PHISC
Private Healthcare Information Standards Committee

PHISC HEALTHCARE INFORMATION GOVERNANCE

GUIDING PRINCIPLES FOR PRIVACY, CONFIDENTIALITY & INFORMED CONSENT FOR HEALTHCARE INFORMATION

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Revision History

Version	Date	By Whom	Changes
1		Hester Huysamen	Initialisation

Definitions, Acronyms and Abbreviations

Abbreviation	Term / Definition
CPA	Consumer Protection Act 68 of 2008
ECT	Electronic Communications and Transactions Act 25 of 2002
EDI	Electronic Data Interchange
EEA	Employment Equity Act 55 of 1998
HIG	Healthcare Information Governance
ISO	International Standards Organisation
MSA	Medical Schemes Act 131 of 1998
NHA	National Health Act 61 of 2003
PAIA	Promotion of Access to Information Act 2 of 2000
PEPUDA	Promotion of Equality and Prevention of Unfair Discrimination Act 4 of 2000
PHI	Personal Health Information
PHISC	Private Healthcare Information Standards Committee
POPI	Protection of Personal Information Act4 of 2013
RSA	Republic of South Africa
SAMA	South African Medical Association

"Anonimised data" refer to "De-identified information".

"Coded data" means a rule for converting a piece of information, i.e. a letter, word, phrase into another form of presentation, not necessarily of the same type.

- In communications and information processing, **encoding** is the process by which information is converted, from a source, into symbols to be communicated.

- **Decoding** is the reverse process, converting these code symbols back into information understandable by a receiver.

"Consent" means an agreement to an action based on knowledge of the action involved and its likely consequences.

- **"Express Consent"** means consent, which is expressed orally or in writing (except where patients cannot write or speak, when other forms of communication may be sufficient).

- "**Informed Consent**" means that for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in the National Health Act (NHA) 61 of 2003 Chapter 2 Section 6. Refer to PHISC HIG Principle 8.1.

"**Critical Data**" means data declared by the Minister in terms of Section 53 of the Electronic Communications and Transactions Act No. 25 of 2002, to be of importance to the protection of the national security of the Republic of South Africa (RSA) or to the economic and social well-being of its citizens.

"**Critical Database**" means a collection of critical data in electronic form, which may be accessed, reproduced or extracted.

"**Data subject**" means the subject of care.

"De-identified information" means information from which the patient cannot be identified or re-identified by the recipient of the information, where re-identifiable information means, according to the POPI Act information that has been de-identified has been resurrected, that:—

(a) identifies the data subject;
(b) can be used or manipulated by a reasonably foreseeable method to identify the data subject; or
(c) can be linked by a reasonably foreseeable method to other information that identifies the data subject

"**Generic Standards**" means that the standards' requirements can be applied to any organisation.

"**Healthcare Provider**" means a person providing health services in terms of any law, including in terms of the:-

(a) Allied Health Professions Act, 1982 (Act No. 63 of 1982);
(b) Health Professions Act, 1974 (Act No. 56 of 1974);
(c) Nursing Act, 1978 (Act No. 50 of 1978);
(d) Pharmacy Act, 1974 (Act No. 53 of 1974);
(e) Dental Technicians Act, 1979 (Act No. 19 of 1979)

"**Healthcare team**" means the healthcare team who comprise the people providing clinical services as defined in the NHA as healthcare providers and the administrative staff who directly support those services.

"**Healthcare role player**" refers to medical schemes, administrators, managed care organisations, service providers, data management entities, switching houses, intermediaries and their employees, governing bodies, trustees and boards of directors.

"**Health Establishment**" means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services.

"**Health information**" refers to all information that pertains to or could be linked or re-linked to a particular person or group, physical and/or mental health and biometric information as defined by the POPI Act. This includes the health status and/or health care, treatment, diagnosis, tests, procedures, visit to and/or stay in healthcare facilities, and any other related healthcare information, including financial information i.e. claims per beneficiary, specific costs per event per patient, of any person or group. It includes any record irrespective of its format or type.

- **"Personal health information (PHI)"** according to International Standards Organisation (ISO) 27799 means information about an identifiable person which relates to the physical or mental health of the individual, or to provision of health services to the individual, which may include:

(a) information about the registration of the individual for the provision of health services;
(b) information about payments or eligibility for healthcare with respect to the individual;
(c) a number, symbol or particular information assigned to an individual to uniquely identify the individual for health purposes;
(d) any information about the individual collected in the course of the provision of health services to the individual;
(e) information derived from the testing or examination of a body part or body substance;
(f) Identification of a person (e.g. health professional as provider of healthcare to the individual).

NOTE: PHI does not include information that either by itself or when combined with other information available to the holder, is anonymised i.e. the identity of the individual who is the subject of the information cannot be ascertained from the information.

"**Hospital**" means a health establishment which is classified as a hospital by the Minister in terms of section 35 of the NHA, 2003 (Act No. 61) published in Government Gazette 26595 dated 23 July 2004

"Patients" means competent patients and parents of, or those with parental responsibility for, children who lack maturity to make decisions relating to their healthcare as authorized by the Children's Act of 2005 (Adult patients who lack the capacity to consent have the right to have their confidentiality respected. Guidance on disclosure of information about such patients is included in paragraph 5.4 hereof.)

"Personal information"
The POPI Act of 2013 refers to de-identified information that can be re-identified and is included within the protected ambit of personal information.

"Personal information" is defined as information relating to an identifiable, living, natural person, and where it is applicable, an identifiable, existing juristic person, including, but not limited to—

(a) information relating to the race, gender, sex, pregnancy, marital status, national, ethnic or social origin, colour, sexual orientation, age, physical or mental health, well-being, disability, religion, conscience, belief, culture, language and birth of the person;
(b) information relating to the education or the medical, financial, criminal or employment history of the person;
(c) any identifying number, symbol, e-mail address, physical address, telephone number, location information, online identifier or other particular assignment to the person;
(d) the biometric information of the person;
(e) the personal opinions, views or preferences of the person;
(f) correspondence sent by the person that is implicitly or explicitly of a private or confidential nature or further correspondence that would reveal the contents of the original correspondence;
(g) the views or opinions of another individual about the person; and
(h) the name of the person if it appears with other personal information relating to the person or if the disclosure of the name itself would reveal information about the person.

