

QUEENSLAND HEALTH POLICY STATEMENT

Policy Title	Informed Consent for Invasive Procedures
Policy Statement	<ul style="list-style-type: none"> • The responsibility for ensuring a patient has the necessary information and advice lies with the medical practitioner who performs a procedure, operation or treatment. In the event that the treating Medical Practitioner asks another Medical Practitioner (delegate) to obtain consent on their behalf, the treating Medical Practitioner remains legally responsible for ensuring that the Medical Practitioner obtaining consent fully understands and discloses the elements of consent to the patient/ parent/ guardian (if a child)/ substitute decision-maker. • The Medical Practitioner (or delegate) obtains consent from the patient/ parent/ guardian/ substitute decision maker according to the protocols which guide an effective communication process, i.e. <ul style="list-style-type: none"> • the procedure outlined in this policy, including the use of procedure- specific consent forms. • relevant legislation, including the <i>Powers of Attorney Act 1998</i> and the <i>Guardianship and Administration Act 2000</i>
Scope and Application	All Queensland Health employees (permanent, temporary and casual) and all organisations and individuals acting as its agents including Visiting Medical Officers.
Effective date	1/3/04
Supersedes	V2:04
Compliance	<p>Compliance with this policy:</p> <ul style="list-style-type: none"> • fosters effective communication between Queensland Health and its patients; and • potentially reduces medico- legal risks to Queensland Health and its employees.
Review cycle and responsibilities	Principal Project Officer (Informed Consent), Patient Safety Centre will review this document at intervals not greater than three years.
Further information	Mariee Piper, Principal Project Officer (Informed Consent), Patient Safety Centre on (07) 3636 9715 or email <i>consent</i> on Groupwise address book.

QUEENSLAND HEALTH INSTRUCTION
to Policy Statement QHEPS 14025

Policy Title	Informed Consent for Invasive Procedures
Effective date	1/05/02
Review Cycle and Responsibilities	Principal Project Officer (Informed Consent), Patient Safety Centre will review this document at intervals not greater than three years.
Legislation and Associated Documentation	<ul style="list-style-type: none"> • Indemnity for Queensland Health and Other Approved Medical Practitioners IRM 3.8-4, December 2002 • Memorandum "Queensland Health Policy "Informed Consent for Invasive Procedures" 27/09/2002 • Common law concerning consent to treatment. • Guardianship and Administration Act 2000 • Powers of Attorney Act 1998 • Cunningham J, Schulz E, The Guardianship and Administration Act 2000. Substitute decision making for adults who lack capacity. <i>Number 2 Circular from the Chief Health Officer, Queensland Health. Issues Number 2, October 2000. Office of the Chief Health Officer.</i> • Faden RR, Beauchamp TL. <i>A History and Theory of Informed Consent</i>. New York: Oxford University Press, 1986. • Guidelines for Consent to Treatment and Treated Medical Procedures, Royal Adelaide hospital, Final Draft: 1/3/00 • Lord R.S.A. Informed Consent in Australia. <i>Australian, New Zealand Journal of Surgery</i> (1995)65:224-228. • Rogers and Whittaker, 175 CLR 490. • Petersen K. The family v the family court: Sterilisation issues. <i>Aust.J. Public Health</i> 1992; 16: 196-201.
Corporate Office file	1236-0355-009 G:\Information Strategy\Strategic Management\Projects\Informed Consent\Informed Consent Policy V0-02.doc

CONTENTS

COMPLIANCE AND RESPONSIBILITIES.....	3
IMPLEMENTATION PROCESS, EG INSTRUCTIONS.... ERROR! BOOKMARK NOT DEFINED.	
GLOSSARY AND DEFINITIONS	11

Compliance and Responsibilities

The following roles, responsibilities and specific accountabilities apply with respect to this Policy and Procedure:

Role/Function	Responsibilities and Specific Accountabilities
Director-General	Ultimately accountable/responsible for the operation of the Department, including the implementation of the Informed Consent Program. The Director-General is supported by the roles/positions below in implementing, evaluating and reviewing the Program.
General Manager, Health Services	Responsible for: Providing strategic advice to the Principal Project Officer (Informed Consent) Patient Safety Centre in terms of the administration, evaluation and review of the Informed Consent Program.
Principal Project Officer (Informed Consent), Patient Safety Centre.	Responsible for: <ul style="list-style-type: none"> • Liaison with the reference group for informed consent • The continued maintenance of the consent forms and patient information sheets i.e. <ul style="list-style-type: none"> • annual review of existing consent forms and patient information sheets • further consent form development • authorisation of consents • authorisation of any requested changes • publication on QHEPS of approved documentation.
Area Health Services, District Managers and Medical Directors	Facilitating sustainability of the Informed Consent Program, within each of the acute public health care facilities in Queensland.
Treating Medical Practitioner	Responsible for: ensuring a patient has the necessary information and advice lies with the medical practitioner who performs a procedure, operation or treatment.
Medical Practitioner	Responsible for: ensuring a patient has the necessary information and advice as delegate of the treating medical Practitioner.

