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Allegations of misuse of African DNA in the UK: Will data protection legislation in South Africa be sufficient to prevent a recurrence?

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Abstract

Concerns have been raised around the alleged commercialisation of South African genetic material by various research institutes nationally and abroad. We consider whether the Protection of Personal Information Act in South Africa will conflict with or complement existing protections in health law and research ethics. The Act is not applicable to de-identified samples that cannot be re-identified but we question whether genetic samples can ever be truly de-identified. The research participants in this matter provided consent for use of their samples for research but did not consent to commercialisation by global research institutions, and neither did the researchers. We suggest that consent models incorporating broad consent as an option should include explicit discussions around benefit-sharing and commercialisation. Mistrust between researchers and participants impedes scientific research and can harm relationships built up over the years between South African researchers and local communities.

KEYWORDS

data protection, benefit sharing, commercialization, South Africa, broad consent, DNA

1 | INTRODUCTION

This article considers the expected legal protections for data privacy in South Africa in the context of human health research and recent events in which African DNA appears to have been circulated amongst international genetic research institutions in a manner that stretches the boundaries of traditional informed consent.

The Protection of Personal Information Act (POPIA) was enacted in 2013 and came into effect on 1 July 2020. The aim of the Act is to give effect to the constitutional right to privacy and simultaneously to create a regulatory environment that gives an equivalent level of data protection to the European Union's General Data Privacy Regulation (EU GDPR) which was implemented in May 2018. At the time of writing, the Regulator was drafting codes of conduct for different sectors. It is not known whether there will be a code of conduct for the health sector, or whether the existing regulatory safeguards and research ethics guidelines will be deemed sufficient protection against exploitation of local sample donors.

2 | CURRENT RESEARCH REGULATION IN SOUTH AFRICA AND THE SPECIAL CASE OF GENETICS

South Africa is a research-rich environment with multiple national, continental and international collaborations. Since the 1990s, research has been regulated by both international and national research ethics guidelines such as the Declaration of Helsinki,

Council for International Organization of Medical Sciences (CIOMS), International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use: Good Clinical Practice (ICHGCP), Ethics in Health Research (DOH 2015), Good Clinical Practice (SA-GCP) and the National Health Act (NHA) and its regulations. The country has a well-established regulatory infrastructure in the form of a National Health Research Ethics Council (NHREC), the South African Health Products Regulatory Authority (SAHPRA) and forty-six Research Ethics Committees (RECs). Unlike existing regulations, POPIA refers to 'special personal information'. This includes, inter alia, information on race or ethnic origin, political persuasion, sex life, biometric data and health. Biometric information refers to identifying information related to physical, physiological or behavioural classification based on blood typing, DNA analysis, finger-printing, retinal scanning or voice recognition. All data collected in the course of medical practice and research falls under the ambit of POPIA, unless it has been anonymised. It is therefore unsurprising that the research community in health sciences has been curious and interested to establish how this Act will affect research in South Africa.

Genetic research challenges traditional approaches to informed consent and data privacy. International research collaborations are commonplace and result in samples and data being aggregated and shared amongst research institutions around the world. Research on African genetic data is especially desirable given that African people are more genetically diverse than any other population in the world and given the possibility that African human genes may contain undiscovered disease-causing variants.[1] POPIA will not apply to de-identified data that cannot be re-identified, but there are concerns that genetic data by its nature can in fact be 're-identified' and linked to specific individuals, population groups or physical locations by determined researchers using genetic genealogy databases.[2]

The 'Sanger Institute' incident described below illustrates the complexity of cross border sharing of personal health data during research when there is the potential for commercialisation as a result of the research. Questions also arise as to the research participants' knowledge of, and informed consent to, sharing and commercialisation of their data and whether the potential for benefit-sharing is adequately explained during the consent process.