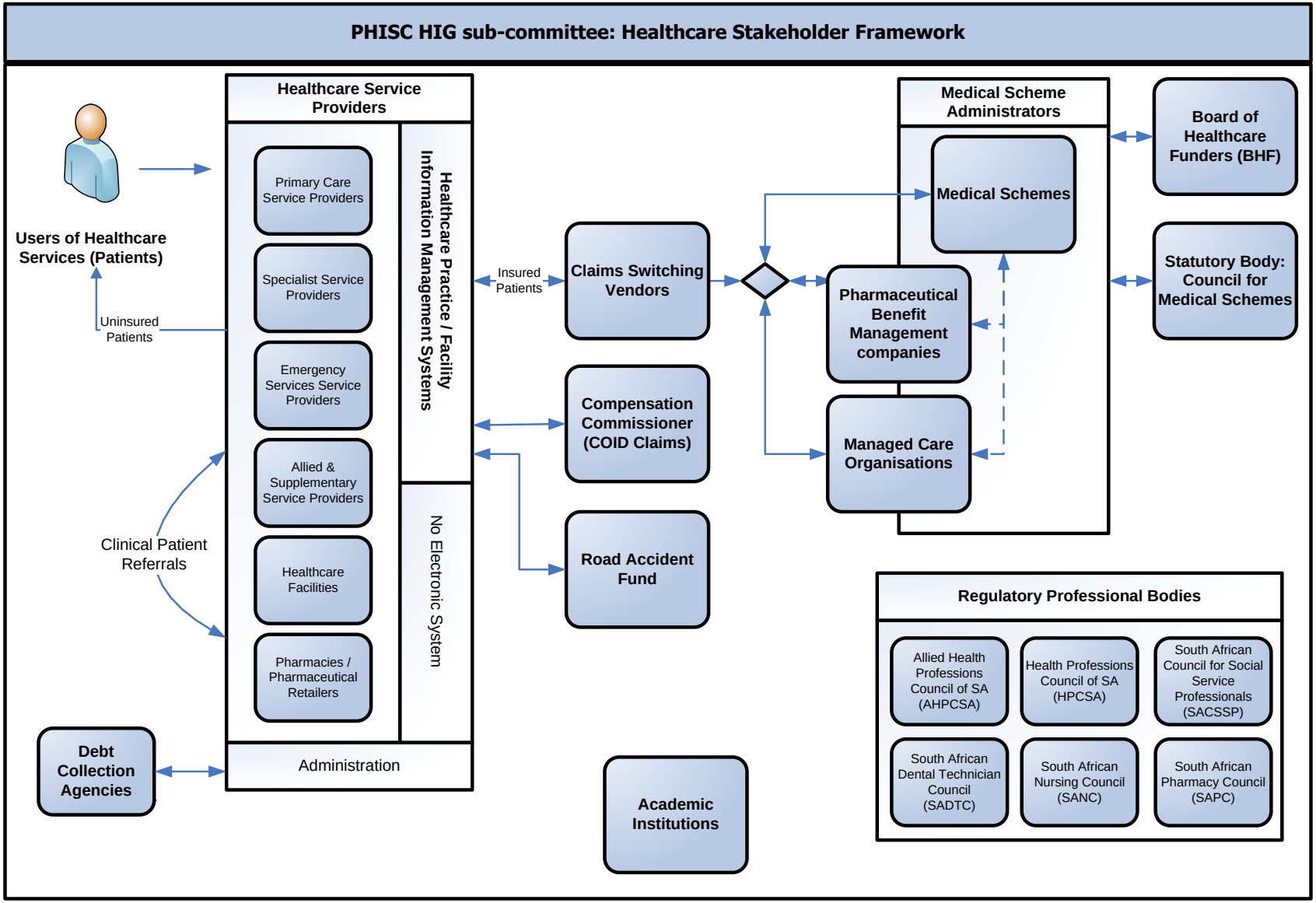
"Personal health information" refers to "Health Information".

"**Processing**" means, as defined in the POPI Act any operation or activity or any set of operations, whether or not by automatic means, concerning personal information, including—

(a) the collection, receipt, recording, organisation, collation, storage, updating or modification, retrieval, alteration, consultation or use;
(b) dissemination by means of transmission, distribution or making available in any other form; or
(c) merging, linking, as well as restriction, degradation, erasure or destruction of information.

"Standards" refer to documented agreements containing technical specifications or other precise criteria to be used consistently as rules guidelines or definitions or characteristics to ensure that materials, products, processes and services are fit for their purposes.

Figure 1: Healthcare Stakeholder Framework



A. PHISC HEALTHCARE INFORMATION GOVERNANCE SUB-COMMITTEE: GUIDING PRINCIPLES ON PRIVACY AND CONFIDENTIALITY FOR HEALTHCARE INFORMATION

Guiding principles set by the PHISC Healthcare Information Governance sub-committee for healthcare information

Date : [to be inserted when final]

A1. Executive Summary

This document contains a Definitions Clause and the 15 guiding principles relating to privacy and data-protection as it pertains to the health funding area. These are:

1. Adherence to legislation governing rights to privacy and confidentiality
2. Non-discrimination principles, as enshrined in the Promotion of Equality and Prevention of Unfair Discrimination Act (PEPUDA) and the Employment Equity Act (EEA), should be adhered to
3. Healthcare stakeholders should establish privacy policies and procedures
4. Privacy protection should follow data throughout the communication cycle
5. The applicable ISO standard to be adhered to in cross-border transfer of data
6. Stakeholders should be held accountable for breaches of information
7. De-identification of data
8. Notification to data subjects on uses of their information
9. Data subjects must have access to their own information held by third parties
10. Disclosure of information may only take place on authorisation by a law, a court of law or with written consent of the data subject
11. Disclosures to law enforcement officials should not take place outside of the applicable legal requirements
12. Financial or organisational links do not permit free flow of personal information
13. Contractual and commercial relationships should respect personal information principles
14. Marketing using personal information to take place within scope of legislation
15. International standards and local legislation and policy should be adhered to in cases of research

A2. Introduction

The Private Healthcare Information Standards Committee (PHISC) is a grouping of representatives of organisations committed to, *inter alia*, the development and promotion of common health information standards in the private healthcare sector in South Africa.