PROCEDURE:

- (a) Presume all adults have legal capacity¹ to consent. If in the event that the patient does not have capacity see the Guardianship and Administration Act 2000. For further information on obtaining consent for patients with impaired capacity, please refer to the consent flow charts on the Office of the Chief Health Officer's site on QHEPS <http://qheps.health.qld.gov.au/cho/resources/pdf/17229.pdf>
- (b) The treating Medical Practitioner or delegate, seeking consent to Medical Treatment of the patient/ parent/ guardian (if a child)/ substitute decision-maker must be able to comprehensively discuss the issues in relation to medical treatment set out in paragraph (c) and (d) below.
- (c) Ensure that, in so far as it is possible:
Consent is voluntarily given, in absence of the influence of therapeutic or other drugs or alcohol, family, religious, cultural and medical staff influences;

The patient/ parent/ guardian (if a child)/ substitute decision-maker has sufficient time to consider the information provided by the Medical Officer.
- (d) The patient/ parent/ guardian (if a child)/ substitute decision-maker is advised in lay terms of:
- The diagnosis
 - Recommended treatment;
 - Material risks² in percentage terms associated with:
 - The recommended treatment;
 - Alternative treatment options;
 - The no treatment options,in so far as a reasonable person would expect to be advised of significant risks;
- AND**
- Significant risks for the particular patient,
- AND**
- That no assurance can be provided that the treating Medical Practitioner will carry out the treatment option.
- (e) A competent adult may refuse any and all medical treatment contrary to medical recommendations even in circumstances where such refusal may result in the death of the patient.
- (f) Generally, a parent makes the decision for their child. However, where the child has sufficient maturity and understanding of the proposed procedure, then the child is legally able to make their own decision. In the event of a conflict between a parent and a child, the Family Court or the Supreme Court (depending upon the circumstances) have the general power to intervene in the interests of the child

¹ Guardianship and Administration Act 2000. Power of Attorney Act 1998.

² A reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it; or if the medical practitioner is, or should be reasonably aware, that the particular patient, if warned of the risk, would be likely to attach significance to it. *Rogers v Whittaker*.

DOCUMENTATION:

The Informed Consent Program has developed patient information sheets and consent forms for those invasive procedures considered to be highest risk, namely;

- Anaesthetic
- Bowel surgery for tumours
- Lumpectomy (removal of lump) and mastectomy (removal of breast)
- Colonoscopy
- Hysterectomy
- Inguinal Hernia Repair - open and laparoscopic
- Laparoscopic cholecystectomy
- Female sterilisation
- Prostatectomy - open and TURP
- Total hip replacement
- Total knee replacement

The patient information in these forms should be offered to patients to assist with the consent process. In addition, procedure-specific consent forms have also been developed for use in relation to most invasive procedures performed in Queensland Health hospitals, and these forms should be used for these procedures. (See Appendix A for Index). These forms are available through your facility.

In the event that a procedure- specific consent form is not available for the procedure, the generic consent form may be used. The treating Medical Practitioner (or delegate) must complete the sections for the condition, the procedure, the risk and significant risks on the generic consent form.

It should be noted that the executed consent form provides valuable evidence of the communication process used to obtain the patient's consent.

In the absence of a specific consent form the details of the conversation between the patient/ parent/ guardian (if a child)/ substitute decision-maker and the treating Medical Practitioner (or delegate) at (c) and (d) above are recorded in the chart.

Details of any further documentation provided to the patient/ parent/ guardian (if a child)/ substitute decision-maker should be recorded in the patient's' medical record (date, document, version provided.)

The name, signature and title of the treating Medical Practitioner (or delegate) obtaining the patient/ parent/ guardian (if a child)/ substitute decision-maker's consent is to be recorded on the consent form or in the patient's medical record as applicable.

