Special issue

Ethico-legal analysis of international sample and data sharing for genomic research during COVID-19: A South African perspective

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ABSTRACT: COVID-19 is a global pandemic that requires a global response, with a clear need for African involvement. Meaningful participation in global initiatives supports local knowledge-based opportunities for African researchers, builds local capacity and brings research in-house. However, the historical exploitation of vulnerable population groups within South Africa (SA) have given rise to legitimate ethical concerns including mistrust by communities when international transfers of samples and data are contemplated. Historical, cultural and ethical considerations have informed the development of regulations that apply to genomic research in many African jurisdictions. On 1 July 2020, SA's Protection of Personal Information Act No 4 of 2013 (POPIA) came into force, during an exponential rise of COVID-19 cases. Amid this evolving regulatory landscape, it is unclear what impact the South African regulatory framework will have on international sample and data sharing.

KEYWORDS: South Africa; international sample and data sharing; genomic research; COVID-19; broad consent; trust

1. Introduction

Genomic research involves the use of biological samples and the generation of large data sets. The ease with which samples and data can be collected, used and re-used has brought about a shift in practice towards "open science" and a push towards the open sharing of biological samples, data and research results.[1] Open science can result in more reproducible science, encourages the optimal use of resources and can promote innovation using

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[1] M. WALPORT, P. BREST, *Sharing research data to improve public health*, in *Lancet*, 377, 2011, 538-539. See also : C. ALLEN, D.M.A. MEHLER, *Open science challenges, benefits and tips in early career and beyond*, in *PLOS Biology* 17, 12, 2019, 1-14.

existing data sets.[2] Despite the reported benefits of open science, there are tensions and challenges associated with sample and data sharing. In South Africa (SA), there are legal, ethical and historical factors which impact this type of sharing.

In SA, concerns regarding the use and international sharing of samples and data are perpetuated by the country's colonial past coupled with apartheid and power asymmetries in international collaborative research.[3] As occurred in many lower to middle-income countries (LMICs), in SA, local research facilities and researchers have been viewed as collectors of specimens only. Samples were then sent to high income countries (HICs) for use in research, with limited capacity development at the site of origin or local oversight of the sample at the research facility.[4] Attitudes towards the use of samples and data in these regions are influenced by previous experiences, but such practices are not consigned to the past. In 2019 a scandal emerged involving the Wellcome Sanger Institute who were accused of commercializing a gene chip without agreement from partner institutes or consent from hundreds of Africans who donated their DNA which was used to develop the chip.[5] This came not long after the controversies surrounding a phase I/II clinical trial of a candidate Ebola virus vaccine in sub-Saharan Africa was exposed, that involved a complete disregard of local regulatory procedures and secrecy approaches; practices that would be inconceivable in HICs.[6] Incidents such as these result in enormous setbacks to the trust relationship that is so necessary between researchers and participants, and researchers and sponsors.[7]

In addition to such power asymmetries, SA researchers are grappling with ethical issues that relate to sample and data collection, storage, use and sharing. Issues of privacy, confidentiality, autonomy, and the feedback of findings have and are currently being debated and explored in the context of genomic research in SA.[8] In addition, some African communities attach a deep cultural significance to their blood and human materials that must be respected.[9] These historical, cultural and ethical considerations have informed the development of regulations that apply to genomic research in

[2] M. WALPORT, P. BREST, *Sharing research data to improve public health*, cit., 538-539. See also: C. ALLEN, D.M.A. MEHLER, *Open science challenges, benefits and tips in early career and beyond*, cit., 1-14.

[3] K. MOODLEY, S. SINGH, *It's all about trust: reflections of researchers on the complexity and controversy surrounding biobanking in South Africa*, in *BMC Medical Ethics* 17:57, 2016, 1-9.

[4] B-J. HARDY, B. SEGUIN, R. RAMESAR, P.A. SINGER, A.S. DAAR, *South Africa: From Species Cradle to Genomic Applications*, in *Nature Reviews Genetics*, S19, S.20 ,2008.

[5] https://www.sciencemag.org/news/2019/10/major-uk-genetics-lab-accused-misusing-african-dna (last visited 29/01/2021).

[6] G.B. TANGWA, K. BROWNE, D. SCHROEDER, *Ebola Vaccine Trials, Chapter 6,* in D SHROEDER et al. (eds), *Ethics Dumping: Case studies from North-South Collaborations*, Switzerland, 2018, 49-60.

[7] P. TINDANA, S. MOLYNEUX, S. BULL, M. PARKER, *"It is an entrustment": Broad consent for genomic research and biobanks in sub-Saharan Africa*, in *Developing World Bioethics,* 19, 9, 2019.

[8] Academy of Science of South Africa Consensus Study, Human Genetics and Genomics in South Africa: Ethical, Legal and Social¸ Implications, 2018. Available at: https://bit.ly/3sH15hH (last visited 29/01/2021).

[9] K. MOODLEY, N. SIBANDA, K. FEBRUARY, T. ROSSOUW, *"It's my blood": ethical complexities in the use, storage and export of biological samples: perspectives from South African research participants*, in *BMC Medical Ethics,* 15, 4, 2017. See also: K. MOODLEY, S. SINGH, *It's all about trust: reflections of researchers on the complexity and controversy surrounding biobanking in South Africa*, cit., 1-9.

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many African jurisdictions. Regulations are at times precautionary and restrictive in nature,[10] very much focused on the samples themselves and often silent on the use and sharing of data.[11] This is changing with the emergence of general data protection regulations in many jurisdictions across the continent, and although not specific to the research sector, impact the use and sharing of data for genomic research.[12]

In SA, genomic research is regulated through the National Health Act No 61 of 2003, (NHA) its Chapter 8 Regulations, the SA Material Transfer Agreement (MTA) template and the 2015 Department of Health Ethics in Health Research guidelines (DoH ethics guidelines). The Protection of Personal Information Act No 4 of 2013 (POPIA) finally came into force on 1 July 2020 during an exponential rise of COVID-19 cases in SA and researchers have until 1 July 2021 to ensure that their data practices comply with the law. Like other data protection regulations such as the European Union's General Data Protection Regulation (GDPR), POPIA provides a high-level principle-based approach to the use of personal information,[13] that includes genomic data. It introduces strict requirements that must be met prior to the use of personal information and the transfer of data outside of SA.