The forerunner to PHISC was the Electronic Data Interchange (EDI) Steering Committee, which developed common EDI message standards, and the work of this committee continues in the Message Standards Task Group of PHISC. Other sub-committees have been established within PHISC, one of which if the Sub-Committee for Healthcare Information Governance (HIG) (previously known as the Privacy and Confidentiality sub-committee).

The final product of the deliberations at this PHISC Privacy and Confidentiality sub-committee was the "Guiding Principles on Privacy and Confidentiality of Healthcare Information" document. Since publication, PHISC has reviewed and updated this document to ensure appropriateness in today's healthcare environment.

In the spirit of co-operation, the members of PHISC would encourage all stakeholders in the healthcare industry to make their protocols freely available to the industry via PHISC. In this way, information and ideas can be united and the best solution for South Africa can be debated and recommended as a National Guideline.

Where parties feel unable to participate in the PHISC processes, it would be most helpful, and welcomed, if they would be prepared to indicate where conflicts occur between their protocols / guidelines / standards and that published by PHISC, with a view to resolving such conflicts wherever possible.

Should you wish to familiarise yourself with the operations of PHISC, this information is accessible on the PHISC website www.phisc.net.

A3. Guiding Principles

Principle 1: Adherence to legislation governing rights to privacy and confidentiality

(1.) All parties dealing with patient healthcare and personal information have to **adhere to the relevant legislation**, such as the Constitution of the RSA of 1996, the Medical Schemes Act of 1998, the PAIA, the NHA, the POPI Act, the Children's Act of 2005 and specific provisions contained in health, healthcare and health professional legislation.

(2.) Personal information, health information and coded data can only be disclosed on the basis of a **clear legislative mandate** (i.e. lawful processing), and in accordance with the conditions set in the PAIA, viz. accountability, processing limitation, purpose specification and further processing limitation.

(3.) Administrators and intermediaries are **obliged to keep confidential all information and material in their possession** whether related to beneficiaries and/or service providers, commercial entities and/or suppliers; and are bound by the same principles governing the conduct of the scheme and/or service provider in relation to patient information confidentiality and disclosure.

(4.) Any **third party request for information** is to be dealt with in terms of the PAIA. The provisions of Sections 14, 15 and 16 of the NHA should also be adhered to.

Principle 2: Non-discrimination principles, as enshrined in PEPUDA and EEA should be adhered to

(5.) Health privacy protections should be implemented in such a way as to enhance and not undermine existing laws prohibiting discrimination, such as PEPUDA, EEA and the MSA. This principle also applies to issues such as profiling of practices and patient groups.

Principle 3: Healthcare stakeholders should establish privacy policies and procedures

(6.) Healthcare role players and healthcare providers should, in effecting their duties in terms of section 57(4)(i) of the MSA, and the POPI Act, establish policies, procedures and review mechanisms regarding the protection of personal information, the processing, retention, destruction and duration of storage thereof.

Principle 4: Privacy protection should follow data throughout the communication cycle

(7.) Privacy protection should follow the data, irrespective of the number of intermediaries between the patient, as initial provider of the information, and any final destination. This also applies to electronic messaging and information that crosses borders into, or outside of the RSA.

(8.) Section 17 of the NHA places a duty on health establishments to ensure that there is no unauthorised access to records, which implies the setting up of mechanisms to verify record and data requests, even where these are from funding institutions or data warehouses. Failure to do so constitutes an offence under the Act.

(9.) The onus of protecting confidential information vests with the holder thereof, as well as the responsible party, who in terms of the POPI Act means "a public or private body or any other person which, alone or in conjunction with others, determines the purpose of and means for processing personal information". Healthcare role players should therefore, implement security safeguards for the storage, use, and disclosure of health information, irrespective of the format of such information. Confidentiality agreements should also be entered into with third parties to whom information is disclosed beyond the extent of the principles herein contained.

(10.) Health information handed over to an attorney or debt collection agent for legal proceedings should not include medical records, i.e. only the quantum and course of action should be disclosed. The nature and extent of treatment would only be raised should there be a dispute to which this information is pertinent and if such is raised by the patient him/herself.

Principle 5: The applicable ISO standard to be adhered to in cross-border transfer of data

(11.) PHI on the subject of care may be transferred across national borders and collected, stored, processed, and published for many purposes, including clinical research and health statistics. Since the extent of the protection afforded to personal health data varies from country to country, the common and internationally accepted ISO Standard, which provides a uniform set of guidelines acceptable to all health-related organisations in countries worldwide, whether transmitting to, or receiving personal health data from, other countries, should be complied with.

(ISO 22857:2004 Health Informatics- Guidelines on data protection to facilitate trans-border flows of PHI).

(12.) Chapter 9 of the POPI Act contains detailed provisions relating to data quality and security safeguards, as outlined in sections 16, and 19 to 22.

Principle 6: Stakeholders should be held accountable for breaches of information.

(13.) All role players who handle healthcare information should be held accountable for breaches of privacy and confidentiality for information in their hold. Aggrieved persons should have access to internal procedures and/or outside institutions at which to lodge complaints.

(14.) The NHA specifies penalties for health establishments and their staff in terms of violations of privacy/data protection.

(15.) Section 57(4)(h) of the MSA requires of all medical schemes to ensure adherence to all laws.

(16.) The POPI Act contains remedies and sanctions, including enforcement and complaints mechanisms.

(17.) The provisions of the South African Constitution of 1996 could also serve as the basis of a complaint to the South African Human Rights Commission, or as basis of legal action against those violating the applicable human rights as outlined in Principle 1.

Principle 7: De-identifying data

(18.) For all uses and disclosures of health information all healthcare role players should remove personal identifiers consistent with maintaining the usefulness of the information, unless legislation authorises specific personalised disclosures and such disclosures comply with all legislative criteria, such as written consent (if applicable) and/or criteria set by the POPI Act.

(19.) Nothing prevents the compilation and/or manipulation of anonymous or de-identified information (i.e. information that is not identifiable and/or that cannot be re-identified) for the purposes of financial or other planning, for risk calculation within the scope as permitted by legislation or for statistical purposes, related to the core business of the entity in possession of the information. The role player compiling and/or manipulating such information lawfully owns such information.

