

Guideline 1

Informed Consent for Administration of Blood, Blood Components, and/or Plasma Protein Products**Purpose**

- 1.0** To provide best practice guidelines that aligns with the standards set forth by the American Association of Blood Banks (AABB), Accreditation Canada (AC), Transfusion Services, Canadian Standards Association (CSA) and the Canadian Society of Transfusion Medicine (CSTM) for informed consent for blood, blood components and/or plasma protein products.

Refer to Appendix 3

[Frequently-asked-questions-regarding-informed-consent-for-blood-transfusions.pdf](#)

Informed consent is:

- ✓ Required for the administration of all blood products
- ✓ An ongoing process that includes the provision of information that is understood by the person providing consent.

- 1.1** The standards state that informed consent **must:**
- Have up to date information regarding the blood component or blood product
 - Involve discussion regarding risk and benefits of:
 - ✓ Transfusion vs no treatment
 - ✓ Any clinically appropriate alternatives to transfusion
 - Provide opportunity to ask questions
 - Be voluntary
 - Be documented in the patient's record
 - Ensure the patient has the capacity to provide consent
 - Understand the patient has the right to refuse transfusion
 - May be withdrawn at any time
- 1.2** In the event that patients are unable to provide consent, the health care team refers to the patient's advance directives or obtains consent from a substitute decision maker (SDM). If the SDM is providing consent, the SDM's name, relationship with patient and decision made must be documented in the patient's record.

Whenever possible, the discussion between the physician/authorized practitioner and the patient or SDM should take place well in advance of the planned surgical procedure or transfusion of product. This may enable the patient to explore other available alternatives to blood transfusion

Policy for Informed Consent

- 1.3 Health care facilities/RHAs in Manitoba must implement a policy for informed consent for blood, blood components and/or plasma protein products.
- 1.4 Documented and informed consent is valid for over the course of hospital admission or medical treatment plan. If substantive medical changes have occurred between the time of consent and the need for transfusion, the consent should be reviewed. The informed consent process must be reviewed at least every 12 months for patients with chronic conditions.
- 1.5 Informed consent must be obtained by a physician or authorized practitioner, according to facility/RHA policy. An authorized practitioner may include but is not limited to:
- ✓ Registered Nurse Extended Practice
 - ✓ Registered Clinical assistant
 - ✓ House Medical Officer
 - ✓ Physician Assistant
- 1.6 Both verbal and written information from the physician/authorized practitioner should be provided to the patient or substitute decision maker (SDM) to allow them to make an informed decision as to the treatment plan.
- 1.7 In emergency situations a blood transfusion may be given without informed consent, **only if all the following apply:**
- ✓ An urgent transfusion is required to preserve the patient's life, limb, or vital organ.
 - ✓ A patient does not have decision making capacity and a substitute decision maker is not readily available.
 - ✓ A reasonable patient would consent in his/her circumstances.
 - ✓ No evidence that the patient objects to transfusion for personal or religious reasons.

- 1.8 The physician/authorized practitioner must document, in the patient's health record, why informed consent was not obtained. The patient shall be informed as soon as possible.
- 1.9 Refusal of consent to receive blood, blood components, and/or plasma protein products must be documented in the patient's health care record.

Telephone Consent is used when informed consent is not obtainable in person, it is acceptable to obtain consent via telephone. The physician/ authorized practitioner must discuss the elements on the informed consent with the patient/SDM. A witness must be present to this conversation and is required to sign the consent form. The signature of the witness does not imply responsibility for the consent, only that he/she witnessed the process.

- 1.10 The nurse will ensure informed consent for any blood, blood components, or plasma protein products have been obtained prior to the administration of any product.

In the event that there is no signed consent or relevant documentation in the health record and/or the patient disclaims knowledge or understanding of the intended transfusion, the nurse will notify the physician/authorized practitioner and **will not** initiate the transfusion until the situation has been rectified.

- 1.11 Written notification, a patient notification card, must be provided to each patient (or SDM) who has received a transfusion/infusion of blood, blood components, or plasma protein products. It is recommended that this be provided at the time of discharge and include information on signs and symptoms of potential adverse events.

Documentation

- 1.12** Documentation regarding consent must always be included in the patient's health care record. This includes non-consent and emergency situations where a patient may require blood, blood component or plasma protein products as part of their care. Documented informed consent should be obtained at all times with the exception of emergency situations.
- 1.13** Informed consent must be documented according to facility/RHA policy in the patient's health care record with signatures by the patient/SDM and the physician/authorized practitioner present. Use of the informed consent or refusal of consent forms is recommended.
- 1.14** Details of the consent discussion should be documented whenever possible. This might include specific individualized risks and alternatives discussed.
- 1.15** In an emergency when the patient cannot provide consent and no SDM is available then, in good faith, emergency treatment/transfusion can be given. Consent must be obtained as soon as the patient or SDM is able to render an informed decision. The details of the situation and discussion should be clearly documented in the patient's health record.
- 1.16** Refusal of consent to receive blood, blood components, and/or derivatives must be documented in the patient's health record.
- 1.17** In addition, the nurse will document in the health care record:
- ✓ Any further actions taken pertaining to informed consent
 - ✓ On completion of transfusion or discharge from hospital the patient was provided with written notification regarding their transfusion of blood, blood components, and/or plasma protein products.

Refer to Appendix 13 Page 1 Patient Resources

[A-Blood-Transfusion-Reaction-what-you-should-know-patient-information-sheet-1.pdf](#)

Informed Consent for Treatment or Procedure Form is used for surgical patients or those going for certain diagnostic procedures. There is a statement of consent that includes the administration of blood products within these forms. This is considered a general informed consent form.

Refer to Appendix 1 [Sample of a General Informed Consent Form \(sample A\)](#)

Health care providers should initiate a specific informed consent form for the administration of blood products whenever possible.

Refer to Appendix 2 [Sample of Specific Informed Consent Form \(general form with transfusion as procedure\)](#)

Quality Control

- 1.18** A facility-based quality improvement system or process should be in place to monitor compliance to the informed consent for blood, blood components, and/or derivatives through random patient and health care record audits and/or other quality improvement mechanisms. Health care facilities/Regional Health Authorities should implement a quality improvement system facilitated through the Transfusion Practice Committee to monitor compliance.

Notes/Special Consideration

- 1.19** Pediatric patients – the term patient refers to the patient, parents or care providers, legal guardians or agency responsible for the child's care (Substitute Decision Maker, SDM).
- 1.20** In Manitoba, a person who is 16 years of age or more and has the mental capacity to make health care decisions, have the right to consent, or refuse to consent to medical treatment.