The regulation of genomic research is thus changing with the coming into force of POPIA. This is a change that is occurring at a time of a global pandemic where there is a clear public interest in the rapid access to and sharing of personal information, both within SA and across its borders, to respond to COVID-19. Such sharing is important to better understand disease pathogenesis, for the development of treatment options, for vaccine development and to provide for more effective and humane care. An improved understanding of the pathogenesis of the disease may assist in identifying individuals who are at risk of contracting COVID-19 or of developing more severe diseases.[14] Several local and international consortia have been launched to better understand the genetic determinants of susceptibility to SARS-CoV-2 and COVID-19 disease severity from the perspective of both the host and the virus. From the outset of this pandemic, results and data have been shared.[15] Open science has become the norm,[16] and many journals and funders have

[10] C. STAUNTON, J. DE VRIES, *The Governance of Genomic Biobank Research in Africa: Reframing the Regulatory Tilt,* in *Journal of Law and Biosciences*, 2020, 1-20.

[11] J. DE VRIES, S.N. MUNUNG, A. MATIMBA, S. MCCURDY et al., *Regulation of Genomic and Biobanking Research in Africa: A Content Analysis of Ethics Guidelines, Policies and Procedures from 22 African Countries*, in *BMC medical ethics,* 8, 18, 2017, 1-9.

[12] C. STAUNTON, R. ADAMS, D. ANDERSON, T. CROXTON et al., *Protection of Personal Information Act 2013 and data protection for health research in South Africa*, in *International Data Privacy Law*, 10, 2, 2020, 160–179.

[13] "Personal data" is the term used in the GDPR. "Personal information" is the term used in POPIA. Personal information will be the term used throughout this paper.

[14] The COVID-19 Host Genetics Initiative*, The COVID-19 Host Genetics Initiative, a Global Initiative to Elucidate the Role of Host Genetic Factors in Susceptibility and Severity of the SARS-CoV-2 Virus Pandemic,* in *European Journal of Human Genetics*, 28, 6, 2020, 715-718.

[15] The COVID-19 Host Genetics Initiative, *The COVID-19 Host Genetics Initiative, a Global Initiative to Elucidate the Role of Host Genetic Factors in Susceptibility and Severity of the SARS-CoV-2 Virus Pandemic*, cit., 715-718. See also: Y. HOU, J. ZHAO, W. MARTIN, A. KALLIANPUR et al., *New insights into genetic susceptibility of COVID-19: an ACE2 and TMPRSS2 polymorphism analysis*, in *BMC Med*, 18, 216, 2020, 1-8. See also: *The Public Health Alliance for Genomic Epidemiology* at https://pha4ge.org/ (last visited 29/01/2021). See also: E.J. GRIFFITHS, R.E. TIMME,

committed themselves to sharing COVID-19 data and results.[17] This is a global pandemic that requires a global response and it is essential that SA participates in such research. However, in the midst of its evolving regulatory landscape, it is unclear what impact the South African regulatory framework will have on data sharing during a public health emergency (PHE).

This paper considers the effect of SA's regulatory framework on data sharing for COVID-19 genomic research. It begins by providing an overview of the importance of SA's participation in pandemic research and then considers trust as an ethical concept in genomic data sharing. It then explores consent implications on genomic data sharing, with a focussed discussion on the permissibility of broad consent during COVID-19. The paper further addresses whether the SA regulatory framework allows for the international sharing of data for COVID-19 genomic research and finally, it provides recommendations to the development of a Code of Conduct for Research to ensure more equitable and ethical research.

2. The importance of South Africa's participation in pandemic research

COVID-19 presents SA with an opportunity to contribute towards and participate in a priority global project. As evidenced by the inefficacy of AstraZeneca's vaccine against the South African variant,[18] if vaccine development is only focused on SARS-CoV-2 and its variants found in the global north, then there is a possibility that vaccines may not be effective in Africa. Dosages and frequency as well as transport and storage must be tailored to suit African populations across the differing regions in order to ensure efficacy.[19] Scientific validity in genetic studies depends in part on the amount of data that can be analysed and shared as a collective effort to ensure statistical significance.[20] This needs to be combined with an efficient and rapid analysis, particularly if this is to be effective during a pandemic. This sharing must continue as the virus evolves and new variants continue to be reported across the world. Indeed, it was through the sharing of samples and data that the SA variant that emerged at the end of 2020, was detected.[21]

A.J. PAGE, N-F. ALIKHAN et al., *The PHA4GE SARS-CoV-2 Contextual Data Specification for Open Genomic Epidemiology*, 2020, (https://www.preprints.org/manuscript/202008.0220/v1).

[16] J. HOMOLAK, I. KODVANJ, D. VIRAG, *Preliminary analysis of COVID-19 academic information patterns: a call for open science in the times of closed borders*, in *Scientometrics*, 124, 2020, 2687–2701.

[17] Sharing research data and findings relevant to the novel coronavirus (COVID-19) outbreak, Available at: https://wellcome.org/coronavirus-covid-19/open-data (last visited 29/01/2021).

[18] J. COHEN, *South Africa suspends use of AstraZeneca's Covid-19 vaccine after it fails to clearly stop virus variant,* in *Science*, 2021, available at: https://bit.ly/32F17vM (last visited 29/03/2021).

[19] K. CHIBALE, *Africa should be at the forefront of Covid Vaccine trials – and should be providing scientific leadership*, in *The Daily Maverick*, available at: https://www.dailymaverick.co.za/opinionista/2020-07-30-africa-should-be-at-the-forefront-of-covid-19-vaccine-trials-and-should-be-providing-scientific-leadership/ (last visited 29/01/2021).