(20.) The processing or further processing of information that starts out as personal information or identifiable information is subject to consent that complies with the POPI Act and relevant health-specific legislation and includes the right to object to processing of personal information [also see Principle 9 paragraph 28].

Principle 8: Notifications to data subjects on uses of their information

(21.) Data subjects (individuals) should be given notice and agree in writing to the (possible) uses-, purposes- and disclosures of their health information in the chain of health care and health care financing, even where such information would be de-identified at some stage.

(22.) Data subjects (individuals) have to be informed about their rights with regard to that information and the implications of the processing of such information. The use(s) or purpose(s) of such information has to be specified. The provisions of section 18 of the POPI Act have to be complied with. This should be done at the point of potential delivery of health care, as well as the point of application for medical scheme membership or health insurance.

(23.) In order for members/patients to have control over their information, they should at some point consent to the variety of uses to which their information may be put.

(24.) All processing of information has to take place within the authorised legislated framework or with the data subject's consent to the purpose(s) and has to be adequate, relevant and not excessive in relation to such stipulated purpose(s).

(25.) Cognisance should be taken of the provision of section 52ff to the ECT Act of 2002, whereby some databases may be declared "critical databases" and certain measures have to be instituted to secure the database and access to it.

Principle 9: Data subjects have access to their own information held by third parties

(26.) A data subject (individual) has the right to access his or her own health information, as regulated by the PAIA and other relevant legislation, and the right to, where necessary, requests the correction, destruction or deletion of personal information.

(27.) In terms of the NHA, a person's right to know his or her health status may be withheld "in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user". This section gives statutory recognition to the common law doctrine of therapeutic privilege.

(28.) In terms of the POPI Act, a person is entitled to be notified that his/her personal information is being collected, accessed or acquired.

Principle 10: Disclosure of information may only take place on authorisation by a law, a court of law or with written consent of the data subject

(29.) Personally identifiable health information should not be disclosed, except in circumstances authorised by law, court order or with the patient's specific, full and informed consent in writing, bearing in mind the provisions of the POPI Act.

(30.) Informed consent means that the patient or member should know the reasons why the disclosure is necessary. For example, for the execution of duties in terms of a specific section of the MSA, such as waiting periods, and/or a specific regulation.

(31.) The patient should also know and understand the implications such disclosure means for him or her in terms of health care delivery and financing.

(32.) Healthcare role players are encouraged to formulate the various purposes for which private information is required or should be disclosed, and whether such are authorised by legislation or whether specific patient or member consent is required.

(33.) The provisions of Section 7 and 8 of the NHA, The Children's Act of 2005, Section 9(1) of the Mental Health Care Act, the PAIA and other relevant legislation relating to consent and participation in decisions affecting a patient's personal health and treatment should be taken into account.

(34.) Where written patient authorisation is not possible as is required by the NHA, alternative generally acceptable means of identification may be used e.g. biometric consent, subject to compliance with relevant legislation. The processing of any such biometric information is however subject to the provisions of the POPI Act.

(35.) The same rules of confidentiality and consent to disclosure apply to dependants of medical schemes who, as patients have the same rights to protection of their personal information as the principal member of a scheme and steps have to be taken to ensure sufficient protection of dependant / beneficiary confidentiality.

(36.) Care should be taken in relation to the rights of children to consent, which includes the right of the child to have such information held in confidence. The potential conflict with the consent that could be provided in terms of the POPI Act is recognised, but proposed to be resolved by means of the application of the specific legislation overriding general legislation rule of interpretation, which would require the provisions of the Children's Act and HPCSA Ethical Rules to be followed.

Principle 11: Disclosures to law enforcement officials should not take place outside of the applicable legal requirements

(37.) Healthcare role players should not disclose any information to law enforcement officials or any other person acting in a capacity of investigating any alleged or suspected offence, in the absence of the requisite legal process and criteria, such as a warrant or court order. The principle of lawfulness in accessing information applies to all instances, not only personally identifiable information.

(38.) Only relevant information may be supplied concerning the purpose for which the information is to be disclosed, as stipulated within the framework of such warrant or court order.

(39.) Caution should also be exercised when investigators acting on behalf of medical schemes request information. In such cases, written informed consent from the patient is a pre-requisite prior to any form of disclosure.

Principle 12: Financial or organisational links do not permit free flow of personal information

(40.) Contractual, commercial and/or ownership linkages between healthcare role players and/or healthcare providers, and/or employment relationships that facilitate medical scheme cover, do not warrant the sale, distribution, disclosure or sharing of personal information from one such entity to another without adherence to the applicable legal provisions and the principles contained in this document.

Principle 13: Contractual and commercial relationships should respect personal information principles.

(41.) Strong and effective remedies for violations of privacy protections shall be established, including employee training and -disciplinary measures, appropriate contractual provisions and penalties with respect to any party contracting with healthcare role players.

Principle 14: Marketing using personal information to take place within scope of legislation

(42.) All marketing within the healthcare sector that uses the personal information of patients and/or potential or existing clients or consumers, has to take place with due regard to the provisions in relation to consent and/or refusal as outlined in the Consumer Protection Act (CPA) of 2008 and chapter 8 of the POPI Act.

Principle 15: International standards and local legislation and policy should be adhered to in cases of research

(43.) All health research is subject to the provisions of sections 11, 15 and 16 of the NHA, and in particular, Chapter 9 of the NHA and all research policies issues pursuant thereto, such as internationally accepted research documents, such as the Helsinki Declaration.

(44.) The legislation applies to all research, even where the researcher only uses existing files of patients, existing records such as those kept by medical schemes, managed care organisations or administrators and has no patient contact at all.

A4. References and Further Reading

The following is a list of all Acts and other documents, as well as resource documents, referred to in this document.

