Enabling the use of health data for research: Developing a POPIA code of conduct for research in South Africa

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Globally, there has been a move toward 'open science' that includes the sharing of health data for research. The importance of data sharing for research is generally acknowledged, but this must only be done with legal and ethical procedures and protections in place. The use and sharing of health data for research in South Africa has changed with the coming into force of the Protection of Personal Information Act (POPIA). POPIA should ensure greater transparency and accountability in the use of personal information. POPIA, however, adopts a principle-based approach to the regulation of personal information, and there is a lack of clarity and uncertainty in the application of some of these principles to the use of health data for research. POPIA provides for sector-specific responses through the development of codes of conduct. In this article, we discuss the need for a code of conduct for health research, and an approach that could be adopted in its development.

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Data sharing in research promotes collaboration and optimises the use of resources. It can lead to more reproducible science, but this essential part of knowledge exchange and scientific breakthrough is also fraught with legal and ethical concerns. Stemming from the need to protect the data subject's privacy and confidentiality, there is ongoing debate about the safeguards required to protect data subjects, and the appropriate legal and ethical framework under which to oversee collection, use and sharing of health data for research. Owing to the importance of international data sharing and the need for harmonisation of national policies, the World Medical Association (WMA),[1] the Council for International Organisations of Medical Sciences (CIOMS),[2] the Organisation for Economic Co-operation and Development (OECD)[3] and the Council of Europe[4] have all developed policies to guide international sharing of health data for research. Globally, national data protection laws have been strengthened by international and regional legal frameworks, including the European Union (EU) General Data Protection Regulation (GDPR), which came into force in May 2018.

In South Africa (SA), the use of health data for research is primarily governed by the National Health Act No. 61 of 2003 and its 2012 regulations,[5] the Department of Health research ethics guidelines[6] and the Promotion of Access to Information Act (PAIA) No. 2 of 2000.[7] This has changed with the coming into force of the Protection of Personal Information Act (POPIA) No. 4 of 2013[8] on 1 July 2020. All researchers have a 1-year grace period to ensure that they comply with the law by 1 July 2021. Its purpose is to give effect to the Constitutional right to privacy by outlining the conditions for the processing of personal information. POPIA provides a general legal framework that adopts a principle-based, and not a sector-specific, approach to the processing of personal information. Thus, while POPIA clearly states the general grounds on which personal information may be used and the rights afforded to data subjects, there is considerable uncertainty regarding how this new framework and its principles will apply specifically to the use of health data for research.[9]

The uncertainty posed by how these high-level data protection principles will apply in practice to a particular sector, for example health research, is not unique to SA. In Europe, similar uncertainty has resulted in initiatives that aimed to develop sector-specific guidance. For instance, the European Data Protection Board and the Biobanking and BioMolecular Resources Research Infrastructure are currently developing guidelines for processing of health data for scientific research and biobanking. In SA, chapter 7 of POPIA permits the development of codes of conduct that can apply to specified information or a class of information, such as health information, a specific activity, such as research, or a specific industry, profession or vocation. POPIA thus foresees the need for codes that describe how the obligations and conditions for the lawful processing of personal information can be applied and complied with in a particular sector. Such codes can provide practical guidance on how the general high-level principles should be applied in practice. Once a particular code comes into force, it is legally binding on the sector, profession or industry that is specified in it.

We have previously called for a POPIA code of conduct for research (hereinafter referred to as 'the code') to provide guidance for complying with POPIA.[10] We consider it essential that the development of this code begins before the grace period ends. The development of such a code is the subject of this article. We begin by reflecting on the need for the code in SA, before exploring its scope. Finally, this article considers the different options for determining where responsibility for leading the development of the code should lie, as well as the possible process preceding its development.

POPIA and the need for a code of conduct for research in SA

The stated purpose of POPIA under s2 is to give effect to the Constitutional right to privacy. In so doing, it balances the right to privacy with other rights and interests, including the free flow of information within SA and across its borders. Significantly, it also seeks to harmonise the standard for the processing of personal information in SA with other international standards. Although POPIA adopts a principle-based approach to the regulation of personal information across all sectors, it does make certain specific provisions for research.

The general prohibition on the retention of personal information beyond the period contemplated at the time the data were collected, the general ban on secondary use of personal information for a purpose other than that for which they were collected, the requirement to notify data subjects that their personal information is being processed and the general prohibition on processing of personal information concerning inherited characteristics do not apply if processing of the personal information is for research purposes. However, it is currently unclear whether these exemptions apply to all research or only to certain categories, and whether additional safeguards or measures must be put in place to protect the privacy of data subjects if these exemptions are invoked.

