

Changes to Consent Policy Forms

Staff and Physician Q & A

Based on staff and physician input, the *Consent to Specific Treatment/Procedure* form (09741) has been revised into three separate forms: *Consent to Treatment Plan or Procedure* (09741); *Consent to Surgery or Invasive Procedure* (18628); and *Emergency Health Care: Documentation of Exception to Consent* (18629). A separate consent form for blood borne virus testing when not associated with a specific procedural consent has also been developed: *Consent to Blood Testing for Blood Borne Viruses* (18213).

The new forms will go into effect **Tuesday October 22, 2013**.

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Has the consent policy changed?

No, the consent policy remains the same.

Why was the consent form changed?

The Consent Policy Implementation Project members gathered and utilized feedback from clinicians and managers across the zones and the various health-care service sectors to better understand user needs and further refine the required elements of the consent-to-treat form.

This work has resulted in development of the four separate consent forms noted above.

What are the benefits of the new forms?

The four forms noted above are designed to better support the practice of the Most Responsible Health Practitioner by ensuring that the required consent elements are included in the forms.

Specifically:

- 1) *Consent to Treatment Plan or Procedure (09741)* – The language has been clarified and the form is written from the patient perspective, allowing greater ease in explanation and understanding; as well the various alternate decision-maker roles are outlined and defined.
- 2) *Consent to Surgery or Invasive Procedure (18628)* – The elements required to support higher risk and more invasive procedures are contained within the form to provide structural support for the informed consent process. Also, the form has been written from the patient perspective for ease of explanation and understanding.
- 3) *Emergency Health Care: Documentation of Exception to Consent (18629)* – Greater clarity for the clinician and increased system accountability are achieved by documenting the provision of emergency health care on a specific form, as an exception to the informed consent process.
- 4) *Consent to Blood Testing for Blood Borne Viruses (18213)*: Providing the elements required to support the informed consent process for this testing. It is expected that this consent will be sought and documented either as part of an admission process or when an unforeseen blood and body fluid exposure occurs. For surgical procedures this will be rolled into the procedural consent. However, for non-surgical admissions where there is risk of exposure, this should be completed at admission by one of the health-care team. This will align with the Workplace Health and Safety procedures to ensure that front line staff can be managed with the best information to guide post exposure care.

For which procedures should the new forms be used?

All care and interventions happen in the context of appropriate consent, and the *Consent to Treatment/Procedure(s)* policy applies to all procedures. The new forms are to be used specifically for all invasive procedures, those requiring sedation or anesthesia, blood product transfusions, testing for blood borne infections after blood or body fluid exposure (BBFE) i.e. needle stick injury or body fluid splash occurs. In addition, the form(s) are to be used for any other treatment or procedure for which the physician (or other Most Responsible Health Practitioner) deems written/signed consent to be appropriate.

The *Consent to Surgery or Invasive Procedure* form (18628) should be used for all surgical or invasive procedures including endoscopy or cardiac catheterization. This form includes sections about possible transfusion and testing for blood borne viruses in the event of needle stick injuries or body fluid splashes as well as for the retention of tissue and the involvement of trainees.

The *Consent to Treatment Plan or Procedure* form (09741) should be used for lesser or non-invasive procedures or treatment plans that are deemed to reach the threshold of requiring written/signed consent such as a bedside procedure or blood product transfusion.

The *Emergency Health Care: Documentation of Exception to Consent* form (18629) should be used in situations where it is deemed that a procedure, which would otherwise require written consent, is occurring in an emergency situation where it is not possible to do so.

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.

What happens if I use the wrong consent form?

Consent is less about the consent forms that are completed than the discussion that should take place between the Most Responsible Health Practitioner (MRHP) and the patient. Technically, the MRHP could use either form (*Consent to Surgery or Invasive Procedure* (18628) or *Consent to Treatment Plan or Procedure* (09741) provided that all elements are documented on the consent form. The *Consent to Surgery or Invasive Procedure* form (18628) simply incorporates elements that are normally part of the consent process for such procedures (i.e. the form includes: blood borne virus (BBV) testing, blood transfusion consent, and/or retention of tissue). Use of the form is meant to make things easier for the MRHP by highlighting the areas to be included in the discussion, removing the need to write them out in the details of treatment section as it is already articulated in the form.

What is being suggested (to ensure consistency in practice) is for a department discussion to clarify what form makes the most sense to be utilized for the procedures that are offered by the specific clinical area.

When will the previous form no longer be accepted?

As the prior *Consent to Specific Treatment/Procedure* form is in keeping with the policy, it will continue to be accepted in AHS institutions. However, the revised forms should be used as of **Tuesday October 22, 2013** for all current and future consent situations requiring written (signed) consent.

How long does a signed consent form remain valid?

Consent forms—including those used prior to the introduction of the new consent forms—remain valid indefinitely unless:

- the patient's condition has changed substantively;
- medical knowledge about the patient's condition or available treatment has changed; or
- the patient has withdrawn consent for part of the proposed treatment or the involvement of a specific clinician.

In the above noted circumstances, new consent forms will need to be signed.

Who can complete a consent form?

A clinician who has the authority and accountability for the procedure and the appropriate skills and training to complete the procedure, can complete a consent form. In most instances, this should be the actual person performing the procedure, but may also be another clinician within a group who fulfills the criteria of authority and skills. Medical trainees may obtain consent for procedures that they are able to complete independently based on experience and training and can be delegated to take part in the consent process at the discretion of the Most Responsible Health Practitioner when they have the experience to do so.

What is the role of nursing in completion of a consent form?

