Western Cape Government
Health

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Guidelines on requests for access to patient data and patient information systems from Western Cape Government: Health (WCGH)

1. Background

WCGH, as a result of its service provision function, collects and processes large amounts of data. Much of the data is individual-based and includes personal details (including health-related information regarding birth, morbidity and mortality) and demographic details of patients. To uphold patient rights, this data is treated as confidential. It cannot be divulged to any third party, without proper authorisation by WCGH.

Patient data held by WCGH can be very useful for planning, monitoring and research, both within and outside the health sector. Data can be used to identify vulnerable populations or populations most affected by the burden of disease (BoD) and to provide an indication of where policy makers should be focussing efforts to reduce and prevent any increase in the BoD.

In addition to managing patient data, WCGH is custodian of electronic patient information systems which are used by clinical or clerical staff. A key characteristic of these systems is that they contain named patient data. Access to these systems should be restricted and based largely on the needs of authorised users to provide patient care.

WCGH is committed to ensuring that data, and patient information systems supporting the provision of health care and other essential services, are available to appropriate users. This guideline outlines procedures to be followed for parties requesting access to and use of specified aggregated data, specified individual patient data, with or without identifying information, and direct access to patient information systems. Whilst facilitating access to data and information systems, this guide intends to ensure that confidentiality and appropriate use of information and access to patient records is maintained.

Access to patient information is simplified into three broad categories: (1) access to discrete aggregated data, (2) access to person-level data (identified or non-identified) or (3) access to patient information systems which contain patient information together with patient identifiers. The application procedures which need to be followed with respect to each of these categories are described below.

Users interested in accessing patient data should complete the *Application for Access to Health Data form* (Annexure A), while those interested in accessing Patient Information Systems should complete the *Application for Access to Electronic Patient Information Systems form* (Annexure B). The flowchart (Annexure C) illustrates these user application processes.

2. Applicability

These guidelines are applicable to:

a) All national, provincial and local government employees who wish to access individual or aggregated data outside of the facilities where they are based, for whatever purpose.

b) All other public entities defined as *"institutions that operate a system of financial administration separate from the national, provincial and local spheres of government and in which the State has a material financial interest"*;[1]

c) Non-Governmental Organisations (NGOs) or Non Profit Organisations(NPOs);

d) Academic institutions;

e) Research Councils;
f) Other private organisations; and
g) Researchers.

These guidelines *do not apply to:*

a) Clinicians who access identified individual level data across facilities to ensure continuity of care for their patients cared for at their local facility. These clinicians are required to assure confidentiality through recognised professional ethical standards.
b) Government employed officials whose KRAs include responsibility for the collation and analysis of data for programme monitoring and evaluation or planning purposes.

3. Policy Context

WCGH is committed to working with other data users, NGOs/NPOs and other stakeholders to share information in order to help improve the health outcomes of the people of the Western Cape. However, this commitment must be contextualised against and guided by several policy and legislative documents:

3.1 The National Health Act (Act 61 of 2003) that establishes the National Health Research Committee and the National Health Research Ethics Council that provide advice to the National Minister to ensure that research on human subjects, including the use of health related data, is of benefit to the population and meaningfully contributes to the improving of health outcomes. Provision is made for the disclosure of a patient's health records for study, teaching or research purposes with the consent of:

a) an adult competent patient or the parent or care-giver of a patient who is a child;
b) the head of the concerned health establishment; and
c) the relevant Health Research Ethics Committee.

3.2 The Protection of Personal Information Act (Act 4 of 2013), provides for the protection of the constitutional right to privacy. It furthermore aims to align South African

legislation with international data protection standards, the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, and seeks to balance the right to privacy against other rights such as access to information.[i]

3.3. The Promotion of Access to Information Act (PAIA) (Act 2 of 2000) provides for access to (i) information held by the State; and (ii) any information that is held by another person **and** is required for the exercise or protection of any rights, of which health is one such right.

