

## Vignettes on Genomic Data

Genomic data is an especially sensitive form of health data, and its collection and use support scientific research, improved diagnosis and disease treatments that underscore precision medicine. Genomic data collection is accelerating, including in low- and middle- income countries (LMICS), to fill critical gaps in understanding of populations not traditionally included in genomics and precision medicine. Without future looking data policies, countries face two main risks: 1) their genomic data do not inform scientific research that may lead to more population-relevant diagnostics and treatments; or 2) their genomic data may be used by and benefit primarily outside parties.

The Leapfrogging with Genomic Data workshop in San Francisco on 18 July 2019 brought together thought leaders in policy, bioethics, academia and industry to identify the design challenges and ethical tensions that need to be addressed in order to positively shape the trajectory of genomic data policy development.

This was achieved, in part, by using vignettes on the issues of consent, data privacy, data access and benefit sharing, that highlighted opportunities and risks germane to LMICs, to identify priority elements of data policies that are future oriented and address growing ethical issues. The vignettes, while fictionalized, are based on real situations that have or may cause points of conflict but do not yet have solutions. Each vignette was addressed by two groups with opposing personas, neither of whom is clearly right or wrong. Groups had to work through a situation as their persona before addressing their counterpart group in the plenary sessions.

## Patient Consent Group Discussion

In your breakout group, identify a volunteer to fill out the large template with team input. This will be collected. Also, identify two volunteers to share their 30-second reflections on the group's discussion and insights during the Popcorn Share-Out following this activity.

Please read the following vignette on [Patient Consent](#) and discuss the questions from the perspective of a [major US Corporation's Vice President of Genomic Research](#).

### Patient Consent Vignette

By 2024, a major US corporation announces that massive parallel sequencing (MPS) has dropped the price of whole genome sequencing to less than \$20 per genome. A country in eastern Africa, seeking to become a continental leader in healthcare as well as an attractive location for healthcare companies seeking to do work on the continent, decides to institute a new-born baby screening policy for all infants born in a hospital. The new-born baby screening policy will require screening and treatment for dozens of conditions to reduce preventable death and disabilities. It will also include a provision that requires taking enough biologic sample to conduct whole genome sequencing. This biologic sample will inform research into population genomic markers and the development of a reference genome.

This country does not yet have the economies of scale or resources to conduct affordable whole genome sequencing nor the workforce to study the results. To make this plan happen, the country has come to a 5-year agreement with the US corporation whereby the company will provide training on sample collection, development of a biobank in the country, inclusion of local researchers in research and sharing of information on certain findings. The company will also subsidize the cost of shipping, sequencing, storage and analysis of the genomic information in one of their own out-of-country facilities, so work can begin right away. Both sides are happy with this approach.

As a first step, both sides agree an appropriate consent form needs to be put into place for parents of new-born babies subject to this policy. The company's Vice President of Genomic Research recommends a broad consent form that will enable the use of genomic data in a range of future research endeavours so long as the data is de-identified to keep the participant's identity hidden. The country's Director of the National Ethics Review Committee in the Ministry of Health believes there should be a tiered approach to consent, as parents may want to limit the types of research for which the data could be used. Additionally, he is concerned about the lack of consent given by the actual owners of the data, who will not remain infants forever.

The country's Director of the National Ethics Review Committee and the corporation's Vice President of Genomic Research meet to discuss what model of consent is appropriate.

### Template Questions

<b>Consent Vignette</b> <b>Persona: Major US Corporation's Vice President of Genomic Research</b>	
What is the conflict about in this scenario?	Describe your persona's desired or ideal approach to a resolution in this scenario?
What underlying need(s) should your persona meet to resolve this situation?	What gaps or barriers are preventing this desirable future from being reached?
Is there anything else you'd like to mention?	

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## Data Privacy Group Discussion

In your breakout group, identify a volunteer to fill out the large template with team input. This will be collected. Also, identify two volunteers to share their 30 second reflections on the group's discussion and insights during the Popcorn Share-Out following this activity.

Please read the following vignette on [Data Privacy](#) and discuss the questions from the perspective of [Maria, the researcher](#).

### Data Privacy Vignette

After several meetings with tribal elders and other members from an indigenous community living in a secluded region of the Andes Mountains, a researcher has earned their trust to participate in her research study. Maria knows this is quite special given the group's well-founded mistrust of outsiders, who have disrupted the community in the past.

She receives broad consent from community members to collect genomic data to search for the biomarkers that may provide clues to their remarkable ability to live at such high altitude. As one way to show her appreciation for their participation, Maria offers to share the results of her study with the tribal elders and study participants.

Her research does not find the biomarkers she was looking for, but it does reveal new information about the tribe's ancestry and how they came to settle in the region they currently occupy. Maria knows this tribe has a strong cultural mythos around their origins and homeland: they believe they are descendants of celestial deities assigned to be stewards of the land since the beginning of time. To her surprise, she finds evidence of a blend of primarily European ancestry with African, Middle Eastern and indigenous ancestry.

These results could be devastating to the identity of the members of the indigenous tribal community. Furthermore, if she publishes, this information could reignite territorial tensions with another nearby indigenous population that has been simmering for years and, potentially, even attract government involvement to settle claims on land rights between these two groups. On the other hand, this research represents new information on migration patterns that scientists have sought to understand for years.

What is the appropriate balance between maintaining privacy and advancing knowledge? When is it appropriate not to share information?

Before bringing this to her university's institutional review board, Maria meets with the head of the tribal council to discuss.