Looking at the general provisions for the processing of personal information, the code should assist researchers to understand how to use special personal information and the personal information of children for research. According to s27(1)(d), the general prohibition on processing of special personal information (which includes health data) does not apply if the use is for research, if there are sufficient guarantees in place that processing will not disproportionately affect the privacy of the data subject and if one of two grounds are met: the research is in the public interest; *or* it would be impossible or involve a disproportionate effort to ask for consent. Similarly, the general ban on the processing of personal information of children can be exempted in terms of s35(1)(d) if the research is in the public interest or if it would be impossible or disproportionate to ask for consent, and if there are sufficient guarantees put in place to ensure that the processing does not disproportionately affect the privacy of the data subject. Understanding these sections is essential to ensure that research that uses special personal information and the personal information of children can continue to operate in SA in a manner that is compliant with POPIA. Currently, without any specific policy guidance, these sections raise more questions than they provide answers for those involved in the area of health research.

Firstly, it is unclear what is meant by a disproportionate effect on the privacy of a data subject. Can there be some risk as to the identification of the data subject? What are the factors that the responsible party (the person with the overall responsibility for ensuring compliance with POPIA) must take into consideration when making this determination?

Secondly, what these 'guarantees' should be is unclear. Are they similar to 'safeguards' referred to in the GDPR, or something else? Does this involve considerations of restriction of access, and if so, who can decide on access to this personal information? Must the personal information be anonymised, or is pseudonymisation, which is not mentioned in POPIA but permitted under the GDPR and used by many international collaborative research projects, permitted? Are these guarantees akin to the 'technical and organisational safeguards' referred to within the GDPR? The exact nature of these guarantees in terms of POPIA must be clarified.

Thirdly, the meaning of a 'disproportionate effort to ask for consent' is unclear. It might be a subjective decision taken by the responsible party in light of resources at its disposal. However, such decisions should be guided by some objective factors to ensure consistency in approach in the application of POPIA, and to guard against unethical decision-making.

Finally, although s37(2)(e) states that research is in the public interest, the parameters of what is to be considered in the public interest are unclear. Can all research be considered to be in the public interest? For example, research on COVID-19 is clearly within the public interest, but can the same be said for research aimed at improving aesthetic appeal through cosmetic surgery? Too broad an interpretation obviously defeats the purpose of POPIA, and may constitute unjustifiable invasions of individuals' privacy; however, too narrow an interpretation may place undue restrictions on research. For example, while research on the augmentation of bodies for vanity purposes may lie outside the public interest, one would assume that the same could not be said for cosmetic surgery as part of a cleft lip operation.

In sum, clarity is needed on how the exemptions operate in practice. The rules of engagement for research must be sufficiently clear so that they can be applied in a harmonised and uniform fashion throughout SA and when engaging in international collaborative research. In its preamble, POPIA states the importance of harmonising SA data protection frameworks with other international frameworks. Much of SA's research is funded by international bodies such as the

EU and the US National Institutes of Health. Although international funders should not have undue influence over local legal rules, norms and practices, the code should, where possible, align itself with international standards. Equally it should specify where there are divergences and differences of approach.

Scope of the code

We thus consider the development of a code of conduct for research to be essential for research in SA. The scope of the code is considered here. No definition of research is provided for in POPIA. It could apply to all research, or be narrower in focus and apply to scientific research or health research. We propose that the code should target health research as a start, and should adopt the definition of 'health research' in the National Health Act. The advantage of this approach is that development of the code aligns itself with the National Health Act and the Department of Health research ethics guidelines, thereby helping to ensure a clear and consistent approach to the regulation of health data for research. Research that falls outside the definition of health research may require a separate code.

Development of the code

Finally, this article considers who should lead the development of the code. The information regulator published guidance on 26 February 2021 on the development of codes.[11] The development of a code can be initiated by the information regulator or another body. Irrespective of who develops the code, s61 requires the regulator to give notice in the Government Gazette that a code of conduct is being considered, the details of the code and how comments can be submitted. The guidelines also require information about the code to be posted on the regulator's website and in public notices in newspapers or relevant industry publications, and direct engagement with relevant government departments and industry groups. A code cannot be issued until stakeholders have had the opportunity to comment. Thus, stakeholder engagement is a key component in the development of any code of conduct, a process that is to be lauded.