Nurses with advanced training and practice may provide and document the consent process for procedures that fall within their scope. In other consent processes, such as when a physician is responsible to obtain consent, nurses are able to provide witness of the patient's signature.

What is the role of trainees in the provision of written consent?

Trainees are able to complete the consent process and forms for procedures that fall within their training, expertise and scope of practice. For procedures that fall outside of their expertise, they can take part in the consent process but the Most Responsible Health Practitioner (MRHP) remains responsible for ensuring that the consent process is appropriate, complete and documented. Trainees can function as the MRHP for certain procedures that they have the training and experience to complete. All or part of the consent process can be delegated to a trainee or other physician team member by the MRHP. Trainees must defer to the MRHP's completion of the consent process if they do not have the knowledge or experience to do so or if they are unable to answer all of the patient's questions regarding consent.

Do you need to provide separate consents for procedures with multiple possible components?

Multiple component procedures can be documented with a single consent form, and can include possible blood product transfusion and testing for blood borne infections after needle stick injury or body fluid splash. The revised *Consent to Surgery or Invasive Procedure* form (18628) includes these elements as a standard component of the consent. Description of the components should otherwise be outlined in the details of treatment.

Does anesthesia require a separate consent form?

Unless the anesthesia is a stand-alone procedure, a separate consent form is not needed for its use. Documentation of the consent process using existing anesthetic records and notes is sufficient; assuming a signed consent form for the surgery itself has been obtained.

What about the 'general admission consent' we used previously?

The consent policy does not include expressed written consent for general treatment and admission. The previously used 'general admission consent' form also included such items as: blood product transfusion, testing for blood borne infections after blood and body fluid exposure (BBFE) and use of surgical tissues. There was general agreement that these previous forms alone did not constitute an adequate consent process for these interventions.

Where needed, these procedures should be included within a procedural consent process, or if they arise independently, an additional written consent should be obtained.

If blood products or a blood transfusion is ordered, who is expected and able to provide the consent?

The ordering clinician will engage the patient in the process of consent, fill out the consent form, and sign the section that attests to the completion of the consent process.

Nursing staff will seek and verify completion of the consent prior to transfusion of blood and blood products. If it is clear (such as from the progress notes or from telephone discussion) that the consent process has been completed but not documented on a consent form, the transfusion may proceed with the understanding that the consent form will be completed by the ordering clinician at the first possible opportunity.

In the event that a blood transfusion is urgently required, the nursing staff can verify that emergency conditions exist (per the consent policy) and proceed with transfusion in the absence of a documented consent, with clinician documentation and signature at the first possible opportunity. Alternatively, if no physician is physically present, and the transfusion is elective in nature, then transfusion can be delayed until consent can be documented in a standard fashion.

What are the consent documentation requirements for recurrent procedures such as transfusion or dialysis?

A single consent form may be used for recurrent equivalent procedures as long as the patient's condition has not changed substantively. In such cases, it would be appropriate for the consent discussion and documentation to specifically identify a series of treatments.

Where and when should consent be obtained and how should it travel between facilities?

The consent form should be completed at the time that consent is obtained, as part of the documentation process for the procedure. If additional documentation is required to clarify specific elements of risk and uncertainty, then additional documentation can and should be attached to the consent form. These documents should travel to the appropriate facility and should be included in the medical record, prior to starting the procedure.

What about areas like Critical Care?

The majority of care provided within the critical care environment falls under an exception to the requirement for signed/written consent as outlined in the *Adult Guardianship and Trusteeship Act (AGTA)*. In general, emergency care will take place and efforts to complete the *Emergency Health Care: Documentation of Exception to Consent* form (18629) and/or documentation within the patient care record should occur as soon as possible. When care within critical care falls outside of the requirements of the exception, the appropriate consent discussion and documentation should be completed.

How does documentation of consent within the electronic health record work?

As we are moving toward a true electronic health record (EHR), but remain in a hybrid with a paper and electronic component, there will continue to be issues with ensuring that the documentation of consent travels with the patient or that a copy is available for access as the patient transitions to other settings. It is preferable to avoid the need for multiple consent forms to be completed unless the clinical situation changes or evolves, necessitating further clarification. In addition, electronic form completion and signature would be preferred and supported once the electronic health record can support the legal and privacy requirements. In the interim, programs can use electronic versions of the forms to allow for access/use within doctors/program offices. These forms must travel with the patient to the AHS facility pending development of a scanned method to enter the forms into the electronic health record locally and provincially.

When will BBV testing consent be acquired?

Consent for blood borne virus testing will be included in the *Consent to Surgery or Invasive Procedure* form (18628) at the time the procedural consent is completed. For non-surgical admissions where there is more than minimal risk of treatment provider exposure to needle stick injuries or body fluid splashes, the *Consent to Blood Testing for Blood Borne Viruses* form (18213) should be completed at the time of admission. In situations where these issues occur outside of admission or where there was not deemed to be significant risk, then the *Consent to Blood Testing for Blood Borne Viruses* form (18213) will be completed at the time of the blood or body fluid exposure.

What should be done with the prior consent forms that are still available?

It is expected that with implementation of the revised forms, prior issues with the consent forms will largely be resolved and therefore these forms can be retired. Effective **Tuesday October 22, 2013**, managers and supervisors should remove previously unused forms from units and clinical service areas. Future development of additional forms or versions to manage new or unforeseen issues or changes to legislation or policy should be referred to the forms group or escalated through Clinical Policy to the appropriate leaders/owners for review.

Who do I contact with questions and feedback?

All questions and feedback should be directed to clinicalpolicy@albertahealthservices.ca. Clinical Policy will respond to all inquiries that are received.