[20] C.L. BORGMAN, *The conundrum of sharing research data*, in *Journal of the American Society for Information Science and Technology*, 63, 6, 2012,1059–1078.

[21] H. TEGALLY, E. WILKINSON, M. GIOVANETTI, A. IRANZADEH et al., *Emergence and rapid spread of a new severe acute respiratory syndrome-related coronavirus 2(SARS-CoV-2) lineage with multiple spike mutations in South Africa*, in *BMJ Yale*. Pre-print available at: https://www.medrxiv.org/content/10.1101/2020.12.21.20248640v1.full (last visited 20/01/2021). See also: C.K. WIBMER, F. AYRES, V.T. HERMANUS, M. MADZIVHANDILA et al., *SARS-CoV-*

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Outside of the scientific need for involvement, meaningful participation supports local knowledge-based opportunities for African researchers, builds local capacity and brings research in-house. This, in turn, assists with preparing local infrastructure for future pandemics. Currently however, not all African researchers and research institutions have the required tools and infrastructure necessary to rapidly process data during a pandemic. The Africa Centres for Disease Control and Prevention (Africa CDC) has committed to capacity building and has collaborated with the European & Developing Countries Clinical Trials Partnership (EDCTP) and more recently, the Foundation for Innovative New Diagnostics (FIND). The EDCTP collaboration will contribute towards the development of epidemiologists and biostatisticians who can collectively conduct surveillance, public health research and support timely responses to disease outbreaks in Africa in the future.[22] The collaboration with FIND aims to build technical capacity in readiness for the introduction of new, high-quality antigen rapid diagnostic tests (RDTs) for COVID-19.[23] Monitoring interventions during the early stages of a pandemic is critical to prioritising future control efforts.[24] These collaborations, infrastructural development and personnel development not only ensures a local response to a global pandemic but will go towards ensuring that African jurisdictions have the infrastructure in place to respond to future pandemics. However, an effective response in a pandemic requires meaningful collaboration between all stakeholders including the scientific community, affected population groups and policy makers.

3. "Trust" in genomic data sharing

Trust is central to the legitimacy of health research systems and it forms the basis to which the social contract between researchers and participants is honoured.[25] It can ensure acceptance of and compliance with preventive or curative interventions, that can include the uptake of vaccines as well as changes in individual behaviours to reduce risk.[26] In the SA context, mistrust appears to be linked to the country's broader socio-political context including racial discrimination under apartheid and the continued marginalisation of vulnerable groups.[27] In addition, questions around what constitutes

2 501Y.V2 escapes neutralization by South African Covid-19 donor plasma. Pre-print available at: SARS-CoV-2 501Y.V2 escapes neutralization by South African COVID-19 donor plasma (biorxiv.org).

[22] EDCTP and Africa CDC collaborate to develop capacity for outbreak and epidemic response in sub- Saharan Africa. Available at: https://africacdc.org/news-item/edctp-and-africa-cdc-collaborate-to-develop-capacity-for-outbreak-and-epidemic-response-in-sub-saharan-africa/ (last visited 29/01/2021).

[23] EDCTP and Africa CDC collaborate to develop capacity for outbreak and epidemic response in sub-Saharan Africa. Available at: https://africacdc.org/news-item/africa-cdc-find-partner-to-build-capacity-for-covid-19-rapid-diagnostic-tests-in-africa/ (last visited 29/01/2021).

[24] A. CORI, C.A. DONNELLY, I. DORIGATTI, NM. FERGUSON et al., *Key data for outbreak evaluation: building on the Ebola experience*, in *Philosophical transactions of the Royal Society of London. Series B, Biological sciences*, 372, 1721, 2017, 1-14.

[25] A. KERASIDOU, *The role of trust in global health research collaborations*, in *Bioethics*, 33, 2019, 495– 501.

[26] P. VINICK, P.N. PHAM, K.K. BINDU, J.B. BEDFORD et al., *Institutional trust and misinformation in the response to the 2018-19 Ebola outbreak in North Kivu, DR Congo: a population based survey*, in *The Lancet*, 19, 5, 2019, 529-536.

[27] S. THABETHE, C. SLACK, G. LINDEGGER, A. WILKINSON et al., *"Why Don't You Go Into Suburbs? Why Are You Targeting Us?": Trust and Mistrust in HIV Vaccine Trials in South Africa*, in *Journal of Empirical Research on*

meaningful community engagement and challenges in its implementation do little to build confidence in genomic research.[28] For instance, community mistrust in researchers and government authorities negatively impacted public health interventions in the DRC's North Kivu during the Ebola outbreak.[29] It is therefore of utmost importance that research practices during a PHE foster trust. COVID-19 genomic research is playing out in a world where there is evidence globally that the general public is reluctant to donate data and mistrust the idea of sharing with multiple users (doctors, researchers, governments).[30] There is also little familiarity with or awareness of the concepts DNA, genetics and genomics,[31] suggesting that the research community not only needs to be trusted by the public, but that urgent steps must be taken to actively communicate the importance of genomic research, data donation, and subsequent sharing, with communities.

It is not just the participant in research relationships where trust is important, but trust is also necessary between researchers who share samples and data. Data sharing practices should be cognisant of global perspectives, including African perspectives and experiences. Involvement of African researchers and samples and data in a global response to COVID-19 should be met with reciprocal benefits that include equity of access to diagnostics, therapies and vaccines. However, data sharing in the context of health emergencies is a challenge[32] and this is in part fuelled by a lack of trust in data sharing relationships.

Indonesia's refusal to share its H_5N_1 samples with the World Health Organisation (WHO) without a legally binding agreement outlining benefit sharing arrangements and intellectual property rights, points to a lack of trust of the motives of HICs and global authorities when samples and data are transferred from LMICs.[33] The concerns prompting these stipulations by Indonesia included that samples freely provided to and subsequently used by HICs for vaccine and product development are

Human Research Ethics, 13, 5, 2018, 525-536. For the purposes of this paper, vulnerability is defined in accordance with the South African National Department of Health Ethics Guidelines, 2015 as follows: "the diminished ability to fully safeguard one's own interests in the context of a specific research project; may be caused by limited capacity or limited access to social goods like rights, opportunities and power." Section 3.2 on page 26 of the same Guideline further outlines that "advanced age, very young age, personal or environmental factors like extreme poverty and ordinarily poor access to health care may increase vulnerability."