3 | 'GENETICS UK LAB ACCUSED OF MISUSING AFRICAN DNA'[3]

Blood samples and data were obtained from several populations in Africa including the Nama people from South Africa, Namibia and Botswana.[4] In 2013, a South African research site shared data and samples with a university in the United States as part of a legitimate, agreed-upon research collaboration. The samples were then transferred to the Wellcome Sanger Institute for genome analysis for research.[5] Researchers and participants were all still proceeding as per the protocol at this point, with informed consent and an export permit in place for sending samples out of South Africa both to Stanford University and to Sanger, in the United Kingdom. Research participants were told that the samples would be used for research into population history and human evolution but did not consent to widespread data sharing for the purpose of commercialisation by research institutes abroad. The samples and data were sent to the United States for research purposes only. There was no explicit consent from participants or from the researchers for commercialisation.[6]

According to a whistleblower, since dismissed from Sanger, the institute allegedly entered into negotiations with Thermo Fisher Scientific to make gene chips using the African data. Gene chips, also known as 'microarrays' are tiny glass slides each containing DNA from a different gene. These gene chips allow for rapid genetic testing of samples. Gene chips or microarray tests provide a cheaper method of genomic testing than whole genome sequencing. There was no informed consent or data transfer agreement in place for the Thermo Fisher arrangement.[7] Stellenbosch University researchers, from one of the research sites, demanded the return of their samples on the basis that they and their research participants did not provide explicit informed consent to commercialisation of the genetic material in their Material Transfer Agreement (MTA) with the American collaborator. A data sharing agreement was not in place, according to Stellenbosch University for the transfer of data or samples to Thermo Fisher or any other party. The University of KwaZulu-Natal (UKZN) has also demanded that Sanger 'cease, desist and refrain [...] from all acts which amount to commercialisation of data.'[8]

[1]African populations have higher numbers of average variant single nucleotide polymorphisms (SNP) sites at 3.3 million per individual, compared to Europeans with 2.9 million and Japanese/Chinese with 2.8 million per individual. Retrieved June 18, 2020 from https://ghr.nlm.nih.gov/primer/genomicresearch/snp.

[2]Grymek, M., McGuire, A., Golan, D., Halperin, E., & Erlich, Y. (2013). Identifying Personal Genomes by Surname Inference. *Science*. *339*, 321–324. https://doi.org/10.1126/science.1229566.

[3]Stokstad, E. (2019). Major U.K. genetics lab accused of misusing African DNA. *Science*. https://doi.org/10.1126/science.aba0343.

[4]Wellcome Sanger denies charge of misusing African DNA. (2019). Retrieved February 11, 2020, from https://africatimes.com/2019/10/17/wellcome-sanger-denies-charge-of-misusing-african-dna/.

[5]Njilo, N. (2019). Stellenbosch University demands return of DNA samples. Retrieved February 11, 2020, from https://www.timeslive.co.za/news/south-africa/2019-10-16-stellenbosch-university-demands-return-of-dna-samples-but-uk-lab-hits-back/.

[6]The United Kingdom has adopted the General Data Protection Regulation which requires purpose specificity (informed consent must relate to a specific purpose) and the further processing of data must be compatible with the initial reason for collecting the samples. In the United States, federal regulations require that research subjects must give informed consent to commercialisation arising from the research and the issue of benefit–sharing must be addressed.

[7]Grens,K. (2019). Sanger Institute accused of misusing DNA samples. Retrieved February 11, 2020, from https://www.the-scientist.com/news-opinion/sanger-institute-accused-of-misusing-african-dna-samples-66573.

[8]Blanchard, S., & Randall, I. (2019). South African scientists demand the return of hundreds of tribal DNA samples after a British institute was accused of trying to use them to make money. Retrieved February 11, 2020, from https://www.dailymail.co.uk/sciencetech/article-7570501/UK-lab-told-return-DNA-African-tribes-accused-trying-commercialise-them.html

Research participants from UKZN and Stellenbosch had provided consent for research on population history and human evolution.

Both Sanger and Thermo Fisher deny that there was a breach of contract, infringement of intellectual property rights or commercialisation of the genetic data.[9]

4 | ACCOUNTABILITY

Section 8 of POPIA refers to accountability where the 'responsible party' must take responsibility for compliance with lawful processing of information as per the Act. This is consistent with the ICHGCP E6R2 as well as the South African GCP guideline where the Principal Investigator and Co-Investigators are held accountable for compliance with relevant regulations and guidelines. POPIA, however, is silent on commercialisation of research data.

In keeping with well-established legal and ethical policies on informed consent, research participants would need to consent to commercialisation of their data and either enter into purely altruistic arrangements waiving any benefits or enter into benefit-sharing arrangements.[10] Such arrangements usually consist of free access to treatment and any tests developed as a result of the research. In some instances, sharing of royalties on the products developed is recommended.[11] Even if no commercialisation is envisaged at the time of sample taking, the rapid pace of scientific development and thus the unforeseen potential for commercialisation is such that benefit-sharing must be explicitly addressed in the informed consent process.

