empower institutions, researchers, ethics review boards and community advisory boards to negotiate fair benefit-sharing terms for research.</b>   |  |
| <b>06</b> | <b>Provide guidelines and templates for Intellectual Property, translation and innovation agreements to promote African localisation of translation value chains.</b>   |  |

## Appendices

### Appendix 1: References

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### Appendix 2: Abbreviations

|        |  |
|--------|--|
| CE     | Community Engagement   |
| ABC-RJ | Africa and Access Benefit Sharing and Compliance with Reparative Justice |
| HGP    | Human Genome Project   |
| SNP    | Single Nucleotide Polymorphism   |
| DSMB   | Data and Safety Monitoring Boards  |

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