

## MEDICINE AND SOCIETY

### How Should Biobanking Be Governed in Low-Resource Settings?

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#### Abstract

Development of biobanks in Africa raises ethical questions related to particular features of African cancer research contexts, such as underresourced health care and research infrastructures and low-average research literacy. This article describes ethical challenges of informed consent, benefit sharing, and stigmatization and proposes navigating these challenges by developing a comprehensive governance framework to ensure African leadership in biobanking research programs in Africa.

#### Biobanking in African Research

Recent years have seen increased efforts to capture global genetic diversity in an attempt to ensure that the [benefits of genomic innovation](#) filter down to all people around the globe, including Africans.<sup>1,2,3</sup> Efforts such as the Human Heredity and Health in Africa (H3Africa) Consortium<sup>2</sup> and the Bridging Biobanking and Biomedical Research Across Europe and Africa (B3Africa) Consortium<sup>4</sup> are aimed at achieving this diversity, increasingly through the inclusion of African researchers and populations in genomics studies. These initiatives either set up new biobanks or strengthen the capacity of already existing ones.<sup>4,5</sup>

Biobanking—the practice of collecting, curating, and archiving biospecimens for research purposes—is one key tool that is available to scientists to accelerate genomic cancer research. A biobank stores large numbers of samples and associated data and makes these resources available for further research. To serve its purpose as a research resource, biobanks are expected to (1) have defined mechanisms for accessing biospecimens, (2) ensure that the use of biospecimens is in accordance with the [informed consent](#) of the participants who donated the samples, (3) have policies for biospecimens disposal, and (4) have a benefit sharing plan.

Several features of the African research context raise ethical challenges for biobanking. In most African countries, these include, for instance, limited resources available for research, health and research institutions that are understaffed or have underskilled workers, old or outdated infrastructure, and limited or no regulation of biobanking.<sup>6,7,8</sup> Prevailing norms that govern research also raise ethical challenges for informed consent, given that the African context tends to prioritize values like communitarianism and reciprocity over respect for autonomy.<sup>9</sup> While respect for autonomy is important, relations between people and considerations of community benefit are considered equally important. Taken together, these features raise a range of ethical challenges including not only consent for the storage and reuse of biospecimens, but also limited country regulations for the export of biospecimens, benefit sharing, and genetic discrimination and stigmatization.

### **Challenges of Obtaining Informed Consent**

Although informed consent holds a special position in research, in biobanking research, consent is also required to store a specimen—sometimes for an indefinite period of time—as well to use specimens for unspecified future research. Yet consent forms are often specific to a particular study, for which biospecimens' aims and uses are defined. This apparent clash between consent for a specific study and consent to future unknown uses of biospecimens has caused considerable debate in bioethics. Broad consent, which is consent for future research subject to a number of restrictions,<sup>10</sup> has been proposed as an appropriate consent model for African genomics research and biobanking.<sup>11</sup> It has also been recommended for secondary research on unidentified biospecimens in the revised Common Rule that guides research in the United States.<sup>12</sup> While a growing body of evidence suggests that African research participants recognize broad consent as the "best compromise,"<sup>13,14,15</sup> it has also been argued that broad consent increases the risk of exploitation of African research populations,<sup>16</sup> which suggests that a decision to use broad consent is context dependent and that there might be particular instances when its use is inappropriate.

Broad consent has been proposed for African genomics research,<sup>17</sup> but given the appeal of communal values in most African settings, it is important that broad consent be accompanied by governance mechanisms that incentivize biobanks to promote the interests of biospecimen providers<sup>11</sup> as well as communities' health and research needs. Toward this end, genomics research and biobanking initiatives are setting up data and biospecimen access committees (DBACs) to review secondary biospecimen use and consider risks posed to study communities. DBACs are critical not only in mitigating risks of

multiple uses of samples and data but also in building trust between researchers and study communities. Trust is particularly important because DBACS are expected to serve as custodians of samples and to provide some oversight of the use of samples and data with an aim of benefiting study communities.