The regulations to the National Health Act on research, require that 'expected benefits of the research' and 'the availability of beneficial products or interventions post-research' must form part of the informed consent process.[12] Research Ethics Committees(RECs) should be alive to this issue and ensure that the wording of informed consent documentation is such that benefit-sharing arising from possible commercialisation is well understood by research participants. This allows for purely altruistic participation in research or for participation with the expectation of sharing in the possible benefits of commercialisation, while respecting ethical principles of autonomy and justice. From a consequentialist perspective, nurturing trust between the parties enhances participation in research by African participants.[13]

5 | PURPOSE SPECIFICATION

Section 13 of POPIA introduces a requirement for specificity that has important implications for research. 'Personal information must be collected for a specific, explicitly defined and lawful purpose related to a function or activity of the responsible party'. Furthermore, the data subject must be aware of the purpose for which personal information is collected. If the samples sent to the Sanger Institute were indeed used to develop microarray test kits for commercial use, research participants should have been informed of this purpose. If, as is alleged, even the researchers who collected the samples were unaware of this, they could not have communicated this to their research participants hence the deficit in informed consent is compounded. It is unclear whether the data was shared by Sanger with any other research organisations or institutions in South Africa or elsewhere. If this had occurred, the responsibility to establish whether a Data Sharing Agreement was in place prior to accepting the data would have rested with the recipients of the data. The samples held by Sanger have since been returned to Stellenbosch University and the data is in the process of being transferred back to the university as well.[14] How the data was used by Sanger and other recipient organisations developing gene chips or microarrays remains under investigation. No report arising from the investigation has been published at the time of writing. While H3Africa claims that data used in their chip development with Illumina was sourced from other population groups, the matter is under investigation by H3Africa and universities in the Western Cape.[15]

6 | FURTHER PROCESSING LIMITATION

According to section 15 of POPIA, 'Further processing of personal information must be in accordance with or compatible with the purpose for which it was collected in terms of section 13' of the Act. It is unclear what exactly is envisaged by compatibility. It may be that if a specimen was collected for medical research, then any other medical research is compatible. However, compatibility may be interpreted in a narrower sense, meaning that if the data was collected under a consent to conduct research on, for example, diabetes, then medical research on hypertension may not be covered by the consent taken. It remains to be seen whether compatibility will be broadly or narrowly construed.

However, such further processing is presumed to be compatible – 'not incompatible' – with the original purpose for which the data was collected if the data subject (research participant) has consented to the further processing and 'the information is used for historical, statistical or research purposes and…will not be published in an identifiable form'.

This section of the Act indicates that the data subject may indeed give valid consent to unknown future use of their data i.e.

[9]Sanger Institute. (2019). Sanger Institute refutes allegations of misuse of African DNA from partner institutions. Retrieved 11 February 2020, from https://www.sanger.ac.uk/news/view/sanger-institute-refutes-allegations-misuse-african-dna-data-partner-institutions.

[10]Schroeder, D. (2007). Benefit sharing: It's time for a definition. *Journal of Medical Ethics*. https://doi.org/10.1136/jme.2006.016790.

[11]Aboriginal and Torres Strait Islander Social Justice Commissioner. May 3, 2002. The protection of genetic information of indigenous peoples. Submission to the Australian law reform Commission inquiry into the protection of genetic information. Retrieved February 11, 2020, from https://www.humanrights.gov.au/our-work/legal/protection-genetic-information-indigenous-peoples.

[12]National Health Act. Regulations Relating to Research with Human Participants: *Government Gazette* 38000 of September 19, 2014.

[13]Moodley, K., Sibanda, N., February, K., & Rossouw, T. (2014). It's my blood: Ethical complexities in the use, storage and export of biological samples: Perspectives from South African research participants. *BMC Medical Ethics*. https://doi.org/10.1186/1472-6939-15-4; See also Moodley, K., & Singh, S. (2016). 'It's all about trust': reflections of researchers on the complexity and controversy surrounding biobanking in South Africa. *BMC Medical Ethics*. https://doi.org/10.1186/s12910-016-0140-2

[14]Newsdesk. (2019). DNA samples being returned to South Africa after consent row. Retrieved February 11, 2020, from https://www.researchprofessionalnews.com/rr-news-africa-partnerships-2019-10-dna-samples-being-returned-to-africa-after-consent-row/.