RESPONSIBILITY OF THE TREATING MEDICAL PRACTITIONER:

The responsibility for ensuring a patient has the necessary information and advice lies with the medical practitioner who performs a procedure, operation or treatment.

In the event that the treating Medical Practitioner asks another Medical Practitioner (delegate) to obtain consent on their behalf, the treating Medical Practitioner remains legally responsible for ensuring that the Medical Practitioner (delegate) obtaining consent fully understands and discloses the elements of consent, as described in (d) above, to the patient/ parent/ guardian (if a child)/ substitute decision-maker.

Note: Please refer to glossary for definition of Treating Medical Practitioner and Medical Practitioner.

LIFESPAN OF THE CONSENT:

The consent is useful for as long as the patient/ parent/ guardian (if a child)/ substitute decision-maker:

- is able to recall the comprehensive information required for an informed consent
- AND

- as long as there has been no significant change in health status.

To address the possibility of long surgical waiting times and/ or risks that may have changed over time, the consent is only considered valid for a period of twelve months. A new consent must be obtained if the patient/ parent/ guardian (if a child)/ substitute decision-maker is unable to recall the information as described in (d).

COMMUNICATION AND CULTURAL ISSUES:

The patient/ parent/ guardian/ substitute decision-maker who does not speak English, or is profoundly hearing impaired must be offered a qualified interpreter during the informed consent process.

The qualified interpreter shall:

- countersign the consent form to indicate that he/ she has given a verbal translation of the procedure/ operation relating to consent in the language that the patient understands.
- specify the language.

In the event that the only interpreter available is a telephone interpreter service, the interpreter's name and contact details must be documented on the consent form by the treating Medical Practitioner (or delegate) in the "Interpreter's statement" section.

The patient who has specific cultural needs will also be asked if they require a Cultural Support Worker and same provided as indicated.

In the event that the patient is illiterate, appropriate communication methods must be employed and methods documented in the patient's medical record.

INFORMATION SOURCES TO AID DISCLOSURE:

The facility will provide the patient with a variety of comprehensive information sources, which could include but are not exclusive of;

- A brochure on "12 important questions to ask about your surgery" which may be included in their initial Outpatient appointment letter and available at the initial consultation and on the Internet. The brochure provides a list of Internet sites that provide professionally written information that is regularly updated.
- An information sheet "12 important questions to ask about your surgery" available from the Internet and QHEPS.
- A video on "12 important questions to ask about your surgery" available through the Outpatients Department. (This will also be available through public libraries, the Internet and GP Practices who request them.)
- a copy of the procedure specific consent form at the initial consultation when the need for an invasive procedure is indicated.
- A specific patient information sheet, for each of the high-risk procedures.
- Patient information sheets that include diagrams.
- Patient education videos.

CONSENT PROCESS:

Consent should be obtained from the patient/parent/guardian/substitute decision-maker as soon as possible after the need for a procedure has been identified. The treating Medical Practitioner (or delegate) should follow the process outlined in the flow chart on page 8 to obtain a valid consent.

