Consent Form Revisions

Presented in January 2014 by:

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Background

- Single AHS Consent policy implemented 2010
- Concerns about success of implementation led to creation of Consent Policy Implementation Project in 2011
- Steering committee and working groups formed to provide support for implementation, education and support provision of needed revisions
- Identified Physician Leadership and support for Physician Advisor Role and included physician working groups
CPIP Consent Form Revisions

- Physician issues identified
- Identified need for physician specific tools, education, capacity assessment support, surgical vs nonsurgical form
- Revised forms process lengthy and requires multiple loops through steering, forms, legal
- Revised available June, 2013
- Significant AHS organizational changes and difficulty supporting implementation until late in 2013.
Physician Consent Issues

- Surgical consent elements missing
- Support for electronic consent forms and electronic signatures
- Blood transfusion consent requirement and process
- Blood Borne Fluid Exposure BBFE process to ensure consent available up front
- Providing Capacity Assessment for Specific Decision Maker designation: process and risk, form 6 issues
- Minors in ED without parent/guardian
- What procedures require written consent: list or not?
- Recurrent encounter consent management: transfusions and cancer care across sites/time; Rhogam in community and in hospital
- DI Consent: who is MRHP
- Critical Care Consent process: when in emergency health care exception
- Second practitioner signature in emergency health care provision: who can do this and why can’t residents?
- Public health consent process for Immunoglobulins as blood products
Consent Form Revisions Key Messages

- Policy hasn’t changed.
- Forms revised to better support consent process across different areas.
- Surgical consent includes transfusion, BBV testing, retention of tissue.
- Consent to Treatment plan/ procedure same as prior 09741 with improved clarity/simplicity.
- Emergency Health Care documentation of exception to consent has been separated to its own form with clearer indications.
- BBV testing consent to be completed as part of admission process or with BBFE occurring outside of planned procedure.

- MRHP determines type of consent to use.
- Areas with non-surgical but invasive procedures can use either surgical or treatment plan consent.
- Usual care procedures do not typically require written consent but explicit verbal consent can be supported with other forms of documentation.
- Blood product transfusion and surgery as only AHS directed requirements for written consent.
The following table outlines examples to guide the use of the new forms.

<table>
<thead>
<tr>
<th>Procedure/Intervention</th>
<th>Surgery or Invasive Procedure</th>
<th>Less Invasive Procedures / Treatment Plans</th>
<th>Emergency Health Care</th>
<th>Blood Borne Virus Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Form #</strong></td>
<td><strong>18628</strong></td>
<td><strong>09741</strong></td>
<td><strong>18629</strong></td>
<td><strong>18213</strong></td>
</tr>
<tr>
<td><strong>Title</strong></td>
<td>Consent to Surgery or Invasive Procedure</td>
<td>Consent to Treatment Plan or Procedure</td>
<td>Emergency Health Care: Documentation of Exception to Consent</td>
<td>Consent to Blood Testing for Blood Borne Viruses</td>
</tr>
<tr>
<td><strong>Examples</strong></td>
<td>Surgery, Cardiac Catheterization, Endoscopy, Interventional Radiology</td>
<td>Paracentesis, Lumbar Puncture, Bone Marrow Biopsy, Bedside procedures, Community Pediatric Assessment and Treatment, Blood Product Transfusion, Hemodialysis or recurrent transfusions in cancer setting, ECT, Counseling incorporating EMDR or hypnotherapy, Allied Health procedures of higher risk or invasiveness as determined by the MRHP or program</td>
<td>Initial Critical Care procedures, Emergency Surgery: ruptured Abdominal Aortic Aneurysm (AAA), Trauma and shock requiring immediate procedures or resuscitation, Invasive procedure in an unstable patient (i.e. unable to get consent without risk of worsening physical harm or severe pain)</td>
<td>As part of admission process in areas with risk of exposures (i.e. most medical/non-elective surgical admissions), At time of exposure when not part of admission or expected risk exists</td>
</tr>
</tbody>
</table>

*The form includes:*
- BBV testing
- Blood transfusion consent
- Retention of Tissue
- Involvement of trainees
Specific inclusion of BBV testing, retention of tissue, blood transfusion, Involvement of trainees
## Consent to Surgery or Invasive Procedure

(Policy PPR-01)

### Witness Statement

I observed the person providing consent sign the consent form. **(Witness must be at least 18 years of age)**

<table>
<thead>
<tr>
<th>Witness name (print)</th>
<th>Signature</th>
<th>Date (yyyy-Mon-dd)</th>
<th>Time</th>
</tr>
</thead>
</table>

### Most Responsible Health Practitioner Statement

I have explained the details of the surgery or invasive procedure to the person providing consent. In my opinion, this person understands the nature, benefits, risk, consequences, and alternatives.