[28] C. STAUNTON, P. TINDANA, M. HENDRICKS, K. MOODLEY, *Rules of engagement: perspectives on stakeholder engagement for genomic biobanking research in South Africa*, in *BMC MED Ethics*, 19, 13, 2018.

[29] *Build trust to combat Ebola*, in *Nature*, 2019. Available at: https://www.nature.com/articles/d41586-019-00892-6 (last visited 29/01/2021)

[30] A. MIDDLETON, R. MILNE, M.A. ALMARRI, A.V. WEST et al., *Global perceptions of genomic data sharing: What shapes the willingness to donate DNA and health Data?* In *The American Journal of Human Genetics,* 107, 2020, 743–752.

[31] A. MIDDLETON, R. MILNE, M.A. ALMARRI, A.V. WEST et al., *Global perceptions of genomic data sharing: What shapes the willingness to donate DNA and health Data?,* cit., 743–752.

[32] S. ABRAMOWITZ, T. GILES-VERNICK, J. WEBB, J. TAPPAN et al., *Data sharing in public health emergencies: Anthropological and historical perspectives on data sharing during the 2014-2016 Ebola epidemic and the 2016 yellow fever epidemic, 2018 final report.* Available at: https://www.glopid-r.org/wp-content/uploads/2019/07/data-sharing-in-public-health-emergencies-yellow-fever-and-ebola.pdf (last visited 29/01/20201).

[33] X. ZHANG, K. MATSUI, B. KROHMAL, A.A. ZEID et al., *Attitudes towards transfers of human tissue samples across borders: An international survey of researchers and policy makers in five countries*, in *BMC Med Ethics*, 11, 16, 2010.

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ultimately sold back to LMICs at unaffordable prices.[34] These issues have emerged once again during this pandemic. The absence of appropriate benefit sharing arrangements with LMICs, the early shortage of COVID-19 diagnostic material in Africa, and the scramble by many HICs for access to COVID-19 therapies and vaccines (so-called vaccine nationalism, in the case of the latter) to the disadvantage of LMICs, does little to assure equity of access to diagnostics, therapies and vaccines for COVID-19.[35] Some jurisdictions have bought more doses per person than required,[36] once again reminding us of the impact that skewed global power imbalances have on equitable access to a possible COVID-19 People's vaccine, where a vaccine is available free of charge with distribution based on need.

As a key principle, trust cannot exist as a standalone concept but rather needs to be incorporated into a governance system that is founded on accountability and transparency. This is particularly significant for pandemic research where fostering mutual trust remains a challenge.[37] One method of empowering and developing trust amongst LMICs through the research process is for them to be at the forefront of COVID-19 trials with ongoing involvement. The Access to COVID-19 Tools (ACT) Accelerator, or ACT-Accelerator, is a global collaboration formed to accelerate development, production and equitable access to COVID-19 tests, treatments, and vaccines.[38] COVAX, one of three pillars of ACT-Accelerator aims to ensure equitable access to COVID-19 vaccines.[39] SA's President Cyril Ramaphosa, was recently named the ACT-Accelerator Facilitation Council co-chair and as of December 2020, at least 184 countries have expressed willingness to participate in COVAX.[40] In addition, ACT-Accelerator recently published a framework for the governance of personal data that is used to respond to COVID-19, intending to complement existing national and international regulatory instruments to enable access to and use of data without compromising fundamental rights.[41] The principle of trust is emphasised and underpinned by a governance framework that includes respect for persons and communities; equity; transparency; accountability; privacy; engagement; and non-exploitation.[42]

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[34] S.E. Davies, *The duty to report disease outbreaks: of interest or value? Lessons from H5N1*,in *Contemporary Politics*, 17:4, 2011, 429-445.

[35] J.N. Nkengasong, N. Ndembi, A. Tshangela, T. Raji, *Covid-19 vaccines: how to ensure Africa has access,* 2020. Available at: https://www.nature.com/articles/d41586-020-02774-8 (last visited 29/01/2021). See also: *The Economist, Rich countries grab half of projected Covid-19 vaccine supply*, 2020. Available at: https://econ.st/3nreFot (last visited 29/01/2021).

[36] Oxfam International, *Small group of rich nations have bought up more than half the future supply of leading Covid-19 vaccine contenders*, 2020. Available at: https://www.oxfam.org/en/press-releases/small-group-rich-nations-have-bought-more-half-future-supply-leading-covid-19 (last visited 29/01/2021).

[37] N.S. Munung, P.C. Chi, A. Abayomi, M.O. Afolabi et al., *Perspectives of different stakeholders on data use and management in public health emergencies in sub-Saharan Africa: a meeting report*. Open letter awaiting peer review. Available at: https://wellcomeopenresearch.org/articles/6-11 (last visited 29/02/2021).

[38] https://www.who.int/initiatives/act-accelerator (last visited 29/01/2021).

[39] https://www.who.int/initiatives/act-accelerator/covax (last visited 29/01/2021).

[40] https://www.who.int/countries/ (last visited 29/01/2021).

[41] ACT-A Framework p2. available at: https://www.finddx.org/wp-content/uploads/2021/01/ACT-A-Dx-data-governance-framework_15.01.2021.pdf (last visited 29/01/2021).

[42] ACT-A Framework, cit., p3.

Trust is crucial for the international sharing of samples and data, however, a governance framework that enforces trust through transparency and accountability, coupled with meaningful community engagement will assist in the practical implementation of this ethical concept. While legitimate ethical tensions are fuelled by mistrust regarding the transfer of samples and data, there is no doubt as to the global necessity for rapid access to data during pandemics. For SA to meaningfully participate in COVID-19 research, its current regulatory framework needs to provide favourable conditions for the international sharing of samples and genomic data. Based on this rationale, we now explore the SA regulatory framework for the sharing of samples and data for genomic research.

