Conditions for the lawful processing of personal information in health research

POPIA PART A: CONDITIONS FOR THE LAWFUL PROCESSING OF PERSONAL INFORMATION: IN GENERAL		SECTORAL LEGISLATION FOR HEALTH
Condition 1: Accountability	**Section 8: Ensuring conditions for lawful processing**	Health researchers must comply with the NHA, the regulations, DoH Guidelines, HPCSA Guidelines and instructions of registered HRECs. Health research on human subjects needs to be approved by the relevant HREC which is a specialist committee that makes decisions based on DoH Guidelines. The NHREC has a responsibility to recommend discipline for health researchers who violate norms and standards for ethical research (s27(6)(f) NHA).
Condition 2: Processing limitation	**Section 9: Lawfulness of processing** *Personal information to be processed lawfully and reasonably without infringing the privacy of the data subject.*	The NHA and DoH guidelines ensure that personal information is lawfully and reasonably processed. Research protocols must be preapproved by the HREC. HRECs allow researchers to conduct research once satisfied that he or she is 'suitably qualified and technically competent' (2.3.8 DoH guidelines).
	Section 10: Minimality	Researchers are required to justify collection of data for a particular research project and the research protocol must be approved by the HREC.
	Section 11: Consent, justification and objection	Section 11, 71(1)(b) of the NHA and paragraphs 3.1.9 and 3.2 of the DOH Guidelines contain detailed provisions dealing with consent. Informed consent is regulated by paragraphs 3.3.6 and 3.5.2.3 of the DOH guidelines which *inter alia* guarantee the freedom to withdraw consent at any time and regulate circumstances in which data subjects can withdraw their personal information from a study.

Conditions for the lawful processing of personal information in health research

	Section 12: Collection directly from data subject	Collection of new data or use of existing data needs to be approved by the appropriate HREC. Chapter 3 of the DoH Guidelines deals with collection of biological materials or data (3.4 DoH Guidelines).
Condition 3: Purpose specification	**Section 13: Collection for specific purpose** *Personal information must be collected for a specifically defined and lawful purpose related to the function or activity of the responsible party.* **Section 14: Retention and restriction of records** *Personal information should be retained no longer than necessary for achieving that purpose.*	Management of health records is highly regulated by provisions of the NHA and HPCSA Guidelines on retention of records, see sections 13, 15, 16, 17 of the NHA and HPCSA Booklet 9. Much health research including genomic health research requires access to health records, section 16(1)(b) of the NHA provides that health records may only be examined for the purposes of 'study, teaching or research with the authorisation of the user, head of the health establishment concerned and the relevant health research ethics committee'.
Condition 4: Further Processing Limitation	**Section 15: Further processing to be compatible with purpose of collection** *Further processing is only allowed when its use is compatible with the purpose for which it was originally collected. The section sets out considerations that must be taken into account when assessing whether the proposed processing is compatible with the original purpose.*	Section 15 of the NHA deals with access to health records. HRECS take account of any original consent to data collection and check whether the scope of the proposal research is different in order to determine whether new consent is required. In some instances it will not be necessary to reconsent people but HREC regulates how identifying information will be used in order to protect identities of data subjects (3.3.7 DoH Guidelines). When assessing the ethics of proposed genetic research, HRECs must pay particular attention to multiple considerations, including the proposed social value of the research, consent, privacy, confidentiality as well as the potential effect of the research on families, communities and other groups (3.3.8 DoH Guidelines). It is clear from the DoH Guidelines that secondary use of data is encouraged although it is understood that the reuse of data must be responsible. HRECs are also encouraged 'to bear in mind the vision of the H3Africa Initiative and its recommendation that consent should be "broad enough to allow for future and secondary uses of data, in line with the opportunities to use such data in advancing knowledge to improve health" (3.3.6 DoH Guidelines).

Conditions for the lawful processing of personal information in health research

Condition 5: Information quality	**Section 16: Quality of information**	Paragraph 2.3 of the DoH Guidelines states that scientific integrity is a key norm and standard for the conduct of research. Reliable and valid data is required for research quality and rigour (2.3.3 DoH Guidelines). The HPCSA Guidelines require researchers to 'keep accurate and up-to-date records about research participants' (Paragraphs 8.2.3 of Booklets 1, 13,14).
Condition 6: Openness	**Section 17: Documentation**	HRECs require detailed documentation as set out in the DoH Guidelines. These include protocols, information sheets, consent forms etc (3.3.1 , 3.5.2.3 DoH Guidelines)
	Section 18: Notification to data subject when collecting personal information	Collection of new data requires informed consent (sections 11 and 71(1) of NHA and DoH Guidelines). Clinical data can only be used for research purposes with the consent of the HREC (sections 11(2) and 16 of NHA). Section 11(1) of the NHA states that, 'before a health establishment provides a health service for experimental or research purposes to any user and subject to subsection (2), the health establishment must inform the user in the prescribed manner that the health service is for experimental or research purposes or part of an experimental or research project'. HREC supervises the use of secondary data as set out above.
Condition 7: Security safeguards	**Section 19: Security measures on integrity and confidentiality of personal information** **Section 20: Information processed by operator or person acting under authority** **Section 21: Security measures regarding information processed by operator** **Section 22: Notification of security compromises**	Section 17 of the NHA states that records should be securely stored. Tampering with health records or gaining unauthorised access to them is a criminal offence that can lead to imprisonment (section 17(2) NHA). The DoH Guidelines regulate security of databases (see 3.5.2.1, 3.5.2.2, 3.5.2.3). HPCSA Guidelines require encryption in certain circumstances and state that, 'patient information should only be transmitted from one site to the other and stored, with the full knowledge and approval of the patient, in line with the informed consent guidelines' (Paragraph 4.9.6 HPCSA Guidelines Booklet 13). HRECs are mandated to have standard operating procedures that cover privacy and confidentiality regarding participants and their health care information (4.5.1 DoH Guidelines). Confidentiality is defined as 'the responsibility to