(a) Constitution of the RSA,1996
(b) National Health Act (NHA) 61 of 2003
(c) Protection of Personal Information Act (POPI Act) 4 of 2013
(d) Medical Schemes Act 131 of 1998 (as amended)
(e) General regulations in terms of the Medical Schemes Act 131 of 1998 (as amended)
(f) Consumer Protection Act 68 of 2008
(g) The Promotion of Access to Information Act 2 of 2000 (PAIA)
(h) Electronic Communications and Transactions Act 25 of 2002
(i) ISO International Standard 22857: 2004
(j) ISO International Standard 27799: 2008-07-01
(k) Children's Act 38 of 2005 and the regulations of 2010 thereto.
(l) Promotion of Equality and Prevention of Unfair Discrimination Act 4 of 2000
(m) Employment Equity Act 55 of 1998
(n) Criminal Procedures Act 51 of 1977
(o) Ethical Rules of the HPCSA GNR.717 of 4 August 2006, as amended: Ethical Rules of Conduct for Practitioners registered under the Health Professions Act, 1974 and the various booklets issued by the HPCSA pursuant thereto.
(p) PHISC Message Standards on Discharge Status Codes version 2 dated January 2012.
(q) South African Medical Association (SAMA) Doctors and Patients Rights and Responsibilities document
(r) Helsinki Declaration, 2013

Guiding principles set by the PHISC Healthcare Information Governance (HIG) sub-committee on Obtaining Informed Consent

Date : DRAFT 1 dated 22 October 2014 Version 1.00

B1. Introduction

The PHISC HIG workgroup compiled several checklists that could be used by healthcare practices and/or facilities in order to comply with all legislative and bio-ethical requirements as set out in the NHA 61 of 2003, POPI Act 14 of 2013 and the CPA 68 of 2008.

This document aims to describe the legal and bio-ethical requirements in layperson's terms and to demonstrate the practical implementation requirements for healthcare professionals / facilities.

B2. Using the PHISC HIG Informed Consent Check List A – Healthcare Professionals

The PHISC HIG workgroup developed Check List A specifically with healthcare professionals and healthcare facilities in mind. This checklist could be used to document the required process of obtaining informed consent from patients and should be stored as part of the patient's medical record.

B3. Using the PHISC HIG Informed Consent Check List B – Patients

Informed Consent enables patients' rights to autonomy in managing their own health status.

Check List B was developed from the patient's point of view. The healthcare professional and/or facility could supply this checklist, which could enable the patient to exercise his / her rights to information and their right to participate in the decisions affecting their health, treatment and details about the prognosis.

B4. Using the PHISC HIG Informed Consent Check List C – Protection of Patient's Personal Information for Healthcare Service Providers

The Purpose of this checklist is to ensure that healthcare service providers conduct themselves in a responsible manner when collecting, processing, storing and sharing another entity's personal information by holding them accountable, should they abuse or compromise personal information in any way. The POPI Act considers personal information as "precious goods" and bestows to the owner of his/her personal information, certain rights of protection and the ability to exercise control over it.

The guiding principles, as per Chapter 3 of the POPI Act, are as follows:

- Collection of PHI requires consent.
- Consent is required for the processing of PHI.
- PHI must be collected for valid reasons.
- PHI used must be limited to the purpose.
- Notification is required when PHI is compromised.
- Person must have access to his/her own PHI.
- The person has the right to have PHI removed and/or destroyed if so wished.
- Adequate measures and controls must be in place to prevent unauthorised persons accessing PHI.
- Adequate measures and controls must be in place to safeguard PHI.
- The institution is responsible for the correct capture, integrity, continued accuracy and maintenance of the PHI once collected
- Protection by means of using a unique identifier that identifies the data subject in relation to the specific responsible party

As per Chapter 4 of the POPI Act, there are eight conditions for the lawful processing of PHI:

1. Accountability
2. Processing limitation
3. Purpose specification
4. Further processing limitation
5. Information quality
6. Transparency
7. Security Safeguards
8. Data subject participation

B5. Using the PHISC HIG Informed Consent Check List D – Billing Consent

Uses and disclosures for treatment and/or payment.

"Payment" encompasses the various activities of healthcare providers to obtain payment or to be reimbursed for their services and of a health plan to obtain premiums, to fulfil their coverage responsibilities and provide benefits under the plan, and to obtain or provide reimbursement for the provision of health care.

Applicable Legislation:

National Health Act – Chapter 2

User to have full knowledge.

6. (1) Every healthcare provider must inform a user of (c) the benefits, risks, costs and consequences generally associated with each option; and

6. (2) The healthcare provider concerned must, where possible, inform the user as contemplated in subsection (1) in a language that the user understands and in a manner which takes into account the user's level of literacy.

National Patient Rights Charter section 2.4

Knowledge of One's Health Insurance/Medical Aid Scheme

A member of a health insurance or medical aid scheme is entitled to information about that health insurance or medical aid scheme and to challenge, where necessary, the decision of such health insurance or medical aid scheme relating to the member.

HPCSA Ethical Rules Booklet 2 - Main Responsibilities of Health Practitioners; Rule 27A (d)

Provide adequate information about a patient's diagnosis, treatment options and alternatives, costs associated with each such alternatives and any other patient information to enable the patient to exercise a choice in terms of treatment and informed decision-making pertaining to his or health and that of others.

Consumer Protection Act – Chapter 1
Principles:

Principles:

1. Your safety
2. Being treated fairly
3. Making an informed choice
4. Right to information

B6. Using HIG Informed Consent Guiding Principles – Right to Bodily Integrity

Guiding Principles Bodily Integrity

> **The right to bodily integrity** – one of the most fundamental of what we consider human rights — is the right to live without being physically harmed or harassed by others. No one can touch, hit, harm our bodies, or conduct medical testing on us without our consent. Wikipedia

HPCSA Ethical Rules – Booklet 2 27 (A) (b)

> Respect patient confidentiality, privacy, choices and dignity.

> This section is aimed purely at raising awareness on the issue of the right to bodily integrity. It is possible that a lack of clarity and communication in this area could lead to patients perceiving the treatment as sexual harassment, abuse, demeaning and/or humiliating. Healthcare service providers are required to be aware of the bodily integrity rights of patients in both the way they practice and in gaining consent for access to the body, as may be needed for treatment. The patient must be allowed as much personal bodily privacy as is possible.