### **Exporting and Regulating Samples**

One motivation for establishing biobanks in African countries is that doing so will hopefully give those countries and the people whose samples are included in the biobank more control over uses of stored biospecimens. Regulation of biobanking in most African countries is limited,<sup>8</sup> which makes oversight of biobanks challenging. Lack of national regulation enables some unethical practices to go unchecked. An example is specimen transfer without recourse to local country authorities or respect for persons from whom samples were collected, which occurred during the 2014–2016 Ebola virus disease (EVD) epidemic. Biospecimens from EVD patients were shipped out of Sierra Leone and Liberia to be stored in biobanks in other countries.<sup>18</sup> People from whom specimens were collected were not informed that their samples would be taken out of their country of residence; nor were they informed that their samples would be used for health research. Biobanks in countries in which these samples were stored have expressed unwillingness to provide some form of oversight of the samples or access to the samples to researchers or government authorities from countries in which specimens were collected. This example shows that absence of national regulatory frameworks makes it difficult for governments to insist that samples be returned.

To eliminate these kinds of scenarios, which have been described as exploitative “parachute” research (a practice whereby scientists in high-income countries go to low-income countries to collect specimens and publish findings in prestigious journals without properly crediting collaborators in LMICs or returning benefit to study communities),<sup>19</sup> it is important for African governments to develop national guidelines for biobanking. Moreover, given the trend toward multicountry African biobanking, harmonizing countries’ regulations might help facilitate health research across the continent.

### **Benefit Sharing**

Research conducted using biobank resources benefits researchers from Western countries in tangible and intangible ways. When research is commercially driven (eg, pharmaceutical research), expectation of benefit is

more tangible than in knowledge-driven research, which mostly aims to build general scientific knowledge. Ethically, this is important because access to technology, literature, and other resources affords researchers' institutions in high-income countries (HICs) opportunities to use biobank samples in more ways than their African counterparts.

One way to ensure that research is beneficial to all stakeholders is to engage various stakeholders (for example, study communities, policymakers, funders, African researchers, HICs collaborators, and research ethics committees) in discussions of what would constitute likely research benefits and how these could be actualized through biobanking.<sup>20</sup> Two of the most direct ways in which biobanking can benefit Africa is by helping to build research capacity and by ensuring that young African students and scholars have opportunities to lead in ethical uses of samples for health research.<sup>21,22</sup>

### **Risk of Genetic Discrimination**

A recurring fear in population-level genomics research is that genetic information could be used to stigmatize or [socially undermine certain groups](#),<sup>23</sup> particularly those with stigmatized health conditions, such as podoconiosis, human African trypanosomiasis, epilepsy, and some psychiatric or mental health conditions.<sup>24,25,26,27</sup> Historically, some interpretations of biological evidence have been [ethically and scientifically troubling](#).<sup>23</sup> One example of overinterpretation was the conclusion that South African San people's lack of an allele associated with skin pigmentation and their ability to sense a bitter taste confer a survival advantage in the Kalahari desert; the latter "may reflect a need in hunter-gatherers to avoid toxic plants."<sup>28</sup> Problematic interpretations of evidence can also be used to support negative stereotypes, as was the case in a description of a Māori "warrior" gene as a "marker" for alcohol and tobacco use.<sup>29</sup> What these examples suggest is that, at a minimum, researchers must consider the risk that their research and interpretations of results can be perceived by some as offensive, stigmatizing, or otherwise scientifically or ethically inappropriate.

### **Governance Framework**

In a partial response to some of these challenges, a set of principles to ensure inclusion of African populations in biobanking research has been proposed by the Ethics and Regulatory Issues Working Group of the H3Africa Consortium.<sup>30</sup> Recognized in this framework is the need for African researchers to lead in the conceptualization, planning, and implementation of research using stored biospecimens. This framework also recognizes the need for robust governance mechanisms that explicitly promote fairness in

research by ensuring that African populations and researchers are not exploited when participating in international biobanking programs. Such governance mechanisms must provide a role for local country governments to help make decisions about storage and use of specimens collected from their citizens. This role could be recognized through a designated government entity for research or through institutions where African investigators are based. Key to good governance is a mechanism for providing feedback to the ethics committees that approve uses of specimens that are collected from African people and stored in African biobanks. Equally important is promoting fairness in research by ensuring that decisions about access to biobank resources in African countries are made by representatives from African institutions, that African researchers are given preferential access to biobank resources, and that reuse of specimens is prioritized for research about conditions of importance to African communities by African researchers and co-investigators.

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