Balancing biobanks with the law

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When biobanks were created, the idea was that scientists could have quick access to samples they could use without having to get new specimens every time they needed to do research.

But ongoing developments in science and the commercialisation of scientific based products have heightened the need for legislation and guidelines that could specify both the ethical use and legal implications of samples in biobanks. In South Africa there is no legislation around biobanks and the guidelines are not clear enough.

Biobanks are repositories that store large numbers of human biological materials from donors along with their associated data and the information drawn from this analysis. Biobanks should not be confused with tissue banks, which involve services around cells or tissue from living or dead people for transplants.

The biobank challenge

There are two broad categories of biobanks. One category is involved in large cohort studies where tens of thousands of participants are required at a minimum. They are referred to as population biobanks and their function is to promote the health of the population. The second category are disease specific.

In South Africa there are just over a dozen biobanks, which operate on a smaller scale than their international counterparts. Not all are specific to research, and those involved in human health research are from projects

within academic institutions. The country's National Health Laboratory Services tried to establish a population level biobank but this did not materialise.

Currently there is no legislation governing biobanks.The National Health Act and its regulations, which should be providing direction, is silent on the issue of biobanks.The National Department of Health's ethics guidelines make some references to biobanks. It requires all new repositories to have approval from the research ethics committee before opening their doors. Ideally this committee should establish the procedures to guide this process and the use of the repository.

But there's a weakness in this process: oversight from the committees on already established biobanks is not mandatory.

Another problem is that of informed consent and individual autonomy around specimens. Informed consent is an ethical and legal doctrine and a necessary component of health research.

In classical research, the consent emphasis lies with the individual who decides how their samples will be used and how long they will be stored for. Because biobank research involves the contributions of large numbers of people, its ethical emphasis generally centres on the common good.

Here the challenge comes in with the secondary use of specimens. This is because future research may also involve research questions and methods that were not contemplated at the time of sample collection. Because of this, consent for biobank research cannot be truly "informed".

An ideal situation

At the University of the Witwatersrand, the Human Research Ethics Committee (Medical), which is the oldest ethics committee in the country and among the first to be established in the world, set up a Biobanks Ethics Committee in 2013. This committee reviews applications for the establishment of biobanks and all research around the use of specimens from the approved biobanks. It remains the only biobank specific committee in the country.

For biobanks to operate optimally, their governance should be harmonised.

Initial and continuous oversight of biobanks should be provided by research ethics committees. This includes the establishment of a biobank and how it is governed, managed and operated. The biobank must also set up protocols and processes for research activities, consulting with the public and other stakeholders, and establish what the criteria is for sampling and selecting participants.

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