While POPIA and the guidelines provide guidance as to the process for development of a code, it is less clear who should develop a code that covers an activity such as health research. It is submitted that the provisions of POPIA and the guidelines provide the following options:

(*i*) the information regulator

(*ii*) a collaboration between a group of bodies engaged in research

(*iii*) one body that leads the development of the code, which applies to anyone engaged in research in SA.

Section 60(1) gives the information regulator the power to issue a code of conduct. As an independent body with the power to consult with representative bodies under s40(1)(c) of POPIA, the regulator is ideally placed to lead development of a code, and also has the authority to develop such a code. POPIA has come into force and the attention of the regulator is on developing regulations and providing assistance and advice to individuals and bodies seeking to comply with the new provisions. A code of conduct for health research is therefore unlikely to have priority in the short to medium term. Considering the urgent need to develop this code, the SA research community will need to look elsewhere for its development.

The second option is that the code of conduct is developed by a collaborative group of bodies engaged in and knowledgeable about health research in SA, including those with expertise in law, ethics and social science. This would include universities, research centres and the private sector, who could come together to develop a code of conduct for health research in SA through a process of consultative stakeholder engagement. This collaborative effort would have the advantage of being developed by a group of experts who have in-depth knowledge of the particular sector-specific requirements necessary to guide the use of health data in research in SA, and the unique challenges that health research poses in the SA context. It is essential that this includes those with expertise in research ethics. Such an effort would require convergence of a group of individuals to initiate this process, to identify the relevant bodies that should be involved and to establish a core writing party tasked with drafting the code. This process would facilitate democratic participation and ensure that as many stakeholders as possible, and their interests and concerns, are considered and addressed in the resulting code. However, POPIA requires that a code be submitted to the regulator by a 'representative organisation', that compliance with the code must be monitored and that evidence of how these monitoring mechanisms are to be resourced must be submitted with the draft code to the regulator. Therefore, irrespective of the advantages posed by the proposed collaborative effort, it would require one body to take ownership of the oversight of this code.

This leads us to the third option, whereby one body or institution leads the development of a code. This body or institution would initiate the development of the code, follow the engagement procedures outlined in the draft guidelines and submit the code for approval to the regulator. Under s61(1)(b), the regulator must be satisfied that this body or institution is 'sufficiently representative' of the research community in SA. Chapter 9 of the National Health Act tasks the National Health Research Committee (NHRC) with advising the Minister of Health on the application and implementation of an integrated national strategy for health research. The Academy of Science of South Africa (ASSAf) is the national academy that advises the Minister of Higher Education, Science and Technology on matters relating to science. It is also a body that is responsible for both the private and public sectors, and regularly engages with its members. Although ASSAf does not have a policy-making role, the minister can direct ASSAf to carry out certain activities. Thus the NHRC and ASSAf could be directed through their relevant ministers to work together to develop this code. Such an approach would ensure that there is a coherent and uniform approach across the relevant departments to the use of health data for research in SA.

Conclusion

With the coming into force of POPIA expected later this year, the research community in SA must be given support and assistance to ensure compliance with these new rules and duties. Currently, there is much uncertainty as to how the provisions of POPIA apply to health research, which could be clarified in a code of conduct for health research. The process of development proposed here, and the substantive issues that such a code would consider, can be used as a model for subsequent codes that may be developed under POPIA, but owing to the fact that health research processes special personal information, the code proposed should focus on health research. Data sharing for health research is important for the health of South Africans. To ensure the continued involvement of researchers in SA in international collaborative research, clarity and transparency on the use of health data for research are

necessary to foster and promote international health research. In the final instance, the development of the proposed code of conduct for health research should be the result of engagement with the relevant government departments and researchers in both the public and private sectors. Uniformity and consistency are important to promote transparency, certainty and public trust. We suggest that the approach described in this article would help to ensure a clear, consistent and coherent approach to the regulation of personal health data for research in SA.

Since this article was accepted for publication, ASSAf has accepted this call to lead the development of a Code of Conduct for Research. ASSAf is currently engaging with scientists, ethicists, industry, legal experts and other stakeholders to develop a code of conduct for research under POPIA, which will guide the responsible use of personal information for research in all sectors. Following two public stakeholder events in 2020 as part of Open Science Week and the Science Forum SA, a steering committee and supporting drafting committee were appointed, both including diverse expertise and experience in relevant fields. The events were attended by multidisciplinary groups including scientists and researchers from different backgrounds, including genomics, biobanking, ethics and law. The objectives of a single code of conduct for research are to ensure certainty, transparency and clarity in the use of personal information for research purposes, and to provide guidance to the research community on compliance with POPIA.

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