

Health practitioners shall:

- provide information to the patient to support informed decision making.
- determine that the patient has the capacity to make an informed decision.
- obtain informed consent for healthcare.
- document the patient's decision to give or decline consent.

## Informed Decision-making in Healthcare Implementation Standard

### 1. Purpose

This Implementation Standard identifies the minimum requirements for the implementation of the Informed Decision-making in Healthcare Policy and identifies individual position accountabilities and responsibilities in relation to these requirements.

### 2. Scope

Compliance with this Implementation Standard is mandatory for all Queensland Health employees (permanent, temporary and casual), agents and other partners in healthcare including contractors, consultants and Visiting Medical Officers including those health practitioners who are eligible to be indemnified by Queensland Health (under the Indemnity for Queensland Health Medical Practitioners Human Resources Policy I2 (2009) (QH-POL-153:2009) or the Indemnity for Queensland Health Employees and Other Persons Human Resources Policy I3 (2009) (QH-POL-152:2099), when providing healthcare to any patient (private or public) within Queensland Health facilities.

### 3. Definition of Terms

Refer to Glossary of Terms within the Informed Decision-making in Healthcare Policy and the Guide to Informed Decision-making in Healthcare.

### 4. Supporting Documents

#### Authorising Policy

- Informed Decision-making in Healthcare Policy

#### Protocols, Procedures, Guidelines

- Guide to Informed Decision-making in Healthcare

#### Forms and Templates

- Sample Procedural Consent Form Document Audit Tool

## 5. Requirements

### 5.1 Informing the Patient

#### 5.1.1 Health practitioners shall:

- provide patients and/or the substitute decision-maker with information relevant to their healthcare and afford them sufficient time to consider and clarify the information to enable informed decision making by the patient and/or the substitute decision-maker.
- provide information in plain language and in a form that enables the particular patient and/or the substitute decision-maker to clearly understand the issues and healthcare options available for them to make an informed decision.
- check that the patient and/or the substitute decision-maker has understood the information provided for them to enable them to make a healthcare decision.

Relevant sections of the Guide to Informed Decision-making in Healthcare (<http://www.health.qld.gov.au/consent/>) are, respectively:

- Part 1, section 1.6 (process of informed decision making)
- Part 5, sections 5.1 – 5.3.6 (communication and/or cultural issues)
- Part 1, section 1.6.5 (checking understanding)

### 5.2 Gaining Consent

#### 5.2.1 Health practitioners shall:

- identify whether the patient has the capacity to make a decision about their treatment at the time.
- obtain informed consent of the patient and/or the substitute decision-maker for all healthcare (examination, investigation, procedure or treatment). A diverse range of procedure specific consent forms and patient information sheets are available at <http://www.health.qld.gov.au/consent/> (some of these are available in a range of languages)
- only proceed with healthcare without prior informed consent in very limited and exceptional circumstances where this can be justified (e.g. emergency healthcare to adult patients who do not have the capacity to make a decision, or healthcare of some children and young persons)
- reconfirm informed consent in circumstances where consent to the relevant treatment has previously been provided in a non-Queensland Health facility/service or on a non-Queensland Health form
- where a patient or substitute decision maker declines or withdraws consent, document details of the decision in the patient record.

Relevant sections of the Guide to Informed Decision-making in Healthcare (<http://www.health.qld.gov.au/consent/>) are respectively:

- Part 1, section 1.7, 1.8 and Part 2 (patient capacity)
- Part 1, section 1.4 (types of consent)
- Part 3 (children and young people)

- Part 4 (specific healthcare situations)
- Part 1, section 1.4 (types of healthcare requiring consent)
- Part 1, section 1.6.8 (consent and transfer of patients)
- Part 1, section 1.9 (declining or withdrawing consent)

### 5.3 Documentation of informed decision-making

5.3.1 Health practitioners shall document the decision to give, decline or withdraw consent in the clinical record:

- healthcare with significant risks to the patient shall be documented using an approved state-wide Queensland Health or approved District consent form
- completed/signed consent documents and any supplementary documents shall be filed in the patient's clinical record at the facility where the healthcare is provided
- healthcare without significant risks to the patient does not require a consent form but consent shall be recorded in an appropriate section of the patient's clinical record eg clinical pathway or progress notes.

Relevant sections of the Guide to Informed Decision-making in Healthcare (<http://www.health.qld.gov.au/consent/>) are respectively:

- Part 1, section 1.6.7 (alternative forms where approved/organisation-wide form unavailable)
- Part 1, section 1.6.9 (retention of consent documentation)
- Part 1, section 1.6.7 (documenting minor and uncontroversial healthcare)

### 5.4 Monitoring and evaluation

5.4.1 District clinical executives within each facility shall conduct an annual audit to assess compliance with the Informed Decision-making Implementation Standard. A copy of the audit report shall be provided to the Patient Safety and Quality Improvement Service.

5.4.2 The Executive Director, Patient Safety and Quality Improvement Service shall monitor and evaluate facility audit reports and prepare an annual state-wide status report to be reviewed by the Informed Consent Reference Group.

