Genomics Research Ethics

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Disclaimer

- All information provided in this presentation represents my personal perspectives and position and is not a formal submission from my employer

Disclosure

- I work for a private company with interests in genomics data with the aim of increasing availability of genomics data from African populations for academic and development research.

ople issue research code

igenous communities — known for their click languages — are the first ence-ethics guidelines.

OLEKSANDR RUPETA/NURPHOTO VIA GETTY

A traditional San dance performed at a living museum in Namibia.

ern Africa are d indigenous ns of research- nter-gatherer ncient rock art, and San individuals were some of the first from Africa to have their whole genomes sequenced.

But some San want a greater say in such research. On 2 March, three communities in South Africa issued their own research-ethics code — thought to be the first from any indigenous group in Africa. Although the rules will carry no legal weight, their authors hope that scientists will feel compelled to submit proposals for research in San communities to a review panel of community members. And the San may refuse to collaborate with institutions whose staff do not comply, the rules warn.

The code was developed by traditional leaders of the !Xun, Khwe and !Khomani groups of San, which represent around 8,000 people in South Africa.

“We’ve been bombarded by researchers over the years,” says Hennie Swart, director of the South African San Institute in Kimberley, which helped to develop the code. “It’s not a question of not doing the research. It’s a question of doing it right.”

The impetus for the ethics code was the 2010 publication, in *Nature*[1], of the first human genome sequences from southern Africa: those of Archbishop Desmond Tutu, winner of the 1984 Nobel Peace Prize, and four San men from Namibia. The Namibian government and ethics committees at the scientists’ universities in Australia, South Africa and the United States approved the study. The researchers also filmed the San men giving verbal consent with the help of a translator.

But some San leaders were upset that the team did not consult them, and were concerned about how the researchers obtained informed consent from the San men, according to Roger Chennells, a human-rights lawyer based in Stellenbosch, South Africa, who helped draft the code (see go.nature.com/2nwyj1m). The study was a “massive catalyst”, he says.

The paper also used terms, including “Bushman”, that some San individuals consider offensive. “No other recent research has been perceived as being so insulting and arrogant to San leaders,” says Chennells.

He anticipates that communities in Namibia and Botswana will formally adopt the code in the future. Until then, researchers working with those communities will be encouraged to take note of the code, adds Chennells.

However, Stephan Schuster, a genome scientist who co-led the study while at Pennsylvania State University in State College, asks whether the views of San leaders in South Africa are representative of other San groups. “Why would a San council in South Africa know what we are doing in northern Namibia?” ▶

TheScientist
EXPLORING LIFE, INSPIRING INNOVATION

Sanger Institute Accused of Misusing African DNA Samples

Whistleblowers allege the institute intended to commercialize a research tool based on the material, a violation of agreements with African scientists who collected the sequences.

Oct 15, 2019
KERRY GRENS

ABOVE: The Sanger Institute
FLICKR, TEMPORALATA

The Wellcome Sanger Institute in the UK had planned to commercialize a genetics array based on African DNA samples, whistleblowers allege, which would have violated the terms of agreements for using the materials, *The Times* reports. Two universities in Africa have condemned any commercial endeavors using the samples, some of which came from indigenous tribes.

“This conduct of the Wellcome Sanger Institute raises serious legal and ethical consequences,” Stellenbosch University in South Africa wrote to Sanger Director Mike Stratton in March, according to *The Times*.

Whistleblower complaints and documents reviewed by the news outlet indicate that Sanger had discussed a deal with Thermo Fisher to sell an array for investigating the genetic influence behind diseases in Africa and had 75,000 produced. Yet, according to *The Times*, the DNA samples used in the design of the arrays were

The Ethical Issues

- Informed Consent
- Fair collaboration
- Sample and data sharing
- Benefit Sharing

nature

African scientists call for more control of their continent's genomic data

Voluntary guidelines aim to combat 'helicopter' science and ensure that studies benefit African citizens and scientists.

Linda Nordling

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Why a framework?

- Generally, ethical and regulatory infrastructure for research in Africa is not yet well developed to support genomic research and biobanking:
  - Ethical sharing and use of samples and data
  - In ways that promotes the utility of such research in addressing issues of relevance to African populations while contributing to growth in scientific knowledge and break-through
- Need a framework that sets out the principles and actions that ought to be considered to guide the ethical conduct genomics research and biobanking in Africa

A compelling converging philosophy

- One that emphasises respect for diversity, solidarity and reciprocity
- **Ubuntu**
  - Initially suggested
  - But has distinctive South African origin and not likely agreeable among all Africans
- **Communitarianism**
  - Conveys the same ethos as Ubuntu
  - a more universally accepted philosophy guiding research in Africa – but also supported by others that share in the same virtues

Elements

African leadership

Substantive and meaningful contributions of scientists based at African institutions

African political and academic leadership to play roles in funding, systems strengthening and awareness

Consent

Primary samples and data need be supported by a consent model that allows sharing

Broad consent as an acceptable model

Legitimate reasons for access restrictions even with broad consent

A good governance framework is necessary

Ethics Review

Necessary for all primary genomics research and for re-use of samples or data

Primary EC to have a role in review for re-use of samples or data

Joint review or reliance agreement should be supported

To be supported by Sample and Data Access Committees

Avoiding group harm

Careful attention to studies with potential to stigmatise

Work with ECs, communities, funders to agree on ways to mitigate potential group harms where identified

Responsible reporting of study findings in studies with potential to stigmatize

Elements

Community Engagement

Important for trust building and to address myths and misconceptions

Integration of community concerns and values in research process

Strengthen the informed consent process and application of appropriate variant of broad consent

To be an integral part of all community level genomics research and biobanking initiatives

Benefit Sharing

Tangible and in-tangible benefits in genomics research

Discuss a-priori with stakeholders where tangible benefits expected,

Explore ways to confer benefits to communities where no tangile benefits expected – social recognition etc

Capacity Building

Plans for capacity building for young and senior scientists – involvement in relevant aspects of research/biobanking

Include plans to build capacity in grant writing and management as well as EC reviews

In both primary and secondary use research

Elements

Intl Collab. & Sample Export

Should promote reduction in global inequality and strengthen research systems of lower income collaborating countries

Rationale for export to be clear in protocol and consent forms and subjected to EC review

Supported by MTAs that promote interest of local researcher/organization

Results Feedback

Little attention in African context; Requires careful attention due to obligations for ancillary care

African stakeholders to articulate when, how, what to be fedback

In absence of national policies, plans to feedback results to be carefully considered and included in study protocol

Efforts to translate pertinent findings into location-specific diagnostic assays

Good governance

Ensures application of ethical principles in, and responsible use of stored sample and data

Backbone for building trust in genomics research

Needs to articulate a mechanism for review by an oversight committee to provide permission for the re-use of samples and data (DAC and SAC)

Elements

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Reasonable preferential access for African scientists

Outline mechanisms for handling commercialisable outputs

Final words

- Genomics research holds invaluable promise to improve the health of African populations
  - better understanding of disease determinants to inform prevention/management
  - Development of drugs and diagnostics with greater impact on African populations
- There are however ethical concerns that require a system to ensure improved protection of participants
  - National or regional regulation
  - Ethics committees’ empowerment
  - Community engagement – awareness, education about genomics research

Final words….2

- In Nigeria, the National Code for Health Research Ethics provides overarching principles and procedures to ensure ethical conduct of all types of research
    - Includes a policy statement on biobank operations and practice
    - Stipulates requirements for operating biobanks and monitoring obligations by NHREC
    - There is no specificity on genomics research
- What more ought there be for protection of human research participants in genomics research and biobanking?