[15]Stokstad, op. cit. note 3.

broad consent in the context of research. The EU's General Data Protection Regulation, which provides similar levels of data protection to POPIA, also allows broad consent for research, on the understanding that the eventual use of the data may be unknown at the time of collection. It must be emphasised that broad consent still requires that the research participant is informed of the possibility of unknown future use of their samples and of the potential for commercialisation of products developed by the researchers.

Under POPIA, where research is concerned, further processing may occur provided the data is published in a non-identifiable format. When the data has been de-identified, the Act is no longer applicable to the handling of that data. The further processing is also presumed to be compatible with the purpose for which it was collected if the researcher obtains an exemption from the Regulator to process information in a manner that would ordinarily be in breach of a condition of the Act if it is for 'historical, statistical or research activity' (s 15(3)*(f)* and s 37(2)*(e)*).

Under the National Health Act 61 of 2003, the Material Transfer Agreement of Human Biological Materials (MTA)[16] requires that organisations sharing specimens must obtain research ethics committee approval for secondary uses of biological material. The MTA also requires informed consent from donors for secondary use of their biological material (s 10.3 MTA).

Stokstad quotes a bioethicist, de Vries, stating that in relation to a different microarray, the H3Africa gene chip, 'donor consent did not restrict commercial use'.[3] In our view, this statement is ambiguous and possibly misleading. It is not clear whether research participants provided specific and explicit consent for commercial use of their samples and data and by whom, or if an assumption was made that they did not object to commercialisation. In order to object to commercialisation or not, an in-depth consent process would first be necessary to ensure that participants fully understood what commercialisation would entail. Researchers would have to prove that such an explicit detailed consent discussion around commercialisation had occurred and that participants subsequently, after full understanding of patents, royalties or profits being generated, did not object. Such transparency is important to build trust with communities. In order to reap the full benefits of genomic research on indigenous communities underrepresented in genetic databases and genetics research, novel methods of community engagement must be considered to rebuild trust in scientists.[17] Standard informed consent templates in South Africa contain waivers of royalties as the default position, even where commercialisation is not envisaged. One cannot assume that all research participants understand the meaning and implication of this waiver and of possible royalties arising out of the research. In order to avoid disputes and debates about unknown future use, benefit sharing and the nature of broad consent, the norm should be that the wording of informed consent documents relating to these concepts should be in plain language and explicit. Research Ethics Committees have a responsibility to ensure clarity of consent forms as part of the review process.

7 | OPENNESS

Documentation of all processing operations must be maintained to allow access as per the Promotion of Access to Information Act 2 of 2000 (sections 15 and 51). This provision is completely synchronous with document management specified in ICH GCP (section 3.4).

In addition, section 18 (1) of POPIA lists notification requirements to data subjects who must be aware of any intention to transfer the information to a third country or international organisation and the level of data protection there.

> **Section 18 POPIA Notification to data subject when collecting personal information**
>
> (4) It is not necessary for a responsible party to comply with subsection (1) if— (a) the data subject or a competent person where the data subject is a child has provided consent for the non-compliance; (b) non-compliance would not prejudice the legitimate interests of the data subject as set out in terms of this Act…

These requirements are consistent with requirements for consent in most research ethics guidelines except that all data provided in research is voluntary. It is therefore surprising that sub-section 4 of POPIA provides for non-compliance with sub-section 1 if the data subject consents to non-compliance or if data is being collected for research. This is inconsistent with research ethics guidance as well as consent requirements for research as outlined in chapter 9, section 71(1)*(b)* of the National Health Act, requiring informed consent to research, and with the standard MTA in South Africa. It also reflects internal contradiction within POPIA in terms of section 72 on transborder information flows. The concept of openness between researcher and participant is highlighted in the San Code of Research Ethics which 'require[s] open and clear exchange' between the researchers and community leaders, as well as prior negotiations on benefit-sharing.[18]

8 | TRANSBORDER INFORMATION FLOWS

POPIA requires at s 18(1)*(g)* that the researcher must notify the data subject if they intend to transfer the information to another country

[16]Material Transfer Agreement of Human Biological Materials. *Government Gazette* 41781 of July 20, 2018.

[17]Guglielmi, G. (2019). Facing up to injustice in genome science. *Nature*. https://doi.org/10.1038/d41586-019-01166-x. See also Reardon, S. (2017). Navajo nation reconsiders ban on genetic research. *Nature*. https://doi.org/10.1038/nature.2017.22780; and Moodley, K., & Beyer, C. (2019). Tygerberg Research Ubuntu-Inspired Community Engagement Model: Integrating Community Engagement into Genomic Biobanking. *Biopreservation and biobanking*. 17(6), 613–624. https://doi.org/10.1089/bio.2018.0136.