Appendices

1. Informed Consent Check List A – Healthcare Professional
2. Informed Consent Check List B – Questions to ask your Healthcare Professional
3. Informed Consent Check List C – Consent to Collection, Processing, Use and/or Disclosure of Personal and Health Information
4. Informed Consent Check List D – Informed Billing Consent
5. FORM 33 – Application for consent to medical treatment or surgical operation by minister
6. FORM 34 – Consent to surgical operation by a child
7. FORM 35 – Consent to surgical operation of a child by a parent who is aged below 18 years

PHISC
Private Healthcare Information Standards Committee

FORM A – INFORMED CONSENT – HEALTHCARE PROFESSIONAL

Informed Consent process (in terms of the National Health Act (NHA) 61 of 2003, the Protection of Personal Information (POPI) Act 14 of 2013, and the Consumer Protection Act (CPA) 68 of 2008), Act and Guidelines as published by Professional Statutory Bodies

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Date: _____ Patient File Number: _____

Patient Name: _____

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1. The patient's health status – how he / she is doing or appears to be doing ☐
2. The generally available options in terms of (NHA): -
   - 2.1 Diagnostics (if applicable) and PMB status ☐
   - 2.2 Treatment / medication / devices / procedures ☐

The following options were put to the patient:

3. On each treatment / diagnostic / care option: -
   - 3.1 Purpose of treatment (e.g. how it might work / might not work, etc.) and what it might take from the patient in regards of compliance, etc. (CPA) ☐
   - 3.2 Benefits of the medicine / treatment / procedure / etc. ☐
   - 3.3 Risks (NHA), including common and unusual risks, risk of death or serious injury or risk patient cannot be expected to be aware of (CPA) ☐
   - 3.4 Consequences (NHA) e.g. impact on lifestyle, changes required to lifestyle, side-effects that may change things, etc. ☐
4. Opportunity given to patient to ask questions and have them answered (NHA & CPA) ☐
5. Patient says he / she is satisfied with questions being answered (NHA & CPA) ☐
6. Patient informed that he / she may refuse treatment, but that such refusal would have specific implications and these implications have been explained to the patient (NHA) ☐
7. Patient chooses treatment, etc. option (list which): ☐
8. Patient is provided with – and confirm that he / she understands (CPA):
   - 8.1 Instructions on product / treatment use and / or care. ☐
   - 8.2 Explanation of product purpose (and possible failures of treatment) and limitations in product addressing / curing the patient's condition. ☐
   - 8.3 Warnings on product use / treatment, compliance, returning to the Healthcare Professional if symptoms not improving/new symptoms – including unusual risks, risk of death or serious injury or risk patient cannot be expected to be aware of (CPA) ☐

   [Last mentioned three types of risk for which the patient has to sign if it is not on the package insert of the product, or not disclosed elsewhere in a patient information sheet or similar document.]
9. Patient is informed that he / she must return to the practice within a specified period and contact the Healthcare Professional if he / she experiences any health problems, side-effects or similar issues such as not feeling well, etc. (CPA) ☐
10. The patient confirms that he / she has understood everything said. ☐

NOTE: Please refer to the PHISC HIG reference document for assistance on using this form

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Private Healthcare Information Standards Committee

FORM B – QUESTIONS TO ASK YOUR HEALTHCARE PROFESSIONAL

Informed Consent process (in terms of the National Health Act (NHA) 61 of 2003, the Protection of Personal Information (POPI) Act 14 of 2013, and the Consumer Protection Act (CPA) 68 of 2008), Act and Guidelines as published by Professional Statutory Bodies

---

Date: _____

Healthcare Professional's Name: _____

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1. General Questions:

   1.1. What condition(s) do I have?

   1.2. Are this / these conditions PMBs – prescribed minimum benefits?

   1.1 What is the name of the treatment?_____

   1.2 Why do I need this treatment?_____

   1.3 What might happen if I delay or avoid this treatment?_____

   1.4 Are there any other treatment options? If so, describe them:

   _____

   1.5 What is the next step if this treatment does not work? _____

   1.6 How much does the treatment cost? How can I find out? _____

   1.7 Are there other costs to the treatment such as equipment or therapy? _____

2. Questions to ask about the treatment:

   2.1 What kind of preparation is needed for the treatment? _____

   2.2 Where will the treatment be done – hospital or other location? _____

   2.3 How is the treatment done?_____

   2.4 Is the treatment painful? _____

   2.5 Will the treatment be done only once or will it be repeated? _____

   2.6 How successful is this treatment? _____

   2.7 Who will do the treatment and how much experience does the Healthcare Professional in performing this treatment?

   _____

   2.8 What side effects are expected after the treatment? _____

   2.9 What complications might develop – both immediate and long-term?_____

   2.10 Does my Healthcare Professional recommend that I see another health professional? If yes:

   Name: _____

   Address:_____

   Telephone number: _____

NOTE: Please refer to the PHISC HIG reference document for assistance on using this form

FORM C – CONSENT TO COLLECTION, PROCESSING, USE AND/OR DISCLOSURE OF PERSONAL- AND HEALTH INFORMATION

Informed Consent process (in terms of the National Health Act (NHA) 61 of 2003, the Protection of Personal Information (POPI) Act 14 of 2013, and the Consumer Protection Act (CPA) 68 of 2008), Act and Guidelines as published by Professional Statutory Bodies

Date: _____ Patient File Number: _____

Patient Name: _____ Signature: _____

I hereby declare that I have read, understood and agree to the following as indicated. I acknowledge my right to withdraw my consent at any time:

Data Collection and Processing of your Personal and Healthcare Information:

1. My healthcare professional will collect information about me, and my health, in order to provide healthcare services. If I do not disclose all relevant information, or do not disclose full information, I understand that it may have a negative impact on my health and healthcare services to be provided.
2. When a claim is to be submitted to my medical scheme, to the Road Accident Fund and/or the Compensation Commission (for occupational injuries and diseases), I understand that these bodies may require of my healthcare professional to collect and process specific information they require in order to process my claim.

Use of Your Personal and Health Information data:

3. My healthcare professional will use my information for the purposes of providing treatment and care, to bill me for the costs of such treatment, and to do healthcare and or financial follow-ups.
4. Under the National Health Act, various healthcare providers may share my information insofar as necessary and in my interest.
5. Medical schemes, the Road Accident Fund and the Compensation Commission may use my data for their purposes, for example, to process my claim.
6. If my information is to be used for any other purpose, I will be asked to consent to such use separately. For example, if the healthcare professional forms part of a research study where they review patient files.