4. Regulation of genomic research in South Africa

Genomic research is broadly permitted under the National Health Act 2003, its Chapter 8 Regulations[43] and the DoH ethics guidelines which has quasi-legal standing and is legally enforceable.[44] Together they act as SA's general ethico-legal health research framework. POPIA now forms part of this regulatory framework in the context of the use of personal information in research. Personal information is broadly defined as including information relating to an identifiable, living, natural person, implying that genomic data is also covered.[45] POPIA sets out rights and duties which are designed to safeguard personal information and applies to the particular activity of processing personal information. Thus, while human biological samples and data fall under the remit of the National Health Act 2003, its regulations and the DoH ethics guidelines, biological samples themselves fall outside of the remit of POPIA. Data that is derived from a biological sample would be considered "personal information" and thus falls under the remit of POPIA. However, the biological sample itself would appear to fall outside of this legislative scheme. Although POPIA only applies to information relating to an identifiable, living, natural person, the potentially identifiable nature of genetic information needs to be considered more carefully. There may be a fine line between the exact point at which a genetic sample, that is innately identifiable, becomes personal information as contemplated by the Act.

POPIA has strict processing requirements for personal information and specifically prohibits the processing of special personal information which includes health information and biometric data.[46] However, this general prohibition[47] does not apply if consent is provided; if the processing is for historical, statistical or research purposes to the extent that the purpose serves a public interest and the processing is necessary for the purpose; if the processing is for research and it appears impossible or involves a disproportionate effort to ask for consent; or, if the processing is authorised by the Information Regulator (an independent body empowered to monitor and enforce compliance)[48] with appropriate safeguards in place.[49] Section 32(5), specifies that personal

[43] Regulations relating to the use of human biological material. GN R 177 GG 35099 of March 2012.
[44] Sections 3.3 9 and 3.5.2.3.
[45] Section 1.
[46] Section 26(1).
[47] Although the Act includes other exemptions, the exemptions to this general prohibition that are mentioned are the most pertinent ones for COVID-19 genomic research.
[48] Section 39.

information regarding inherited characteristics may be processed for research, thus reinforcing the legitimacy of processing genomic data for research purposes.

The Act therefore provides that some of the strict processing requirements can be limited or exempted from, if the personal information is processed for research. In addition, the Information Regulator may grant exemptions to some of the conditions for the lawful processing of personal information if such processing is in the public interest or where there is a clear benefit to the data subject[50] or a third party.[51] "Research activity" is included as being in the public interest.[52] POPIA thus echoes the approach of many SA national reports that emphasise the importance of the use of data in research, in particular, genomic research.[53] While POPIA clearly recognises the importance of research, the impact of these exemptions and limitations on the processing of genomic data for research during COVID-19 is less clear.

5. Consent for genomic research in South Africa

Prior to the coming into force of POPIA, specific consent, broad consent, and tiered consent were all permitted consent models in SA.[54] Specific consent is consent to one study only. POPIA requires that personal information must be collected for a specific, explicitly defined and lawful purpose.[55] Thus, it clearly permits specific consent. Specific consent however, limits the use of samples and personal data to one study. Therefore, other consent models have been proposed and adopted for genomic research.

Broad consent is a consent model that permits the use of samples and/or data for current research, for storage and for possible research on future unspecified research purposes.[56] Samples and data can be re-used for research, subject to oversight and approval by a research ethics committee. This consent model has been subject to criticism on the basis that it is not truly informed consent and limits the ability of a participant to exercise their autonomous choice.[57] However, it is seen by the H3Africa Framework for Best Practice for Genomics Research and Biobanking in Africa, as ethically appropriate, provided it is supported by community engagement, appropriate governance and a

[49] Sections 27 (1)(a), (c), (d) and (2).

[50] For health research purposes, a data subject under POPIA is referred to as a "research participant". Thus, for purposes of this paper, data subject and research participant are used interchangeably.

[51] Sections 37(1)(a)&(b).

[52] Section 37(2)(e).

[53] Department of Science and Technology Annual Report 2013/2014. Available at: https://www.gov.za/sites/default/files/gcis_document/201409/dstannualreport201314.pdf. (last visited 29/01/2021). See also: Academy of Science of South Africa Consensus Study, *Human Genetics and Genomics in South Africa: Ethical, Legal and Social¸ Implications*, 2018.

[54] As expressly stated in the 2015 Department of Health Ethics guidelines, Principles, Processes and Structures, para 3.3.6.

[55] Section13.

[56] D. WENDLER, *Broad versus Blanket consent for research with human biological samples*, in *Hastings Cent Rep.* 43, 5, 2013, 3-4.

[57] M. SHEEHAN, *Can broad consent be informed consent?*, in *Public Health Ethics*, 4, 3, 2011, 226-235.

mechanism that supports accountability and equity in the use of resources.[58] In the context of COVID-19, the ACT-Accelerator Framework provides for the processing of personal data without informed consent if it is necessary "for reasons of public interest in the area of public health[59]"and where there are "suitable specific measures in place to adequately safeguard the rights and freedoms of data subjects".[60]

Tiered consent offers a participant a series of choices about the research, type of research, subsequent use of samples, and level of data and sample sharing that they agree to.[61] By providing a range of options, it is argued that participants are more easily able to exercise an autonomous choice. But, the use of tiered consent could become restrictive as researchers may not be able to specify the types of research to be performed years down the line. In addition, as science and technology advance, it may become unviable to continue with the same types of research as outlined at the time the initial tiered consent was taken. Furthermore, it is often an option that a tiered consent model includes an element of broad consent in that participants may opt to select their samples and data to be used for further general health research purposes. Thus, the use of a tiered consent model is often contingent on the acceptability of broad consent.