See flow chart on page 8

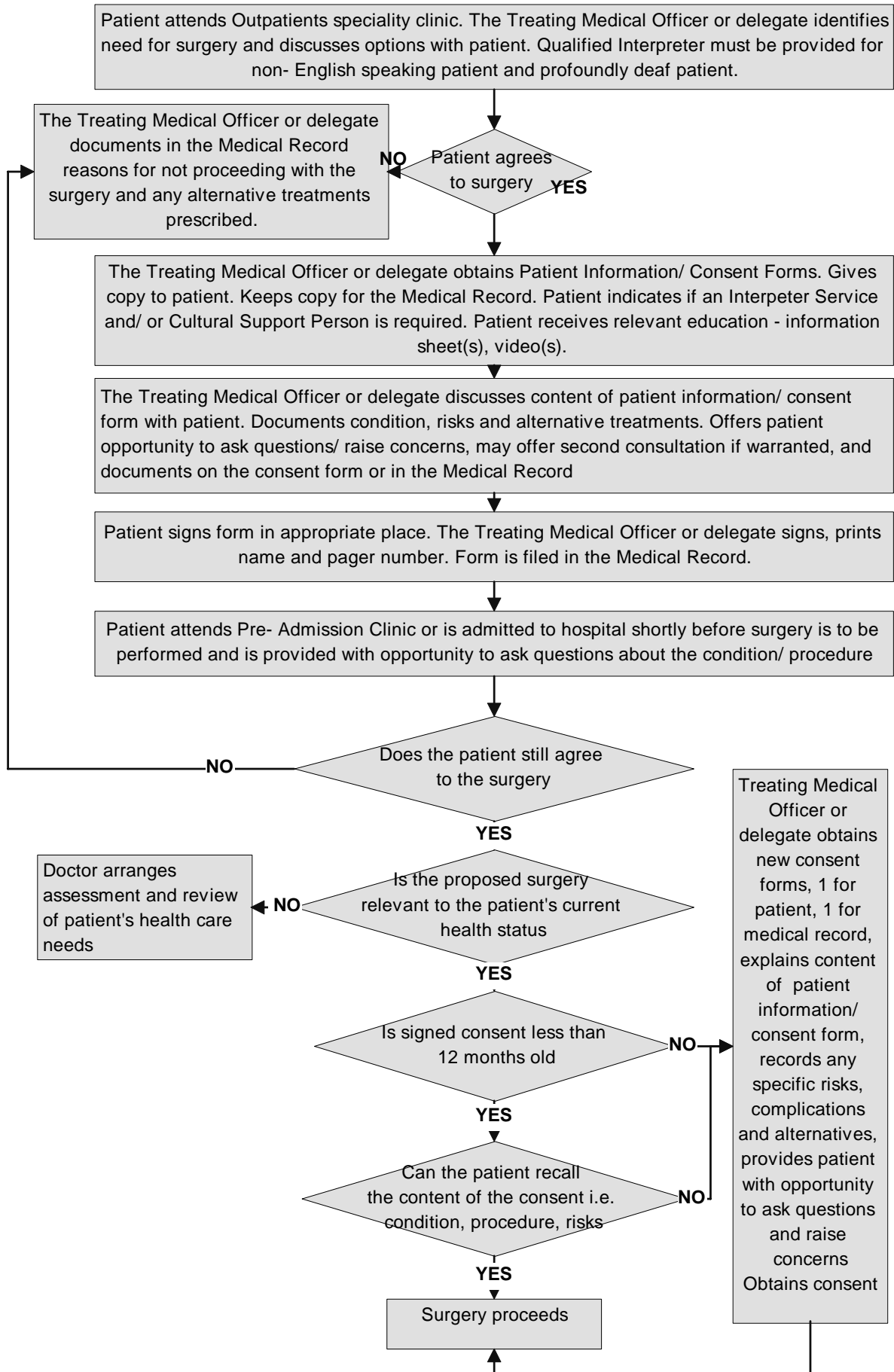
ACCESS AND REVIEW PROCESS:

- *See flow chart on page 9 currently under review excepted completion date 29th June 2007*
- A Reference Group will provide expert advice and direction to the Principal Project Officer (Informed Consent), Patient Safety Centre as the reviewing body.
- The consent forms will be available as “print only” documents on QHEPS and the Internet.
- Each consent will be reviewed at intervals not greater than 3 years or when a change in medical practice and/ or technology occurs. The amended document shall be forwarded to QHEPS for publication on QHEPS and the Internet and the superseded document removed from the site.
- A disclaimer will be placed on the QHEPS and Internet site against unauthorised changes.
- To prevent the possibility of superseded consent forms being distributed, it is the responsibility of each facility to ensure that hard copies are current.

AUDIT PROCESS:

- *See audit tool Page 10*
- Each district will, as part of their quality activities, conduct a medical record audit of the consent documentation at yearly intervals to measure compliance with the informed consent process and forward a report to the Principal Project Officer (Informed Consent), Patient Safety Centre. The audit tool is provided.

THE PROCESS FOR OBTAINING CONSENT



FLOW CHART FOR DEVELOPMENT, REVIEW AND PUBLICATION OF PATIENT INFORMATION AND CONSENT FORMS

Currently under review – expected completion date 29th June 2007

INFORMED CONSENT COMPLIANCE AUDIT

A 1:4 stratified random sample of each surgical specialty for all surgical cases performed over 5 consecutive working days