Disclosure:

7. My information may be disclosed to any entity entitled by law to such information, such as my medical scheme or entities from which I claim.
8. If my information is to be disclosed to any other party or entity, my healthcare professional will ask for my written consent. If I want any other entity to be able to access my information, I will ensure that I provide them with my written consent, and I will stipulate exactly who can access what information.
9. I hereby nominate the following person to whom my information can be disclosed if I undergo treatment or a procedure, and family or friends wish to enquire as to my health status:
   (Name) (Contact no.)

   OR:

   I do not want any person to be informed of my health status when I have, or am undergoing treatment or a procedure. (scrap what is not applicable)

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NOTE: Please refer to the PHISC HIG reference document for assistance on using this form

FORM D – INFORMED BILLING CONSENT

Informed Consent process (in terms of the National Health Act (NHA) 61 of 2003, the Protection of Personal Information (POPI) Act 14 of 2013, and the Consumer Protection Act (CPA) 68 of 2008, Competition Act 89 of 1998, National Credit Act (NCA) 34 of 2005, the Children's Act and Guidelines as published by Professional Statutory Bodies

Date: Patient File Number: Patient Name: _____ Signature: _____

I hereby declare that I have read, understood and agree to the following as indicated.
Please initial in the block to the terms agreed to.

	1. My healthcare professional will require my healthcare funder/insurer details for billing purposes
	2. My healthcare professional will require the details, if any, of a person legally responsible for the account. If I am an adult, I am personally responsible for the settlement of the account, even if I am a beneficiary on someone else's healthcare fund/insurer.
	3. I am a capable adult over 18 years of age and acknowledge that I am responsible for payment of the account if the healthcare funder /insurer does not pay the account in full. **OR** I am between 12 and 18 years of age and acknowledge that the healthcare professional will render an account for services, where I have consented to treatment in terms of the Children's Act.
	4. As a parent or guardian of the patient, I am required by law to cover expenses incurred for healthcare of my child or person legally under my care.
	5. I have received a fee list of general activities/treatment/procedures available to me as the patient with an explanation of the codes applicable to the treatment /procedures I understand my rights and responsibilities relating to the following: • The right to information about the proposed costs of the treatment/services, but I understand I have no right to treatment decisions if that right is not awarded to my in law. • If an exact cost cannot be presented, a written cost estimate should be provided by the healthcare professional. • To enquire as to the level at which the planned treatment is covered by my healthcare funder/insurer • To ensure that the necessary finances are put into place to cover non-insured costs, co-payments or shortfalls. • To obtain the necessary pre-authorisation if it is required. • To be informed if the practice has a preferred / designated provider agreement with a particular healthcare funder/insurer. • To update all healthcare funder/insurer and personal information with the practice. • To know the terms and conditions and benefit of my medical scheme or third party insurance
	6. I understand that accounts are rendered subject to the National Credit Act, the Consumer Protection Act, the Medical Schemes Act, the Competition Act and Guidelines as published by Professional Statutory Bodies.
	7. I have been advised about the payment options and policies of the practice, such as whether accounts are submitted on my behalf to a healthcare funder, whether different rates apply to 'after-hours' services, if I may be liable for an 'appointment not kept' costs and of any discounts that may be applicable, etc..
	8. I have been advised that a sufficiently detailed invoice is payable within a stipulated number of days. I understand that I must receive an exact copy of the invoice if the practice has submitted it electronically to the scheme/insurer.
	9. I have been advised that a service fee may be charged for any credit given according to the provisions of the National Credit Act, Act No. 34 of 2005, collection costs may be imposed to the extent permitted by the NCA and that interest may be applied on outstanding accounts as prescribed in terms of the NCA.

NOTE: Please refer to the PHISC HIG reference document for assistance on using this form

FORM 33

APPLICATION FOR CONSENT TO MEDICAL TREATMENT OR SURGICAL OPERATION BY MINISTER

(Regulation 53(1))

[SECTION 129(7) OF THE CHILDREN'S ACT 38 OF 2005]

Part A: Details concerning the applicant, the child, the particulars of the person/institution providing medical treatment or performing the surgical operation and the parent/guardian assisting the child

Full name of child Date of Birth/ID number/passport no*	
Address of child	
Contact details	
Age of child	

* Please attach copy of birth certificate/ ID Number/ Passport where applicable

Applicant details

Full name of applicant	
Date of Birth/ID number/passport no*	
Address of child	
Contact details Relationship to child/official designation/other details explaining why applicant in this matter	

Particulars of person/hospital/clinic/surgery/other institution* providing medical treatment/performing surgical operation

Name	
Practice no/hospital/clinic/surgery/ staff position	
Address Contact details Nature of surgical operation Details of other institution performing surgical operation*	

*****Please furnish details concerning the name and type of institution in the space provided

Part B: Details of medical treatment/surgical operation

Please provide detailed description of envisaged medical treatment or surgical operation and reason(s) why this treatment or operation is required:-

……
……
……
……
……

Part C: Motivation for seeking consent of the Minister

- Parent/guardian unreasonably refusing to give consent or to assist the child in giving consent

Motivation:……
……
……
……
……
……

- Parent/guardian incapable of giving consent or of assisting the child to give consent

Motivation:……
……
……
……
……

- Parent cannot readily be traced/ is deceased*

Steps taken to trace
parents:……
……
……
……

* attach copy of parent's or guardian's death certificate

- Child unreasonably refusing to give consent

Motivation……
……
……
……
……

Part D: Consent/ refusal of consent by Minister

- I ……(insert name) duly authorized, hereby give consent for the medical treatment to be given to/surgical operation to be perform upon (delete whichever is not applicable)
  ……..(insert child's name).

- I …… (insert name), duly authorized, do not consent to the medical treatment/ the performance on the surgical operation applied for.