6. Broad consent under POPIA

SA's NHA provides a framework for a structured uniform health system, taking constitutional obligations and other laws into account. While a general standard of disclosure is provided for in the NHA, the DoH ethics guidelines established in accordance with section 72(6) of the NHA expressly permits the use of broad consent for health research. However, uncertainty arises as to the permissibility of broad consent under POPIA. According to the DoH ethics guidelines, the nature of the further usage under broad consent should be described as fully as possible and should stipulate that further prior ethics review of the new study is necessary. Permission may be sought to re-contact the person if intended future use is outside the scope of the current consent.[62]

POPIA requires specific consent, but section 15(1) provides for the further processing if this further processing (or secondary use) is compatible with the original purpose for which it was collected. POPIA also states that further processing for research purposes is permitted if: (1) processing is necessary to "prevent or mitigate a serious and imminent threat to" public health[63] (we call this, research on the grounds of public health); (2) processing is necessary to prevent or mitigate a serious

[58] *Ethics and Governance Framework for best practice in genomic research and biobanking in Africa*, 2017, Available at: https://h3africa.org/wp-content/uploads/2018/05/Final-Framework-for-African-genomics-and-biobanking_SC-.pdf (last visited 29/01/2021).

[59] ACT-A Framework, cit., para.4.3.2, p5.

[60] ACT-A Framework, cit., para.4.3.2, p5.

[61] V. NEMBAWARE, K. JOHNSTON, A.A. DIALLO, M.J. KOTZE et al., *A framework for tiered informed consent for health genomic research in Africa*, in *Nature Genetics*, 51, 2019, 1566–1571. See also: E.M. BUNNIK, A.C. JANSSENS, M.H SCHERMER, *A tiered-layered-staged model for informed consent in personal genome testing*, in *European Journal of Human Genetics,* 21, 6, 2013, 596-601.

[62] DoH ethics guidelines, cit., para 3.3.6, p43.

[63] Section15(3)(d)(i).

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threat to "the life or health of the data subject or another individual";[64] or (3) if the personal information is to be used for research purposes and "will not be published in an identifiable form"[65] (we call this, the general research justification). The second ground (i.e. the life or health of the research participant) would appear to apply to the use of an individual's data and would likely apply in the health context, but would not be suitable as a ground for health research that requires the use of large quantities of data. Thus, it would appear that for genomic research in a pandemic, the further processing of personal information is permitted for research on two grounds: (1) research on the grounds of public health; and (2) the general research justification.

There is however, an ongoing debate regarding the legal permissibility of broad consent under POPIA. Thaldar *et al.* argue that the Act should be strictly interpreted, and that specific consent is a prerequisite for research on genomic information.[66] Staunton *et al.* on the other hand argue that a purposive interpretation of POPIA permits broad consent.[67] A purposive interpretation takes into account that the right to privacy can be subject to justifiable limitations. The preamble to POPIA itself states that "economic and social progress" may require the "removal of unnecessary impediments to the free flow of information including personal information". This also takes into consideration that POPIA provides for exemptions to some of the strict processing requirements if the personal information is to be used for research. This debate has real implications for COVID-19 genomic research.

7. The use of broad consent for COVID-19 genomic research

In a 2020 guidance note on the processing of personal information for the management and containment of COVID-19, the Information Regulator recognised the need to process personal information of research participants to curb the spread of the pandemic.[68] However, no further guidance or clarity was provided as to whether broad consent is permitted under POPIA. Should POPIA permit specific consent only, this would mean that already approved studies would have to ensure re-contact and re-consent from participants in order to process samples and data lawfully and that data could not be re-used for other COVID-19 related studies. This may be challenging and will certainly stifle pandemic research where the rapid access to samples and data is essential. A purposive interpretation of the Act is in line with the SA ethico-legal framework; such an interpretation recognises the real need for data-sharing in a public health emergency, and this interpretation is also in accordance with international norms and standards on this point.

[64] Section 15(3)(d)(ii).

[65] Section15(3)(e).

[66] D.W. THALDAR, B. TOWNSEND, *Genomic research and privacy: A response to Stanton et al*, in *South African Medical Journal*, 110, 3, 2020, 172-174.

[67] C. STAUNTON, R. ADAMS, M. BOTES, E.S. DOVE et al., *Safeguarding the future of genomic research in South Africa: Broad consent and the Protection of Personal Information Act 4 of 2013* in *South African Medical Journal*, 109, 7, 2019, 468-470.

[68] Guidance Note on the Processing of Personal Information in the Management and Containment of Covid-19 Pandemic in terms of the Protection of Personal Information Act 4 of 2013. Available at: https://www.justice.gov.za/inforeg/docs/InfoRegSA-GuidanceNote-PPI-Covid19-20200403.pdf (last visited 29/01/2021).

Owing to the uncertainty regarding the legal status of broad consent, researchers may opt to apply for an exemption from one of the processing requirements (in this case the requirement of purpose specification). The Information Regulator may grant an exemption to a processing requirement under section 37 if she is satisfied that the public interest outweighs the interference with the privacy of the research participant or a third party. The public interest is stated as including research. While this would provide clarity, guidance on applying for exemptions has not yet been gazetted, and such a process is likely to take time.

Following the above analysis, the use of personal information for COVID-19 research could thus be done on one of four grounds. First, specific consent is clearly permitted, but it prevents the further use of the personal information and the sharing of the personal information if the third party with whom the researcher is sharing the information is not known at the time of collection. Second, an exemption can be applied for under section 37, but owing to the uncertain procedure and uncertain timeframe, that is impractical in this public health emergency. Third, broad consent is permitted under the general research justification. Fourth, broad consent is permitted for COVID-19 research on public health grounds.

Clarity on the legal status of broad consent is essential and a POPIA Code of Conduct for Research must resolve this. To this end, the Academy of Science of South Africa (ASSAF) which represents SA in the international community of science academies,[69] has begun working towards the development of a Code of Conduct for Research to guide the application of POPIA to research.[70] It is hoped that the Code will be ready and approved by July 2021, in order to avoid the resulting legal impediments on necessary and ethically required and justified research. In the meantime, SA and the rest of the world are in the midst of the devastation caused by the COVID-19 pandemic, and genomic research on COVID-19 is essential.