### Template Questions

<b>Data Privacy Vignette</b> <b>Persona: Maria, the researcher</b>	
What is the conflict about in this scenario?	Describe your persona's desired or ideal approach to a resolution in this scenario?
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<b>Data Privacy Vignette</b> <b>Persona: The head of the tribal council</b>	
What is the conflict about in this scenario?	Describe your persona's desired or ideal approach to a resolution in this scenario?
What underlying need(s) should your persona meet to resolve this situation?	What gaps or barriers are preventing this desirable future from being reached?
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## Data Access Group Discussion

In your breakout group, identify a volunteer to fill out the large template with team input. This will be collected. The template will help you prepare for your “pitch” presentation. Your team will have 5-7 minutes to present your side, acting as your persona: What is the situation at hand, how do you want to see it resolved and why? Get creative and have fun!

Please read the following vignette on [Data Access](#) and discuss the questions from the perspective of the [Minister of Health of Nigeria](#).

### Data Access Vignette

It's 2025, and the new Global Health and Genomic Treaty Organization (GTO) has developed an enforceable framework that governs health data transfers and access between all member countries. Genomic data, as an exceptionally sensitive form of personal data, is included in the framework. Countries or institutions outside of the **GTO** must show they have met certain ‘adequacy standards’ on data collection, privacy, use and security prior to receiving data from GTO member nations through consortia, federated data systems, or other data access models.

Unintentionally, this policy may upend a research project in planning for the better part of a year.

Leon, a researcher at a major university in Nigeria has collected genomic data from over 100,000 cancer patients from several West African countries, forming one of the largest consortium biobanks in Africa. The biobank is run by the Nigerian government. Nigeria is not a **GTO** member.

Leon is collaborating with Genevieve, a researcher at a lab in France that has 50,000 samples from cancer patients of West African descent. Together, they are trying to better identify cancer biomarkers unique to certain African populations as part of a World Health Organization multistakeholder initiative on cancer prevention.

The two researchers received all ethics and institutional review board approvals needed to start the study, when they were informed the Nigerian government has not met GTO adequacy standards related to handling genomic data. This prevents Genevieve in France from sending data to Leon. Nigeria does not have national restrictions on data leaving the country, so Leon can send data to Genevieve.

Upon learning of this, the Minister of Health of Nigeria contacts the GTO Head of Adequacy Standards. The Minister of Health accuses the GTO Head of institutionalizing a uni-directional flow of information, benefiting only the Global North and further increasing global healthcare disparities. Nigeria will not be the only country affected by such standards. The GTO Head defends his organization’s mission to protect and secure genomic information in an age of increasing cyberterrorism, data hacks and genomic espionage.

They acknowledge the current situation stands in the way of research intended to improve health and longevity and both want to find a resolution to data access.

### Template Questions

<b>Data Access Vignette</b> <b>Persona: Minister of Health of Nigeria</b>	
What is the conflict about in this scenario?	Describe your persona’s desired or ideal approach to a resolution in this scenario?

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<b>Data Access Vignette Persona: GTO Head of Adequacy Standards</b>	
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## Benefit Sharing Group Discussion

In your breakout group, identify a volunteer to fill out the large template with team input. This will be collected. The template will help you prepare for your “pitch” presentation. Your team will have 5-7 minutes to present your side, acting as your persona: What is the situation at hand, how do you want to see it resolved and why? Get creative and have fun!

Please read the following vignette on [Benefit Sharing](#) and discuss the questions from the perspective of [Edward, Head of Research at a European Organization](#).

### Benefit Sharing Vignette

As baby boomer populations in the US, Europe and Japan are now in their late 70s and 80s, diseases like Alzheimer’s are the greatest public health issue. Pharmaceutical companies refocused their drug development efforts after numerous failed trials targeting amyloid beta about ten years earlier, but effective treatments remain elusive.

Public health researchers working in the South Pacific islands notice that several native groups show no signs of dementia throughout their lives, which commonly extend well into the 90s.

Edward, the Head of Research at a European organization with strong ties in the region through its global funding initiatives contacts his counterpart, Oliana, at the leading South Pacific research organization. The two have worked together on numerous research projects in the past.

Edward is anxious to get genomic data on this population to begin research studies that may lead to a better understanding of Alzheimer’s disease. Fortunately, Oliana shares that researchers at a nearby university have already collected that data as part of a regional genomic database initiative that was designed to improve health care. Information from the samples have already been digitized and are accessible through the cloud. Edward is thrilled! He asks when he can have access to the data.

Oliana reminds Edward that the long-standing agreement between their two organizations always provided benefits including capacity building and training of local researchers in exchange for genomic information. Edward balks. That was the case for physical samples, but digital samples do not require the same level of engagement or investment, so should not carry the same expectations for benefits. Further, Edward knows that the organizations that fund his initiatives require open data access. Oliana and Edward recognize there is no framework in place to govern the exchange of digital data, even though such agreements do exist for tissue samples and other biological data.

Oliana firmly believes that such benefits must remain so as not to increase disparities in genomic capabilities between Global North and South. Information is information, regardless of its form of storage. She suggests that Edward send researchers to collect biological samples under the current framework that addresses the exchange of samples for health-related resources and capacity building while the organizations work out an approach for digital samples.

But Edward pushes back, emphasizing the extra cost to send personnel to the country and delays in research to address the global need for Alzheimer’s disease treatments. The point of digitizing data is to reduce costs and speed up the access to data to foster more international research collaborations and advance scientific discovery.

Edward and Oliana know it is time to negotiate a benefit-sharing model for digital samples.

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