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Ethics guidelines might serve funders' needs rather than those of research participants.

GIVE AFRICAN RESEARCH PARTICIPANTS MORE SAY ON DATA, SAY SCIENTISTS

Tensions are building over rules governing the donation of biological samples and data in research.

By Linda Nordling

Many human genome studies ask participants to sign a form that gives them little direct control over how their data will be used. But this can fuel distrust between researchers and participants, a panel of researchers in Africa finds, and needs to change.

This stark message comes in a report, *Recommendations for Data and Biospecimen Governance in Africa*, from a committee of 13 African scientists. The researchers were brought together by the African Academy of Sciences, based in Nairobi, and the African Union Development Agency, based in Addis Ababa. The report was commissioned in response to concerns that international research-funding agencies and researchers from high-income countries have a disproportionate influence in setting research priorities and data-sharing rules in Africa.

It is currently accepted practice in genomics research for data-access committees – groups of experts that are independent of researchers and funders – to decide who gets to see and use genomics data. The report's authors want research participants in Africa to have more of a say in decisions made about their data, and, in particular, to avoid what is called broad consent, which allows researchers to reuse data to answer new research questions, subject to access-control regulations.

"Broad consent has been a dogma of the funder," says Godfrey Tangwa, a philosopher and bioethicist, at the University of Yaoundé in Cameroon, and one of the report's authors. He says research funders do make ethics a priority for their research – but that their ethics guidelines often serve the funders' needs, not those of research participants.

International funders, "especially those disbursing public money, need to return tangible deliverables to the countries they represent, increasingly in the form of samples and data", the report's authors write. The same funders can be developing ethics guidelines while also funding research, and this can create a conflict of interest for funders, the authors contend.

"Researchers in Africa work under significant financial restraints, and consequently often remain beholden to foreign research funders," the report adds. "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."

One effort to boost Africa's genomics capacity is a US$180-million project called Human Heredity and Health in Africa (H3Africa). Funded by the US National Institutes of Health (NIH) and the UK biomedical funder Wellcome, it is supporting Africa-based investigators to tackle genomic causes of disease on the continent.

But even when internationally funded projects are led by African researchers, those researchers might not feel empowered to contradict their funders, says Tangwa. "Everybody is afraid of annoying or upsetting the funders, so everyone keeps quiet," he says.

The report recommends that research projects use 'tiered' consent. This allows research participants to select from a list of options they consent to their data being used for. For example, they could say that their data can be used only for the specific study for which it was collected; alternatively, they could allow data to be used in future studies relating to a specific disease. A third tier could allow researchers to use the data for any health-related studies. This option would be similar to broad consent, but with the crucial difference that participants would have a choice about it.

However, opting out of broad consent could put African countries at odds with other nations in which broad consent is common in genomics research. It could also complicate the storage of biological samples in biobanks, which were set up to share samples and the data derived from them, as a resource that can be used for decades, or even centuries, to come.

Jennifer Troyer, the NIH programme director for H3Africa, told *Nature* that the programme recommends broad consent so that African genomics data can be included in global analyses. Without broad consent, she says, such data might be left out of future analyses, which "will only increase the gap in knowledge about communities that are under-represented in available data sets".

But Ambroise Wonkam, a geneticist at the University of Cape Town in South Africa and a member of the committee that drew up the report, says that, in his experience, most participants will choose the broadest consent tier. The spirit behind the tiered approach is not to restrict data use, but rather to create a structure of engagement that fosters trust with participants. "If you really engage with the patient, you will find they are interested in sharing their data," says Wonkam, who is also co-chair of the H3Africa consortium and a co-investigator on one of its projects. The committee, he adds, is not against open science – quite the opposite, in fact.

"I don't think any single one has any interest in gatekeeping science," he says. But that openness can't come at the expense of research that participants trust and support – an issue that he says is crucial in Africa because of the continent's history of colonialism.