[18]The San Code of Research Ethics. Retrieved June 25, 2020 from http://www.globalcodeofconduct.org/; Schroeder, D., Chatfield, K., Singh, M., Chennells, R., & Herissone-Kelly, P. (2019). The San Code of Research Ethics. https://doi.org/10.1007/978-3-030-15745-6_7.

or to an international organisation. This has implications for international collaborative research projects where samples or data are transferred between countries, as in the Sanger matter. The Act places responsibility on the researcher for informing the data subject of the level of protection of the receiving country. The question arises where the researcher, after the fact, wishes to transfer the data in an identifiable form, but has not obtained consent for this from the donor, must the donor be 're-consented'? In this case it would have been reasonably practical to obtain consent from a known community. While the researchers were aware that the data would be transferred beyond their approved collaborator in the USA to the UK, the understanding was that it was for research purposes only.

Section 72 of POPIA states that data may not be transferred out of South Africa unless the recipient is subject to a jurisdiction with a 'substantially similar' level of protection (section 72 (1)*(a)*) and the data subject has consented to the transfer. The EU-GDPR, as is the case with POPIA, allows for broad consent to secondary use of data in research.[19] This section of POPIA also requires proper contractual arrangements between the data subject and the responsible party, presumably, such as informed consent; or between the third party and the responsible party, for the benefit of the data subject.

If it is not reasonably practicable to obtain the consent of the data subject and the data subject would be likely to give consent to the transfer, and the transfer is to the benefit of the data subject, the data may still be transferred out of South Africa (section 72(1)*(e)*). In the Sanger matter, the MTA and the consent obtained from research participants related to transborder flow of samples and data but did not include explicit permission for commercialisation. [3]

9 | CONCLUSION

There is currently debate and uncertainty on the type of consent required for genomics research. On the one hand, POPIA requires purpose specificity, on the other, there is a presumption of compatibility of purpose for secondary research and the possibility of a waiver of the notification requirement that data is being collected.[20]

Research participants may be amenable to granting broad consent for use of their data in specific types of research, or for a specific purpose, or by a specific type of organisation; or they may wish to opt out of certain types of research. This is especially likely where there are religious or cultural beliefs prohibiting certain uses of their biological samples. The parameters of consent should therefore be flexible to take into account individual patients' preferences and values.[21] This may best be achieved using a tiered consent model.[22] More reflection is needed on how 'broad consent' should be defined and implemented. This needs the close involvement of participants as well as researchers.[23] The debates around the types and timing of informed consent for commercialisation, benefit-sharing and unknown future use need not be a loophole for unprincipled researchers if there is clarity on consent rather than negative formulations such as 'I do not object to the following…'[24] In addition, consent templates with generic statements excluding research participants from claiming benefit from patents or royalties should be urgently reviewed. This type of statement does not take the benefit sharing requirement of the San Code of Research Ethics into account nor does it highlight the need for explicit consent for commercialisation of research results. Instead it is based on the assumption that research participants have agreed to commercialisation of research conducted on them. One might also employ Ploug and Holm's meta-consent process where the participant sets out under which circumstances they would object to secondary use or when they would wish to be 're-consented'. [16] Community engagement on genetic and genomics research and the potential for secondary use of genetic material is vital to avoid community distrust and the shut-down of such research in certain communities.[25] Of course, none of these methods will protect participants where the samples or data are obtained and commercialised without the knowledge of even the researchers themselves.[26]

The Information Regulator has indicated that it may be necessary to formulate a code of conduct for the purpose of regulating health research (sections 60-68 of POPIA).[27] Extensive consultation with stakeholders would be welcomed to facilitate the drafting of such a code in order to safeguard research participants without hindering ethical research. This would also remove uncertainty around interpretation of the provisions of POPIA.

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[24]Stokstad, op. cit. note 3. Stokstad quotes de Vries 'donors' consent did not restrict commercial use'.

[25]Reardon, op. cit. note 14, pp. 2. See also Moodley & Beyer, op. cit. note 14, pp. 620.

[26]Tiffin, N. (2018). Tiered informed consent: Respecting autonomy, agency and individuality in Africa. *BMJ Global Health.* https://doi.org/10.1136/bmjgh-2018-001249

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