We believe that when considering POPIA as a whole, broad consent for COVID-19 genomic research is permitted. It is now important to consider the two grounds under which broad consent is justified. Looking first at the general research ground that permits broad consent, it states that the personal information cannot be published in an identifiable form. Genomic data is innately identifiable even if it is de-identified, thus genomic data is likely to be considered identifiable under POPIA. However, POPIA does not define what is meant by "published" and what impact this has on how the personal data is made available. We submit, however, that this requirement not to publish personally identifiable personal information would prohibit making this personal information available via a publically accessible database. Thus, personal information may not be used for any research, collaboration, or be subject to a funding contract or journal requirement that requires the deposition of identifiable personal information in a publically accessible database. To enable researchers in SA to deposit personal information in a database, there must be some mechanism in place to ensure that the personal information is not published. A database that is controlled by an independent Data Access Committee (DAC) and provides access subject to the requirement that the personal information will never be published, would appear to be POPIA compliant. The second public health

[69] https://www.assaf.org.za/index.php/about-assaf/about-assaf (last visited 29/01/2021).

[70] ASSAF steering committee and drafting group for a Code of Conduct for Research under POPIA, formalised in December 2020.

ground has no similar stipulation, but owing to the need to safeguard the rights of the research participant, we argue that access to personal information for research on the grounds of public health must equally be subject to approval by a DAC. Such clarity should be given by the POPIA Code of Conduct for Research, but we consider that such an approach ensures an appropriate balance between safeguarding participant rights and enabling access to personal information for research.

8. Legal status of international sample and data sharing

Broad consent allows the further processing or secondary use of the samples and data, that includes the sharing of the samples and data, subject to REC approval. However, the regulatory framework as to the international sharing of these samples and data needs to now be considered. In 2012, a number of Regulations to Chapter 8 of the NHA were published. One of these regulations relates to the import and export of human tissue, blood, blood products, cultures cells, stem cells, embryos zygotes and gametes.[71] An export permit in relation to samples is required; however, the Regulations are silent as regards data. In July 2018, a national MTA template[72] was published by the national Department of Health and prior to POPIA coming into force, was the only ethico-legal document that regulated the transfer of samples and data where extensive networking is contemplated. However, while POPIA safeguards the processing of data only, the national MTA template provides for both samples and data. It further incorporates benefit sharing arrangements and the regulation of secondary use, allows broad consent with HREC oversight and indicates that custodianship should remain with the providing institute. The MTA template is a living document and although academic debate has unfolded since its publication,[73] it is currently the only national template available which aims to protect institutions, researchers and participants when human material is transferred out of SA.

Section 72 of POPIA outlines conditions for the transfer of personal information outside of SA and there are five possible grounds, of which three are only likely to be possible in the case of research. First, transfer can take place if the law in the jurisdiction of the recipient country provides an adequate level of protection that upholds principles that are substantially similar for the processing of personal information.[74] This can be in the form of a law, or binding corporate rules, or a binding agreement between the parties.[75] Second, the research participant consents to the transfer. Third, if the transfer is for the benefit of the participant and consent to the transfer is not reasonably practicable to obtain, recognizing that if it were reasonably practicable, then the participant would be likely to provide it.[76] As it is written, Section 72 of the Act appears to suggest that if the transfer

[71] GN R 182 in Government Gazette 35099 of 2 March 2012.

[72] National Health Act 61 of 2003. Material Transfer Agreement of Human Biological Materials. Government Gazette No. 41781: 719, 20 July 2018. https://www.gov.za/sites/default/files/41781_gon719.pdf (Last visited 29/01/20201).

[73] D.W. THALDAR, M. BOTES, A.G. NIENABER, *South Africa's new standard material transfer agreement : proposals for improvement and pointers for implementation*, in *BMC Medical Ethics*, 2020, 21, 85.

[74] Section 72(1)(a).

[75] Section 72(1).

[76] Section 72(1)(e).

satisfies one or more of the above set out grounds, then it is permissible. Thus, for example, if the transfer is subject to consent or any of the other grounds, there is no requirement that the recipient country has similar protections in place. However, under Section 57(1)(d), if special personal information, or the personal information of a minor is to be transferred to a country that does not provide an adequate level of protection for processing personal information contemplated under section 72, the prior authorisation of the Information Regulator is required. Section 57(3) states that this prior authorisation will not be needed if a Code of Conduct has come into force for a specific sector. Thus, the forthcoming Code of Conduct for Research may alter this somewhat. However, owing to the importance of the constitutional right to privacy and the sensitivity of the personal information, we would strongly urge that, at a minimum, transfer of sensitive personal information must take place subject to a MTA that requires the personal information to be protected in line with POPIA.

Turning now to the possible grounds for transfer for COVID-19 research. Consent is only practical if the research participant was informed who the third party is with whom the data will be shared and the risks associated with that sharing. Owing to the realities of the pandemic, this is unlikely to be known at the time of collection. In the context of the international sharing of data, the countries to whom research teams may want to share may not be known at the time of consent. Furthermore, as per section 11(2)(b), the research participant must be able to withdraw their consent at any time. If there are no mechanisms in place to respect this withdraw after transfer has taken place, then consent is not a ground that can be used.

The second ground is that the transfer benefits the research participant and they would be likely to provide consent if they could. Decisions on this would need to be made per research participant as the transfer is for the benefit of the individual research participant. Thus, it would need to be demonstrated that the transfer is for the benefit of each individual research participant. This is unlikely to be practical or possible where large data sets are required to be transferred. The Responsible Party would need some basis on which to make this judgment, otherwise risk being sued.