Tick whichever is applicable

……..
Signature

……..
Full name

……..
Designation

……..
Date

FORM 34

CONSENT TO SURGICAL OPERATION BY A CHILD

(Regulation 54(1), (2))

[SECTION 129(3) OF THE CHILDREN'S ACT 38 OF 2005]

NB Child to be 12 years of age or older and of sufficient maturity and having the mental capacity to understand the benefits, risks and social implications of the surgical operation

Part A: Details concerning the child, the particulars of the person performing the surgical operation or Institution where it is to be performed and the parent/guardian assisting the child

Full name of child Date of Birth/ID number/passport no Address of child	
Contact details	
Age of child (12 or older)	

Particulars of person/hospital/clinic/surgery/other institution* performing surgical operation

Name	
Practice no/hospital/clinic/surgery/ staff position Address Contact details Nature of surgical operation Details of other institution performing surgical operation*	

*****Please furnish details concerning the name and type of institution in the space provided

Particular of parent(s) or guardian(s) assenting to surgical operation

Parent/Guardian 1

Full name of parent/guardian	
Date of Birth/ID number/passport no Address of parent	
Contact details	
Relationship to child	

Parent/guardian 2 (where necessary or desirable)

Full name of parent/guardian Date of Birth/ID number/passport no	
Address of parent	
Contact details	
Relationship to child	

Part B: Explanation of nature, consequences, risks and benefits of surgical operation

I …… (Name of person seeking child's consent to perform a surgical operation) confirm that I have explained to …… (Name of child consenting to surgical operation) the following in a manner that is understandable to the child: -

- The nature of the problem requiring a surgical operation
- The most suitable surgical operation in my opinion
- Any risks associated with the surgical operation
- The benefits associated with surgical operation
- Any alternative forms of treatment
- The social implications of the treatment or surgical operation (if any)
- Any other implications or possible consequences of the surgical operation (specify in space provided below)

……
……
……

I have given the child an opportunity to ask questions relating to the above.

I have satisfied myself that the child is 12 years or older and sufficient maturity and has the mental capacity to understand the risks, benefits, social and other implications of the surgical operation.

I have satisfied myself that…… (Insert name of parent(s)/guardian(s)) has duly assisted the child to give consent to the surgical operation.

……
Signature of person seeking consent to perform the surgical operation

……
Name of person seeking consent to perform the surgical operation (write in full)

……
Designation of person seeking consent to perform the surgical operation

Date:

Part C - Consent of the child

I, …… (Insert child's name) understand that the following surgical operation is going to be performed on me:

I……(insert child's name) understand the risks and benefits and possible consequences of this surgical operation that have been explained to me, and I confirm that I have been given an opportunity to ask questions about my condition, alternative forms of treatment, and the risks of non-treatment, and possible consequences of the surgical operation.

I believe that I have sufficient information to give my informed consent, and do so freely.

Signature of child
……
Name of Child (write in full)
Date…….

I……(insert name of parent(s) or guardian (s) assisting the child to consent to a surgical operation) confirm that the child is 12 years or older and is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the following surgical operation……(insert type of surgical operation), and that ……..(insert name of child) has been duly assisted by me to furnish consent.

Signature parent(s)/guardian(s)

……..
Full name of parent or guardian

……
Date

FORM 35

CONSENT TO SURGICAL OPERATION OF A CHILD BY A PARENT WHO IS AGED BELOW 18 YEARS

(Regulation 55(2))

[SECTION 129(3) OF THE CHILDREN'S ACT 38 OF 2005]

Part A: Details concerning the child, the parent aged under 18 years of the child upon whom the surgical operation is to be performed, the parent(s) or guardian of the child parent aged below 18 years, and the particulars of the person performing the surgical operation or institution where it is to be performed

Child upon whom surgical operation is to be performed

Full name of child	
Date of Birth/ID number/passport no	
Address of child	
Contact details Age of child (12 or older)	

Parent aged below 18 years giving consent ("child parent')

Full name of child parent	
Date of Birth/ID number/passport no	
Address of child Contact details Age of child parent	

Parent/Guardian assisting the child parent to give consent

Full name of parent/guardian	
Date of Birth/ID number/passport no Address of parent Contact details Relationship to child parent	

Particulars of person/hospital/clinic/surgery/other institution* performing surgical operation

Name	
Practice no/hospital/clinic/surgery/ staff position	
Address	
Contact details	
Nature of surgical operation Details of other institution performing surgical operation*	

*****Please furnish details concerning the name and type of institution in the space provided

Part B: Explanation of nature, consequences, risks and benefits of surgical operation

I …… (Name of person seeking consent to perform a surgical operation) confirm that I have explained to …… (Name of child parent consenting to surgical operation) the following in a manner that is understandable to him /her: -

- The nature of the problem requiring a surgical operation
- The most suitable surgical operation in my opinion
- Any risks associated with the surgical operation

- The benefits associated with surgical operation
- Any alternative forms of treatment
- The social implications of the treatment or surgical operation (if any)
- Any other implications or possible consequences of the surgical operation (specify in space provided below)

……
……
I have given the child parent an opportunity to ask questions relating to the above.

I have satisfied myself that the child parent is 12 years or older and of sufficient maturity and has the mental capacity to understand the risks, benefits, social and other implications of the surgical operation upon …… (Insert name of child upon whom surgical operation is to be performed).

I have satisfied myself that…… (Insert name of parent(s)/guardian(s)) has duly assisted the child giving consent to the surgical operation.

Signature of person seeking consent to perform the surgical operation

……
Name of person seeking consent to perform the surgical operation (write in full)

……
Designation of person seeking consent to perform the surgical operation

Date:

Part C Consent of the child parent

I, ……(insert name of child parent)
understand that the following surgical operation is going to be performed (insert type of surgical operation):
……
……
on…… (Insert name of child upon whom surgical operation to be performed).

I understand the risks and benefits and possible consequences of this surgical operation that have been explained to me, and I confirm that I have been given an opportunity to ask questions about the health condition of my child, alternative forms of treatment, and the risks of non-treatment, and possible consequences of the surgical operation.

I believe that I have sufficient information to give my informed consent, and do so freely.

Signature of child parent
……
Name of child parent (write in full)

Date……

I……(insert name of parent(s) or guardian (s)) assisting the child parent to consent to a surgical operation) confirm that he / she is 12 years or older and is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the following surgical
operation……(insert type of surgical operation), and that ……..(insert name of child) has been duly assisted by me to furnish consent.

Signature parent(s)/guardian(s)
……..
Full name of parent or guardian
……
Date