		protect information entrusted to researchers for research purposes from unauthorised access, use, disclosure, modification, loss or theft' (Appendix 1 DoH Guidelines). HRECs approve and monitor processes for the maintenance and security of records in health research (4.5.1.10 DoH Guidelines). The sectoral legislation for health follows POPIA in stating that data subjects should be made aware of data breach or leaks (13.4.8 HPCSA Guidelines Booklet 13). The DoH Guidelines require researchers to immediately report serious or unexpected adverse events that might warrant reconsideration of ethical approval to the HREC (4.5.1.2 DoH Guidelines). The latter would cover data breach (4.5.1, 4.5.1.2 DoH Guidelines). HRECs have jurisdiction over the security of databases. They have the power to monitor research practices in the way they deem appropriate and they are empowered to conduct random searches (4.5.1.10 DoH Guidelines).
Condition 8: Data subject participation	**Section 23: Access to personal information** **Section 24: Correction of personal information** **Section 25: Manner of access** *A data subject has the right to access his or her own personal information. However, data subjects can sometimes be refused access to this information as POPIA incorporates the grounds of refusal in PAIA.*	Transparency and openness are fundamental principles in the DoH Guidelines. Paragraph 6.3.11 of the HPCSA Guidelines Booklet 13, states that 'researchers should allow competent research participant's unimpeded access throughout the research period to information concerning the research' (also see 3.5.2.3 of DoH Guidelines). Health researchers are required to keep accurate records. Records would have to be corrected when necessary. In the event that data subjects feel that they were deceived about their personal information collected, they can exercise the freedom to withdraw consent at any time without any reduction of care (3.2.4.3 DoH Guidelines). They can also request withdrawal of their personal information and destruction of their data from the study (3.5.2.3 DoH Guidelines). There is sometimes overlap between research data and clinical data as health researchers rely on clinical records. Paragraph 11 of the HPCSA Guidelines booklet 9 requires health care professionals to give research participants 'access to information in health records' incorporating provisions of the Children's Act,

		the NHA, PAIA and the Choice on Termination of Pregnancy Act 92 of 1996. Also see s10 of the NHA as well as sections 30 and 61 of PAIA (Paragraph 11 of the HPCSA Guidelines Booklet 9). There are also detailed provisions for correction or alteration of clinical records in the HPCSA guidelines (paragraphs 8 and 13 of the HPCSA Guidelines Booklet 9).
PART B : PROCESSING OF SPECIAL PERSONAL INFORMATION		
	Section 26: Prohibition on processing of special personal information **Section 27: General authorisation concerning special personal information** **Section 32: Authorisation concerning data subject's health or sex life**	The NHA and the DoH Guidelines create a complex structure which permits health research and the accompanying data to be processed under rigorously defined circumstances (see particularly sections 71, 72 and 73 of the NHA and DoH Guidelines).
PART C: PROCESSING OF PERSONAL INFORMATION OF CHILDREN		
	Section 34: Prohibition on processing personal information of children **Section 35: General authorisation concerning personal information of children**	Section 71(2) and (3) of the NHA deals with research on children and there are extensive provisions in the DOH guidelines' paragraphs 3.2.2.

KEY	
POPIA	The Protection of Personal Information Act No. 4 of 2013

Conditions for the lawful processing of personal information in health research

NHA	The National Health Act No. 61 of 2003
PAIA	The Promotion of Access to Information Act No. 2 of 2000
DoH Guidelines	National Department of Health (DoH) 2015 Guidelines, Ethics in Health Research: *Principles, Processes and Structures*
HPCSA Guidelines Booklet 1	*Health Professions Council of South Africa Guidelines for Good Practice in the Health Care Professions: General Ethical Guidelines for Health Care Professions*
HPCSA Guidelines Booklet 9	*Health Professions Council of South Africa Guidelines for Good Practice in the Health Care Professions: Guidelines on Patient Records*
HPCSA Guidelines Booklet 13	*Health Professions Council of South Africa Guidelines for Good Practice in the Health Care Professions: General Ethical Guidelines for Researchers*
HPCSA Guidelines Booklet 14	*Health Professions Council of South Africa Guidelines for Good Practice in the Health Care Professions: Ethical Guidelines for Biotechnology Research in South Africa*