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date (yyyy-Mon-dd)</th>
<th>Time</th>
</tr>
</thead>
</table>

If the person obtaining consent has been delegated to do so by the Most Responsible Health Practitioner, specify role:

- [ ] Physician
- [X] Resident

### Telephone/Fax Consent

Consent was given via:

- [ ] Telephone
- [ ] Fax/Scan

<table>
<thead>
<tr>
<th>Name of Most Responsible Health Practitioner</th>
<th>Signature</th>
<th>Date (yyyy-Mon-dd)</th>
<th>Time</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Witness name (to telephone call)</th>
<th>Signature</th>
<th>Date (yyyy-Mon-dd)</th>
<th>Time</th>
</tr>
</thead>
</table>

### Interpreter

**Obtaining Consent from a Non-English Speaking Patient**

I acknowledge that I have interpreted the information given to me about the surgery or invasive procedure and the content of this consent form to the person giving consent and I believe to the best of my ability that the person understands the information.

<table>
<thead>
<tr>
<th>Interpreter name (print)</th>
<th>Signature or “by telephone”</th>
<th>Date (yyyy-Mon-dd)</th>
<th>Time</th>
</tr>
</thead>
</table>

### Withdrawal of Consent (check ONE box only)

- [ ] I withdraw my consent for the entire surgery or invasive procedure as detailed on Side A. I am aware of the risks and consequences of this withdrawal.
- [ ] I withdraw my consent for the following specific portions of the surgery or invasive procedure:

<table>
<thead>
<tr>
<th>Name of person withdrawing consent</th>
<th>Signature</th>
<th>Date (yyyy-Mon-dd)</th>
<th>Time</th>
</tr>
</thead>
</table>

**Note:** Health practitioner who has documented the withdrawal of consent should inform the Most Responsible Health Practitioner of the withdrawal of consent for the surgery or invasive procedure.
Consent can be for larger treatment plan, recurrent procedures

Can use for blood transfusion if outside surgery/procedural

- Recurrent transfusion in MDS
- Hemodialysis
- IVIG infusions
- Paracentesis

- Doesn’t expire
- Revisit if significant clinical change
Consent to Treatment Plan or Procedure
(Policy PPR-01)

Telephone Fax Consent
Consent was given via ☐ Telephone ☐ Fax/Scan
Name of Most Responsible Health Practitioner Signature Date (yyyy-Mon-dd) Time
Witness Name (to telephone call) Signature Date (yyyy-Mon-dd) Time

Interpreter
Obtaining Consent from a Non-English Speaking Patient
I acknowledge that I have interpreted the information given to me about the treatment plan or procedure and the content of this consent form to the person giving consent and I believe to the best of my ability that the person understands the information.
Interpreter name (print) Signature or “by telephone” Date (yyyy-Mon-dd) Time

Withdrawal of Consent
☐ I withdraw my consent for the entire treatment plan or procedure as detailed on Side A. I am aware of the risks and consequences of this withdrawal.
☐ I withdraw my consent for the following specific portions of the treatment plan or procedure:

Name of person withdrawing consent Signature Date (yyyy-Mon-dd) Time

Note: Health practitioner who has documented the withdrawal of consent should inform the Most Responsible Health Practitioner of the withdrawal of consent to the treatment plan or procedure.

Definitions
Legal Representative: acting on behalf of a Minor Patient under the age of 18 years who is not determined to be a Mature Minor (Guardian: divorced parent with custody; person appointed by Guardian to act on behalf of Guardian where Guardian is temporarily absent; any other person authorized by law to consent).
Agent: an adult appointed in an enacted personal directive in accordance with the Personal Directives Act.
Guardian: an adult appointed in a Guardianship Order to act on behalf of an adult patient.
Specific Decision Maker: an adult relative selected to act on behalf of a patient when a patient lacks capacity and an Alternate Decision Maker is not already identified (Guardian or Agent). There is a specific process and form (AGTA Form 6) to follow for selecting a Specific Decision Maker in accordance with the Alberta Guardianship and Trusteeship Act.
Co-Decision Maker: appointed by court order to assist an adult whose ability to make decisions is severely impaired, but who can still make decisions with good support. The Adult and Co-Decision Maker are required to make decisions together and both sign the appropriate consent form when written (signed) consent is required or the Most Responsible Health Practitioner has determined the need for written (signed) consent.

Reference to SDM and Form 6
Would use for procedures that would require written consent in setting where criteria met:

| MRHP and second practitioner where practical /available |

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### For adults being provided Emergency Health Care by Physicians

*In accordance with the Adult Guardianship and Trusteeship Act*

When emergency health care is being provided by a physician to an adult the following three criteria must be met:

- Physician #1 and Physician #2 (or Registered Nurse or Nurse Practitioner) are satisfied that: the emergency health care is necessary to preserve the adult’s life, to prevent serious physical or mental harm or to alleviate severe pain and;

- The adult lacks capacity as a result of drug or alcohol impairment, complete or partial lack of consciousness or another cause, and;

- The adult did not previously object to the treatment while competent.