Thus, for COVID-19 genomic research, initial and onward transfers can likely only take place if there is a similar level of legislative protection in place (such as countries regulated by the European Union's General Data Protection Regulation)[77], or if the recipient in the third country agrees to be subject to a binding agreement or corporate rules which provide an adequate level of protection, for example, a Data Transfer Agreement (DTA) and a data management plan. Decisions on whether there is an adequate level of protection in the third country's legislative framework will need to be made by the Responsible Party. This assessment will be challenging as the Information Regulator has not issued any guidance regarding what levels of protection it considers as adequate. For now, researchers will likely rely upon the guidance of the European Data Protection Board (EDPB) in carrying out this

[77] D. HALLINAN, A. BERNIER, A. CAMBON-THOMSEN , F.P. CRAWLEY et al., *International transfers of health research data following Schrems II: A problem in need of a solution*. (September 7, 2020). Available at SSRN: https://ssrn.com/abstract=3688392 or http://dx.doi.org/10.2139/ssrn.3688392

assessment.[78] This assessment is going to require expertise that may not be budgeted for. Going forward, institutions and research teams will need to ensure that resources are dedicated to such assessments, but this does not resolve the need for such assessment now. This also leads us to another issue: speed. During a pandemic, rapid data sharing can be crucial, but such an assessment can take time. In addition, after this assessment, if the transfer includes the personal information of children, this requires prior authorisation by the Information Regulator, a process that also takes time. Processing this information may thus only occur after the Information Regulator completes its own investigation which could take up to 13 weeks to conduct. This could defeat the purpose of rapid access to and sharing of personal information of children during a pandemic.[79] This need for rapid data sharing in a public health emergency must be balanced with the need to protect the personal information of children. The forthcoming POPIA Code of Conduct for Research should provide guidance on how best to achieve this balance.

If after this assessment, a country is found to not have a similar level of protection through its laws, there must be either a binding corporate rule or binding agreement in place prior to transfer. Unlike the European Union, there are no standard contractual clauses[80] for transferring personal information out of SA, which have been a key legal mechanism for the transfer of personal data out of the European Economic Area (and more recently, the UK) for almost two decades. Thus, researchers will need to rely on DTAs. There is no standard DTA available in SA for researchers to use when transfers of personal information are contemplated. Currently, MTAs, an export permit, and an informed consent document are required by the office of the DoH when human biological materials are transferred outside SA. There is no uniform DTA template, which incorporates the safeguards that POPIA places on data transfer, available for researchers to populate. It may be argued that the current SA MTA template, which includes "data" into its definition of materials, could be used as a DTA; however, the provisions within the MTA template are more useful to the transfer of samples as the intricacies and technical aspects regarding data have not been incorporated into the document. The current MTA may be used as a guide, but researchers must ensure that they require an MTA in advance of sharing. The forthcoming POPIA Code of Conduct for Research must also provide guidance on the DTA and what is to be included. For now, it is clear that if a recipient in a third country does not have an appropriate level of protection in place, transfer for COVID-19 research must take place subject to a DTA, in addition to the other requirements stipulated by the DoH.

9. Recommendations and Conclusion

SA has a duty to participate in and contribute towards international collaborative research in public health emergencies, for the benefit of its diverse population groups. While legitimate ethical tensions

[78] European Data Protection Board Recommendations 01/2020 adopted on 10 November 2020. Available at: edpb_recommendations_202001_supplementarymeasurestransferstools_en.pdf (europa.eu) (last visited 08/04/2021).

[79] Sections 58(2) and (4).

[80] GA4GH GDPR Brief: *International "onward" transfers of genomic data under the EU Standard Contractual Clauses* (December 2020) Available at: https://www.ga4gh.org/news/ga4gh-gdpr-brief-international-onward-transfers-of-genomic-data-under-the-eu-standard-contractual-clauses/ (last visited 29/01/2021).

exist regarding mistrust towards the transfer of samples and data, participating meaningfully in global initiatives can assist with local capacity building and prepare local infrastructures for future pandemics, in the long term. SA's regulatory framework thus needs to be aligned accordingly to achieve this purpose. It is therefore imperative that the current uncertainties are remedied regarding what is or is not permissible for international data sharing during a pandemic. As the ASSAF works towards the development of a Code of Conduct for Research, it may consider providing guidance on how the global shift towards open science will be balanced with the safeguards and rights of research participants outlined within POPIA. In resolving some of the uncertainties in the application of POPIA to research generally, it must also consider research in a public health emergency and how to best balance the rights of the research participants with the need for rapid data sharing in a public health emergency.

As ASSAF continues with this work, we offer some tentative recommendations and points to consider, specifically for research during a public health emergency. First, under POPIA, genomic data can be processed if it is for research purposes. However, clarity is first required regarding the application of broad consent for health research purposes and specifically its permissibility for genomic research during a pandemic. We recommend that the Code should acknowledge that, while genetic data is innately identifiable, the appropriate consent model for health research should be aligned with SA's national ethics guidelines. POPIA must therefore be interpreted amongst pre-existing health regulatory frameworks and broad consent should be considered in addition to specific and tiered consent as provided for under the national ethics guidelines. Second, as POPIA does allow for broad consent for COVID-19 genomic research under the general research ground and public health ground, there should then rather be a shift in focus towards a suitable governance model that supports broad consent. Consideration should be given to DACs, their role and when a decision must be obtained from a DAC. We recommend that at a minimum, a DAC should oversee international transfers. Third, in the absence of guidance from the Information Regulator, clarity on how an assessment of a third country's data protection levels will take place and where the resources to fund such assessments will be sourced, must be contemplated, including expediting this process for research during a public health emergency. Fourth, it is essential that the Code should consider how the rapid transfer of sensitive personal information and the personal information of children should be managed during pandemics. Finally, we recommend making a DTA mandatory for international transfers. Guiding principles on standard provisions to be included within a DTA will also create a minimum standard for data transfers, which SA does not currently have. It is hoped that the forthcoming Code of Conduct for Research will provide much needed clarity not only for research during a public health emergency, but for research at a broader level, while fostering participation in open science as a benefit to SA.

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