## 6. Review

This Standard is due for review on: 01/02/2014

## 7. History

<i>Date of new policy:</i> 01/02/2012	<i>Supersedes:</i> Informed Consent for Invasive Procedures Policy (QH-POL-284:2004).
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## 8. Responsibilities

Position	Responsibilities	Accountabilities / Audit Criteria
<p><b>Policy Custodian</b> <b>Executive Director</b> <b>Patient Safety &amp; Quality Improvement Service</b></p>	<ul style="list-style-type: none"> <li>Support Districts with information and advice to comply with the Informed-Decision making Policy and Implementation Standard.</li> </ul>	<ul style="list-style-type: none"> <li>Monitor and evaluate facility audit reports and prepare an annual state-wide report to be reviewed by the Informed Consent Reference Group.</li> </ul>
<p><b>District Chief Executive Officers</b> <b>Divisional Chief Executive Officers where the division delivers clinical services such as Clinical and Statewide Services and Division of the Chief Health Officer</b></p>	<ul style="list-style-type: none"> <li>Ensure all Districts are aware of, actively support and comply with the Informed-Decision making Policy, and Implementation Standard. Ensure that all staff have access to the Guide to assist in such compliance.</li> <li>Support the Quality and Risk Management programs by monitoring compliance to the Informed Decision-making in Healthcare Policy and Implementation Standard by auditing at regular intervals, at minimum annually.</li> </ul>	<ul style="list-style-type: none"> <li>Assess compliance with the Informed Decision-making in Healthcare Implementation Standard by conducting an annual audit.</li> <li>Take action on the results of the audit reports.</li> <li>Provide a copy of the audit report/s to the Patient Safety and Quality Improvement Service</li> </ul>
<p><b>Health Practitioner</b></p>	<ul style="list-style-type: none"> <li>Ensure the patient and/or substitute decision-maker has received information relevant to their healthcare and has afforded them sufficient time to consider and clarify the information to enable informed decision making.</li> <li>Provide information in plain, simple, non medical jargon language and in a form that enables the particular patient and/or the substitute decision-maker to clearly understand the issues and healthcare options available for them to make an informed decision.</li> <li>Check that the patient and/or the substitute decision-maker has understood the information provided for them to enable them to make a healthcare decision.</li> <li>Identify whether the patient has the capacity to make a decision about their treatment at the time.</li> <li>Obtain informed consent of the patient and/or the substitute decision-maker for all healthcare (examination, investigation,</li> </ul>	<ul style="list-style-type: none"> <li>Compliance with Informed Decision-making in Healthcare Implementation Standard (assessed through an annual audit).</li> <li>Compliance with the recommendations arising from the annual audit report (assessed through subsequent audits).</li> <li>Consent decisions documented in the clinical record.</li> </ul>

	<p>procedure or treatment).</p> <ul style="list-style-type: none"> <li>• Ensure procedure specific consents and patient information sheets, where available and appropriate to the treatment are utilised.</li> <li>• Only proceed with healthcare without prior informed consent in very limited and exceptional circumstances where this can be justified (e.g. emergency healthcare to adult patients who do not have the capacity to make a decision, or healthcare of some children and young persons)</li> <li>• Reconfirm informed consent in circumstances where consent to the relevant treatment has previously been provided in a non-Queensland Health facility/service or on a non-Queensland Health form.</li> <li>• Document the decision to give, decline or withdraw consent in the patient's clinical record.</li> <li>• Document invasive treatments and healthcare with significant risks using an approved state-wide Queensland Health consent form where one is available.</li> <li>• Record minor and uncontroversial healthcare without significant risks that does not require a written consent form in an appropriate section of the patient's clinical record eg clinical pathway or progress notes.</li> </ul>	
<p><b>Clinical Information Management (Facility based Units)</b></p>	<ul style="list-style-type: none"> <li>• File completed/signed consent documents and any supplementary documents in the patient's clinical record at the facility where the healthcare is provided.</li> </ul>	

**Name and position of approving officer:**

Mr Jason Currie  
Acting Chief Executive Officer, Centre for Healthcare Improvement

**Approval Date:** 04/01/2012

**Implementation Date:** 01/02/2012

Attachment 1

**Sample procedural consent form document audit tool** (may not be applicable for some services such as oral health and community services)

- Informed Consent Document Audit**
- For each clinical specialty over 5 consecutive working days.
  - A 1:4 stratified random sample of healthcare episodes requiring written informed consent under the Informed Decision-making in Healthcare Policy / Standard performed.
  - The patient’s medical record is also audited for supporting documentation for evidence of information given to the patient (\* see sections below)

Clinical Speciality				
No.	Criteria	Yes	No	N/A
1	Is there an approved Queensland Health or approved District consent form present (either specific or generic) in the patient’s clinical record?			
2	Is there complete patient identification data on each page?			
3	Has the health practitioner used any abbreviations on the consent record? If yes, note the abbreviation in the comments box below.			
4	Has laterality and site specific information been documented? (for example left inguinal hernia).			
5	*Has any additional healthcare treatment/procedure been performed for which consent is not clearly documented? (check and compare the operating room documentation)			
6	*Are the patient specific risks recorded?			
7	*Are other healthcare options recorded?			
8	Has the name of the patient/substitute decision maker been recorded?			
9	Has the patient/decision-maker signed the consent document?			
10	Has the date of the patient/substitute decision maker’s signature been recorded?			
11	Has the name of the interpreter been recorded?			
12	Has the signature of the interpreter been recorded?			
13	Has the health practitioner signed the consent document?			
13	Has the health practitioner clearly printed their name?			
14	Has the date of the health practitioner’s signature been recorded?			
15	*If any of the above shaded response boxes have been highlighted, has an incident form been lodged with PRIME as a Consent breach?			

Comments: