Blood and Blood Products Informed Consent
Frequently Asked Questions

Why is there such an emphasis on 'Informed Consent' for blood and blood products?

Obtaining informed consent for administration of blood products is a requirement for accreditation of all hospital facilities, including the laboratories that provide the blood products to be transfused. Blood products have known benefits and risks and may have medically appropriate alternatives. Giving this information to patients is necessary to inform their choices. The Krever inquiry made it clear that consent for blood products should not be assumed to be included under the 'umbrella' of the comprehensive care plan without first discussing the information with the patient.

What is the definition of blood and blood products?

Blood & blood products include blood components obtained from blood donors (e.g. red blood cells, plasma, platelets and cryoprecipitate) as well as plasma protein products manufactured and processed from the pooled plasma of thousands of donors (e.g. albumin, IVIG, RhIG) A complete list of blood products can be found at http://www.albertahealthservices.ca/3319.asp

Do I need to fill out a form?

Yes, the new AHS Consent policy - Consent to Treatment/Procedure(s) - requires written consent for the transfusion of blood and blood products, except in an emergency (see AHS consent procedures). It is recommended that the new Consent form be used for that purpose now but, in the short term, you may choose to continue to use existing blood transfusion consent forms.

Do I have to obtain consent for each and every transfusion?

Consent can be for a single transfusion or for a series of transfusions (in a treatment plan). During the conversation to obtain informed consent the discussion should include whether it is one time only or a series of transfusions and that information should be captured on the consent form in the "Details of treatment/procedure/treatment plan" section.

Consent may be obtained in conjunction with a procedure; e.g. "Right total knee replacement and possible blood transfusion" without specifying a particular product or products, as several different products might be used in the surgical setting.

Whenever possible, be as specific as you can when obtaining consent for blood or blood products. For example, if you are intending to give Rh immune globulin write "Rh immune globulin" in the "Details of treatment/procedure/treatment plan" section of the new form (Consent to Specific Treatment/Procedure, #09741).

Consent for blood and blood products may also be obtained as a separate consent using the new Consent form.

How long is consent for blood and blood products valid?

The policy does not identify a specific time for duration of a consent. A new consent should be obtained if one of the following conditions occurs:

- The Patient's condition has materially changed;
- The medical knowledge about the Patient's condition or the Treatment available has materially changed; or
- There has been a refusal to a portion of the Treatment/Procedure(s) originally planned or a refusal regarding the involvement of particular individuals in the Treatment/Procedure(s) (e.g. medical trainees).

What do we do about transfusion refusal such as with Jehovah's Witnesses?

The new consent form is intended to document agreement to proceeding with a treatment or procedure. While there is a section to complete if the patient changes his/her mind and withdraws consent, there is no section to indicate that a treatment has been refused.

In order to avoid confusion, it is recommended that the new Consent form NOT be used to document the refusal of blood and blood products. The refusal should be documented in the patient's care notes in the health record.

A specific refusal form is under consideration and discussions are ongoing regarding strategies as to how refusal of blood and blood products can be prominently featured and communicated.

Some of the patients who refuse blood will accept some blood - derived products and it is important for the physician to document specifics, either on Form 09741 or in the patient record, or both.

Hospital Information Services (Canada) for Jehovah's Witnesses provides information and support to patients and their physicians, 24 hrs per day at 1 800 265-0327.

What if an emergency requirement for transfusion arises and there is not time for the physician to obtain consent, or the patient is sedated or anesthetized and unable to provide informed consent?

An emergency requirement for transfusion does not require specific written consent if the patient lacks capacity and the alternate decision-maker is not immediately available to give such consent. In this case the physician would sign the portion of form 09741 indicating that emergency treatment was necessary. Currently, a request for unmatched blood does require a physician signature so this does not represent a change in the process.

The Consent policy and procedures describe the requirements that must be met for physicians to provide emergency health care without consent under the *Adult Guardianship and Trusteeship Act*. For the specifics of these requirements refer to the policy and procedures and the Consent resources website.

If the most responsible health practitioner has discussed the risks and benefits of transfusion with the patient at an earlier time but not completed a consent form, can a nurse complete the form and witness the consent at the time of administering the blood?

If discussion between the patient and the MRHP about a transfusion has occurred, and, at the time of administration of the blood product the nurse can confirm that the patient is aware of the transfusion and has consented, then the nurse can "witness" the patient signature on the consent form and begin product administration prior to obtaining the physician signature. However, the nurse should ask if the patient has any further questions. If the patient has further questions, written consent would NOT be obtained and the most responsible health practitioner would be notified that the patient has further questions.

What should we do if the patient needs a blood transfusion in the middle of the night but there is no physician or resident on site to provide the order or obtain consent?

Telephone the physician-on-call for an order to give blood and document as you normally would for a telephone order.

If the patient has capacity, a telephone conversation between the patient and the physician should occur to obtain informed consent for the blood or blood products. The following sections of the consent form should then be completed:

- Patient Name
- Details of treatment/procedure /treatment plan (no abbreviations)
- Name of person(s) giving consent (check box next to Patient)
- Signature of person giving consent (in this case the patient)
- Witness (insert name and signature of the nurse observing the patient giving consent)

As soon as possible on returning to the hospital, the physician should sign the MRHP statement and the telephone consent section on the first page of the form.

If the patient lacks capacity and an alternate decision-maker is immediately available, a telephone conversation with the physician should occur to obtain informed consent. The following sections of the consent form should then be completed:

- Patient Name
- Details of treatment/procedure /treatment plan (no abbreviations)
- Name of person(s) giving consent (check box next to Alternate Decision-Maker)
- Signature of person giving consent
- Witness (insert name and signature of nurse observing the patient giving consent)
- Page 2 of the form – Under the tab *Confirmation – Alternate Decision-Maker*. Check the appropriate box and have the person providing consent sign and date.

As soon as possible on returning to the hospital, the physician should sign the MRHP statement and the telephone consent section on the first page of the form. In the case of a Specific Decision-Maker being named, Form 6 (http://www.seniors.gov.ab.ca/opg/guardianship/forms/) should also be completed.

If the patient lacks capacity and an alternate decision-maker is NOT immediately available

The following sections of the consent form should then be completed:

- Patient Name
- Details of treatment/procedure /treatment plan (no abbreviations)
- Page 2 of the form – Under the tab, *Procedure when unable to obtain consent for Emergency Health Care*. Print the name of the physician giving the telephone order to transfuse blood or blood products. Write "by telephone" in the upper part of the signature box leaving room for signature at a later time. Insert date and time and initial.

Since a signature by a second physician in this scenario is not feasible, there are two options:

- With the exception of consent for a minor, a Nurse Practitioner or Registered Nurse may provide the second signature indicating that this situation meets the criteria for emergency health care.
- Proceed with just one physician's signature (to be obtained later).

What should we do if the patient needs a blood transfusion (not an emergency) but there is no physician or resident on-site to obtain consent?

In this case there is time to seek appropriate informed consent even if the patient lacks capacity. Therefore, two physician signatures for emergency health care would not be appropriate.

In this situation telephone consent may be obtained following discussion between the off site physician and the patient and documented as outlined above.

If the patient lacks capacity and no alternate decision-maker can be found, a call can be made to the Office of the Public Guardian (in the case of an adult) or the office of the Director of Child, Youth and Family Enhancement Act (in the case of a minor).

What if parents of a minor child refuse potentially life-saving transfusion for the child?

According to AHS Policy PRR 01-03, if a Mature Minor or Legal Representative (most often the parents) refuses to provide consent the following apply:

- If consent for essential medical, surgical or other remedial Treatment necessary for the health or well-being of the patient is refused, the Director of Child, Youth and Family Enhancement Act must be forthwith notified by the Most Responsible Health Practitioner or delegate.
- The requirement for consent may be overridden by a warrant, subpoena, court order or by operation of legislation.

Every effort must be made to resolve consent issues before the situation becomes an emergency. Social Work, Clinical Ethics and Clinical Legal Services are resources that can be consulted in such cases.

Who determines if a monor child is a mature minor and able to make decisions about transfusion independently?

According to AHS Procedure Consent to Treatment/Procedure(s): Minors/Mature Minors (PRR 01-03):

- A Patient under the age of eighteen (18) years is presumed to be a Minor Patient without Capacity, unless assessed and determined to be a Mature Minor:
    - Health Practitioners shall conduct the assessment for a Mature Minor by asking questions in order to determine whether the Minor Patient has the intelligence and maturity to provide consent for a Treatment/Procedure(s) without the input of their Legal Representative.
    - The outcome of the assessment shall be documented in the Patient's Health Record.