3.4 Children's Act (Act 38 of 2005): The HIV status of a child may only be disclosed with the consent of:

a) The child if the child is 12 years of age or older;
b) A child under the age of 12 years but sufficiently mature to understand the benefits, risks and social implications of such a disclosure;
c) The parent or care-giver if the child is under the age of 12 years and not of sufficient maturity to understand the benefits, risks and social implications of such a disclosure;
d) A designated child protection organisation arranging the placement of the child, if the child is under the age of 12 years and not of sufficient maturity to understand the benefits, risks and social implications of such a disclosure;
e) The superintendent or person in charge of a hospital if the child is under the age of 12 years and is not of sufficient maturity to understand the benefits, risks and social implications of such disclosure *and* the child has no parent or care-giver and there is no designated child protection organisation arranging the placement of the child; or
f) A children's court, if consent is either unreasonably withheld and the disclosure is in the best interests of the child or the child/parent or care-giver is incapable of giving consent.

[i] The act is not yet fully operational and only a limited number of sections, mainly dealing with the Information Regulator is in operation.

3.5 Mental Health Care Act (Act 17 of 2002): A person or health establishment may not disclose any information which a mental health care user is entitled to keep confidential in terms of any other law. However, the head, either of the national/provincial department of health or the concerned health establishment, may disclose such information if failure to do so would seriously prejudice the health of the mental health care user or of other people.

3.6 Choice on Termination of Pregnancy Act (Act 92 of 1996): The identity of a woman who has requested or obtained a termination of pregnancy shall remain confidential at all times unless she herself chooses to disclose that information. Information that a pregnancy has been terminated, without identifying the individual, must be recorded and reported to the relevant head of the provincial department of health.

3.7 Ethical Guidelines guide research and ensure the protection of the rights, safety and wellbeing of study participants and assist with the maintenance of the highest standards of ethical practice in health research, consistent with the National Health Act. These include:

3.7.1 a) Ethics in Health Research: Principles, Structures and Processes (2015, 2nd edition)and

b) Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (2006, 2nd edition).

3.7.2 Key principles of these ethical guidelines are:

a) Respect and dignity of persons;
b) Relevance of research;
c) Scientific integrity;
d) Investigator competence;
e) Investigator responsibility; and
f) Informed consent.

3.8 Protection of Information Act (Act 84 of 1982) - which stands to be replaced by the **Protection of State Information Bill (B6-2010) -** provides for the protection of certain

state information from alteration, loss or destruction or unlawful disclosure and regulates the manner in which state information may be protected.

3.9 **Minimum Information Security Standards (MISS),** provides, amongst other things, for the protection of sensitive information, and will therefore provide for justified exemption from disclosure of such information.

4. Guidelines for access to health related data and patient information systems

The definitions of the different types of data and conditions under which they are released to users are explained in this section:

4.1. Definitions

4.1.1 ***"Non identified data"*** means information that cannot be used on its own or with other information to identify, contact, or locate a single person, or to identify an individual in context.

4.1.2 ***"Identified data"*** means information that can be used on its own or with other information to identify, contact, or locate a single person, or to identify an individual in context.

4.1.3 ***"Confidentiality"*** means not sharing information about people without their knowledge and agreement, and ensuring that written and electronic information cannot be accessed or read by people who have no right to see it.

4.1.4 ***"Informed Consent"*** means consent of a patient or other recipient of services based on the principles of autonomy and privacy; this has become the requirement at the centre of morally valid decision making in health care and research. Seven criteria define informed consent: (1) competence to understand and to decide; (2) voluntary decision making; (3) disclosure of material information; (4) recommendation of a plan; (5) comprehension of terms (3) and (4); (6) decision in favour of a plan; and (7) authorization of the plan. A person gives informed consent only if all of these criteria are met. If all of the criteria are met except that the person rejects the plan, that person makes an informed refusal.

4.1.5 **"Patient information systems"** refers to electronic patient data generated or accessed through software routinely utilised to capture or access data in the

provision of care. Some examples of such systems are: PHCIS, Clinicom, JAC, ETR.Net or TIER.Net.

4.2. Releasing non-identified data

4.2.1 WCGH undertakes to make non-identified person-level data available on request to entities identified in Section 2 only under the following conditions:

a) The release of such data has been approved by the Head of Department or a delegated official;

b) The recipient of the information has agreed in writing

   i. To ensure the confidentiality of the information and compliance with the obligations imposed by the Protection of Personal Information Act (No 4 of 2013) regarding the protection of personal information, where applicable;

   ii. that the data may not be released to a third party without the written permission of the Head of Department, WCGH or a delegated official.

   iii. That provincially-held data covered by this agreement cannot be made available to service partners or to funders, or through publication, without the explicit written permission of WCGH

c) Timeframes for the holding of data and the destruction of files containing data are required and must be specified in the 'Application for Access to health data' (Annexure A).