*Signature of 1st physician is required; second signature when practical*

<table>
<thead>
<tr>
<th>Name of Physician #1 (print)</th>
<th>Signature</th>
<th>Date (yyyy-Mon-dd)</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Physician #2, Registered Nurse or Nurse Practitioner (print)</td>
<td>Signature</td>
<td>Date (yyyy-Mon-dd)</td>
<td>Time</td>
</tr>
</tbody>
</table>

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### For minors being provided Emergency Health Care by Physicians

When emergency health care is necessary, and the Legal Representative is unable to give consent.

*Signature of 1st physician is required; second physician signature when practical*

<table>
<thead>
<tr>
<th>Name of Physician #1</th>
<th>Signature</th>
<th>Date (yyyy-Mon-dd)</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Physician #2</td>
<td>Signature</td>
<td>Date (yyyy-Mon-dd)</td>
<td>Time</td>
</tr>
</tbody>
</table>
Elements needed to clarify consent for testing when not for benefit of source patient

Can get at admission, Or at time of exposure, Bedside nurse or physician can complete
Key Consent Revision Questions:

• What is ‘invasive procedure’?
• What if use wrong form?
• Emergency Health Care: When and who does this in emergency room situation? Critical care? Who can provide the 2nd signature and what is required of that person?
• BBV testing consent: When will this be used, who can do this and what about getting information about source history?
What is meant by an invasive procedure?

Invasive procedures that would fit within the framework of the surgical consent requirements would include those such as Endoscopic Retrograde Cholangiopancreatography (ERCP), endoscopy with biopsy, cardiac catheterization or certain interventional radiology procedures. Situations where there is use of sedation and risk of significant bleeding and/or retention of tissue would more likely benefit from the elements embedded in the surgical/invasive procedure consent form. Bedside procedures are not likely to require this level of documentation but it is at discretion of the individual/program doing the procedure to determine what requires written consent and which consent form works best.
Determination of what constitutes an emergency health care situation is at the discretion of the clinician.

Criteria:
- Health care is required to:
  - Preserve the adult’s life or
  - Prevent serious physical or mental harm to the adult; or
  - Alleviate severe pain

And
- Physician is satisfied adult lacks capacity to consent/insure tx

And
- Physician has no reason to believe the adult expressed a wish/instruction to the contrary when previously capable.

Before providing emergency health care, the physician, when practical, shall obtain a written opinion from a second physician, nurse practitioner or registered nurse that the situation meets the above criteria for providing emergency health care.

If second practitioner is unavailable or disagrees:
- Provide emergency health care
- Document process & decisions

If second practitioner disagrees:
- Do not provide emergency health care
- Consult with Senior Health Care Lead
- Follow direction of senior health care lead

Resources:
- AHS Legal: 1-833-943-0924
- Clinical Ethics (regular business hours only): 403-543-2621
- OPG: The Office of the Public Guardian may be contacted (24/7)
- Toll Free Help Line: 1-877-427-4525 Monday–Friday
- After Hours Consult Line: 1-888-282-9731
- If you require a language interpreter, you can contact a Certified Health Care Interpreter at: 1-866-874-8972. Note: You must be registered to use this funded service. You can register during regular business hours by calling 403-355-1181.
Consent Policy Resources

• On Insite: http://insite.albertahealthservices.ca/2295.asp

• On External web: http://www.albertahealthservices.ca/3084.asp

• Professional Practice Consultation Services: practice.consultation@albertahealthservices.ca

• Clinical Legal Intake Line: 1-888-943-0904

Resources available on Insite and the External web include:

• Memorandum: Revision of Consent to Specific Treatment/Procedure Form
• Information Bulletin: When to Use the New Consent Forms
• Staff and Physician Q & A
• Blood Borne Virus Testing: Patient Information Sheet
• Consent Form Revisions: Cheat Sheet
• Consent to Treatment/Procedures
• Questions and Answers for Addiction and Mental Health Services
Informed Consent – 3D

**DOCUMENTATION**

**DISCUSSION**

**DECISION**
Summary Sheet

AHS Consent to Treatment / Procedure(s) Policy

Alberta Health Services (AHS) is committed to best practice which contributes to Patient safety, and enhances the Patient experience. The new AHS Consent to Treatment/Procedure(s) policy and procedures will facilitate a fair, respectful and informed Consent Process that is achieved consistently across the organization.

The Consent Process

Obtaining consent is a process involving a discussion or series of discussions and interactions between the Most Responsible Health Practitioner and the Patient, his/her Co-Decision Maker or Alternate Decision-Maker (as applicable). There are five steps to the process:

Step 1. The determination of Capacity
Assess the Patient’s Capacity to make the decision at hand

Step 2. The provision of relevant information
Provide the Patient with the information required to understand the proposed Treatment/Procedures and to make an informed decision

Step 3. The verification of understanding
Provide the Patient with the opportunity to ask questions and provide understandable answers

Step 4. The decision-making
Patient makes the health care decision

Step 5. Documentation of the Consent Process and outcome
Ensure appropriate documentation of the Consent Process and outcomes on the Patient’s Health Record