Surgical Specialty					
No.	Item	Yes	No	N/A	
1.	Is there a consent form present				
2.	Is the consent form procedure specific*				
3.	Is there patient identification on each page				
4.	* Has the communication/ cultural needs been identified				
5.	* Has the condition been recorded in patient's own words				
6.	* Has the procedure been described (for generic consents)				
7.	* Are the general risks recorded				
8.	* Are the specific risks recorded				
9.	* Are any additional risks / complications recorded				
10.	* Are there any other relevant treatment options recorded				
11.	Has the name of the patient/ substitute decision maker been recorded in print				
12.	Has the signature of the patient/ substitute decision maker been recorded				
13.	Has the date of the patient/ substitute decision maker's signature been recorded				
14.	Has the name of the Interpreter been recorded				
15.	Has the signature of the interpreter been recorded				
16.	Has the advance health directive section been completed				
17.	Has the doctor printed his/ her name				
18.	What is the designation of the doctor (check chart/ staff list)	RMO	Reg	Consul tant	GP
19.	Has the date of the doctor's signature been recorded				
20.	Have any crossings out or amendments been made to the form				
21.	If yes - briefly describe				
*The patient's medical record is also audited for supporting documentation for evidence of information given to the patient.					
Comments					

Results to be addressed as part of the Facility's Quality Improvement Program.

Glossary and Definitions

Term	Definition	Source
Autonomy	The person acts intentionally, with understanding and without controlling influences.	Faden RR, Beauchamp TL. <i>A History and Theory of Informed Consent</i> . New York: Oxford University Press, 1986.
Child	A person under the age of 18 years and unable to understand the nature and potential consequences of the proposed medical treatment. Parents/ spouses/ legal guardians have the right and duty of consent for minors but their authority is not absolute and most teenagers can be considered autonomous.	Petersen K. The family v the family court: Sterilisation issues. <i>Aust.J. Public Health</i> 1992; 16 : 196-201.
Competence	The person giving the consent must have the legal capacity to do so, or someone with that capacity must consent to treatment on the patient's behalf. The problems generally fall into two groups - minors, and persons who are intellectually or mentally disabled.	Queensland Health Law Handbook. Queensland Department of Health. (P. MacFarlane) ISBN 0724241108.
Disclosure	Accurate and comprehensive information, given in a variety of formats (videos, protocols, printed material with diagrams) that is truthful, includes alternative therapies, risks of treatment and not having treatment. Disclosure should address all aspects of treatment – procedure, anaesthesia, blood transfusion.	Stanley BM. Walters DJ. Maddern GJ. (1998) Informed Consent: How much information is enough? <i>Australian and New Zealand Journal of Surgery</i> ; Nov 68(11): 788-91. Cornwall A. (2000) Facing up to it: A review of the NSW Cosmetic Surgery Inquiry. <i>Australian Health Law Bulletin</i> . Vol 8, No. 7. April, p 92.
Informed Consent	Agreement to a proposed invasive procedure, given after proper and sufficient explanation of the condition, the procedure, the general and specific risks, the benefits and anticipated outcomes, alternative treatment available, the risk of not having the procedure. True consent to what happens to oneself provides an opportunity to evaluate comprehensively the options available and their associated risks. Questions must be answered truthfully and the patient, not the Medical Practitioner makes the final decision. To assist a patient to make an informed choice, it is essential that the Medical Officer has some knowledge of therapeutic alternatives and their associated risks.	Lord R.S.A. Informed Consent in Australia. <i>Australian, New Zealand Journal of Surgery</i> (1995) 65:224-228.
Informed Consent Program	A Queensland Health Quality Improvement and Enhancement Program for the development and production of documentation that supports the informed consent process for patients undergoing elective surgery.	
Material risk	A reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it; or if the medical practitioner is, or should be reasonably	Rogers V Whittaker (1992) 175 CLR 479

Term	Definition	Source
	aware, that the particular patient, if warned of the risk, would be likely to attach significance to it.	
Medical Practitioner	Refers to the delegate of the Treating Medical Practitioner whom the Treating Medical Practitioner has deemed capable of understanding the treatment option(s) and disclosing the elements of consent to the patient/parent/guardian if a child/substitute decision maker.	
Reference Group	<ul style="list-style-type: none"> • NB: Currently under review expected completion date 29th June 2007. 	
Reviewing Body	<p>The Patient Safety Centre has responsibility for the continued maintenance of the consent forms i.e.</p> <ul style="list-style-type: none"> • review of existing consents • further consent form development • authorisation of consents • authorisation of any requested changes • publication on QHEPS and the Queensland Health internet site of approved documentation. 	
Treating Medical Practitioner	<p>Refers to: The Specialist or Consultant under whose care the patient is admitted or The Specialist/ Consultant to whom the patient is referred for an invasive procedure.</p>	