4.2.2 WCGH undertakes to make aggregate, non-identified data available, provided that the use of this information does not breach confidentiality and that the data cannot be connected to a person's identity [e.g. 1 suicide in a town in the last 5 years is easily connected to the person in question]. Where data allows for such a connection to be made, WCGH may:

a) make available aggregated data over a broader geographical area;

b) make available data over a longer period;

c) make available data by broader categories; or

d) enter into a confidentiality agreement with the data requestor.

4.3. Releasing identified data

Identified data can be requested for research and to merge data sets from other government departments for planning purposes. These requests are subject to provisions given in sections 4.2.1 a) AND b).

Requests for *research* purposes require compliance with the following additional conditions:

a) For prospective and retrospective studies requiring access to datasets, proposals must be approved by an accredited Health Ethics Committee and submitted through the Provincial Research processes (See link below for the website to access further information).
b) For prospective studies, appropriately obtained consent of the concerned individual/s as prescribed by legal requirements is required. Consent is only properly obtained if the identified person understands (i) what she/he is consenting to; and (ii) how the data shall be used. The consent must be recorded in writing and signed by the identified person.
c) For both prospective and retrospective studies, research protocols and associated approvals must explicitly cover the identified data requested.
d) The data request only covers data for participants enrolled in the research study, and similar data related to other people not named will not be furnished.
e) In contexts where researchers request that larger datasets be searched for potential matches to research participants. WCGH reserves the right to conduct the linkage or search exercise (within available resources) to protect non-participants from breaches of confidentiality.

4.4. Data required for Legal Purposes

Data required for legal purposes may be requested in terms of the Promotion of Access to Information Act, No. 2 of 2000 (PAIA) or, where applicable, the Protection of Personal Information Act, No. 4 of 2013 (POPI) and shall be subject to the relevant legal prescripts.

These acts, in conjunction with other pieces of legislation, such as the National Health Act, No. 61 of 2003, Children's Act, No. 38 of 2005, Mental Health Care Act, No. 17 of 2002,

Choice of Termination of Pregnancy Act, No. 92 of 1996, the Minimum Information Security Standards (MISS) and the Protection of Information Act, No. 84 of 1982 provide for the access and protection of information in the possession of government department(s).

4.5. Access to Patient Information Systems

Access to patient information systems is managed and governed in accordance with the following categories of users:

4.5.1. **Clinical staff** are governed by professional guidelines, codes of conduct and responsibilities with respect to protecting patient confidentiality, notably the Health Professions Council of South Africa guidelines on keeping of patient records (HPCSA, 2008). Their access should be to improve continuity and quality of patient care. Access to such electronic systems should ideally be logged, in order to be able to audit if non-treating clinicians sought access to patients not in their care.

4.5.2. **Non-clinical staff**, such as clerical staff who do not require access to clinical details, should, through user level security be restricted from accessing patient clinical details, as long as this does not compromise the quality of care or service. Non-clinical staff should have patient confidentiality and conduct around patient information included in their conditions of employment. Non-clinical staff who are not bound by professional conduct nor employment contract to standards of practice related to patient confidentiality should enter into a formal agreement as per these guidelines.

4.5.3. **Data analysis staff:** This refers to persons needed to perform analytical tasks with named patient data (4.3) or access patient information systems. They may be provincially employed, contracted or seconded from other organizations such as universities and/or research councils/partners. These staff are required to apply for access and accept the agreed conditions to access the patient information system.

4.5.4. **Ongoing access by researchers conducting approved operations research** may be required to assist with clinical or clerical processes. In instances where they may require access to electronic patient information systems, this is permitted where they are effectively part of the local service delivery or clinical care team involved through the operational research project. They are further required to enter into a formal user agreement, as above (4.5).

