

Establishing national biobanks in South Africa: The urgent need for an ethico-regulatory framework



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In 2012, the National Health Laboratory Service (NHLS) set up a biobank in Braamfontein, South Africa, which has a storage capacity of 120 000 samples. Recently, the H3Africa Initiative was launched with the aim of endowing several research projects across Africa, funding a bioinformatics network and establishing five biobanks, two of which are housed in Cape Town and Johannesburg respectively. The expectation is that, in a few years, the three sites in South Africa will evolve into full-scale central biobanks capable of storing over 100 000 samples harvested from African research each year. In addition, the Aids Malignancy Consortium sub-Saharan Africa biobank project has also received funding, and the plan is that this biobank will be located in Cape Town next to H3Africa's biobank.^[1]

With the goal of establishing a national or central human biobank, as a national asset that would facilitate South Africa's entry into the bioeconomy, the NHLS hosted a Human Biobank Convention on 2 October this year. According to the NHLS, a strategic national convention was necessary to urgently develop a national agenda for human biobanking. The aim was to facilitate dialogue between the key role players, including the Departments of Science and Technology (DST) and Health (DoH) and the NHLS; to define a national strategy, policies and guidelines pertaining to human tissue biorepositories; to define the roles of the DST, DoH and NHLS; and to create a platform for H3Africa and other funding agencies and stakeholders to meet and build concrete relationships.^[1]

It is interesting to note that public engagement and participation were not included in the aims of the convention – rather, a 'top-down' approach was proposed. However, the importance of public consultation and building trust cannot be adequately underscored. Public consultation and involvement are key to the success of any national biobanking venture, especially on the scale proposed, and ways of addressing the collective aspects of biobank research will therefore have to be explored. Public and community participation in research is not a new phenomenon. The public and even patient-support groups are being increasingly recognised as active participants in the research process.^[2] In fact, during discussion, all stakeholders at the convention agreed on the importance of including public engagement in the way forward.

Biobanks are repositories where organised collections of human biological materials, and associated data from large numbers of individuals, are collected, stored and distributed for the purpose of health research. Biobanking is not a new concept. What is new is that with rapid advances in science and technology, the reliance on the use of human biobanks, as well as the numbers and size of biobanks, have increased dramatically. Unlimited numbers of future research studies can now be supported. Biobanks involve global networks and extensive computerised processing of personal and health data over prolonged periods, on a scale not seen before. Suffice to say, all of this gives rise to complex ethical, legal and social issues.^[3,4]

The ethical complexities of biobanking were discussed extensively during all three consultations of the amendment process of the Declaration of Helsinki, first in Cape Town, then in Japan and later in Washington – an obvious indication of the concerns this practice evokes. The Declaration has been amended^[5] to include reference to biobanks as follows: 'For medical research using identifiable human material or data, *such as research on material or data contained in biobanks or similar repositories*, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.' (Section 32, my italics). Because of the many complexities associated with biobanks, the consultations also discussed the possibility of the World Medical Association developing a full guideline document.

In South Africa, Section 8.7 of the DoH guidelines *Ethics in Health Research: Principles, Structures and Processes* describes human tissue repositories, and situates the responsibility for oversight of repositories' operations on research ethics committees.^[6] The National Health Act 60 of 2003 and its regulations are silent on biobanks. Nor do any of these instruments mention material transfer agreements, which should be an integral component of any ethico-regulatory framework governing research involving human tissues and biobanks.

Against this background, and to facilitate ethical research, the Human Research Ethics Committee (HREC) of the University of the Witwatersrand (Wits) established a Biobanks Ethics Committee. This committee will develop principles, policy and guidelines for the review and approval of applications for the establishment of biobanks; review all applications for the establishment of biobanks; and review all research using tissue samples and/or associated data from approved biobanks. The Wits biobanks policy document was officially approved and adopted in August this year.^[7] It was also supported by the National Health Research Ethics Council (NHREC) and approved for inclusion into the national DoH research ethics guidelines (Communication from NHREC to Wits HREC Chair, 20 June 2013).

With the many initiatives afoot to establish biobanks at a national level in South Africa, it is imperative that the law and ethics keep abreast of these developments and respond appropriately. Any guideline or regulatory instrument must weigh the potential benefits

of knowledge to be gained from the research emanating from biobanks against the potential harms for participants and society as a whole. While the proposed NHLS national biobank initiative is laudable, it will only succeed if the South African public is involved every step of the way, and if they play a participatory role in determining the ethico-regulatory framework for the governance of their human biological materials and data. The ethico-regulatory framework cannot be formulated only by those who are socially and culturally removed from the proposed donors.

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