4.6. Dissemination and Publication

4.6.1 The data derived from data requests or extracted through permitted access to information systems may only be used for publication if:

a) this is agreed to by WCGH;
b) WCGH has been given the opportunity to comment on any evaluation, analysis or interpretation prior to publication subject to an agreed time limit for comment;
c) full acknowledgement of the source of the data is made in the publication.

4.6.2 Where data are requested for use within WCG only, the data may be used by the individual requestor or requesting organisation (e.g. Research Councils, Universities, Health Research NGOs, City of Cape Town, Government Departments) for the purposes of analysis and evaluation, but findings may not be disseminated to a broader audience in any way,

4.6.3 WCGH reserves the right to request co-authorship by identified staff members on published analysis undertaken on service-generated data where such staff member(s) have contributed substantially to the collection of the data and/or other steps in the process recognised as meriting co-authorship.

4.7. Data and Information Systems user Agreement

Requests for access to data and patient information systems shall only be processed upon receipt of a signed application form(s) by a designated WCGH official (See Annexure A and B) and approval for release of data signalled by the signature of the designated official.

4.8. Process for applying for access to data or information systems

An overview of the application process for access to data and information systems is given in Appendix C. The Data Use Application Process serves to ensure that there is an understanding between WCGH and user(s) on the type, time period, frequency and security of the data when they are released to the applicant(s). However, application for use of data does not guarantee that the request will be approved. If the intended purpose for data is altered or extended in anyway, a new agreement must be entered

into with WCGH. Applicants will have to complete and sign Annexure A.

Similarly, application for access to patient information systems serve to ensure understanding between WCGH and user(s) on the type of access required, user category, time period covered, frequency and the purpose for which access is requested. If the intended purpose for systems access is altered or extended in anyway, a new agreement must be entered into with WCGH. Applicants will have to complete and sign Annexure B.

4.8.1 All **non-identified aggregated data** requests should be directed to:

Name: Ms Lesley Shand
Ph No: 021-483 2639
E-mail: Lesley.Shand@westerncape.gov.za

4.8.2 All requests for **patient-level (identified and non-identified) data for research purposes** shall be directed to the secretariat for the Provincial Health Research Committee (PHRC) that shall facilitate access to such data based on these guidelines. Guidelines for research approval are found from the following link: www.capegateway.gov.za/eng/pubs/public_info/H/213781

Contact details for secretariat

Name: Sabela Petros
Ph No: 021-483 6857
E-mail: sabela.petros@westerncape.gov.za
Website: www.westerncape.gov.za

4.8.3 All **identified data requests *other than* for research purposes** should be directed to:

Name: Dr Melvin Moodley (Director: Health Impact Assessment)
Ph No: 021-483 9366/9341
E-mail: melvin.moodley@westerncape.gov.za

4.8.4 **Media Requests**

All requests by journalists must be directed to the Director: Communications,

Contact details

Name: Mrs Marika Champion (Director)
Ph No: 021-483 3235

E-mail: marika.champion@westerncape.gov.za

4.8.5 **Promotion of Access to Information** (PAIA)

Requests for information via the PAIA process should be directed to the department's PAIA Deputy Information Officer. The PAIA manual is available at: http://www.westerncape.gov.za/sites/www.westerncape.gov.za/files/doh-paia-section-14-manual.pdf

Contact details

Name: Mr Eugene Reynolds
Ph No: 021-483 4661
E-mail: Eugene.Reynolds@westerncape.gov.za
Website: www.westerncape .gov.za

4.8.6 **All patient information systems access requests must be directed to:**

Name: Dr Melvin Moodley (Director: Health Impact Assessment)
Ph No: 021-483 9366/9341
E-mail: melvin.moodley@westerncape.gov.za

[1] Public Entities Amendment Act, No. 30 of 1997.

ACRONYMS

BoD	Burden of Disease
CDU	Chronic Dispensation Unit
CoCT	City of Cape Town
WCGH	Western Cape Government: Health
HIA	Health Impact Assessment
HPCSA	Health Profession Council of South Africa
KRAs	Key Results Areas
MISS	Minimum Information Security Standards
MOU	Memorandum of Understanding
NGOs	Non Governmental Organizations
PAIA	Promotion of Access to Information Act
POPI	Protection of Personal Information Act,
SINJANI	Standard Information Jointly Assembled by Networked Infrastructure