Guideline 1

Informed Consent for Administration of Blood, Blood Components, and Blood Products

1.1 Purpose

To provide best practice guidelines for nurses that align 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 obtaining informed consent, or refusal for consent, for the administration of blood, blood components, and blood products.

1.2 Policy

Informed consent is a *requirement* for transfusion of blood, blood components, and blood products. Policies must be implemented for obtaining informed consent prior to the to the administration of blood, blood components, and blood products.

Procedures/Policies must be in place for:

- Consent
- Refusal of consent
- Interpreters
- Age of consent/pediatric considerations
- Emergency situations without consent

1.3 Documentation

Documentation of consent or non-consent shall be recorded in the patient's health record according to the Health Care Facility/Service Delivery Organizations (SDO). It must include signatures from both the patient/substitute decision maker (SDM) and the authorized health practitioner present. Use of a consent form/refusal of treatment form is recommended.

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 Informed consent (general) 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 Informed consent from documenting (specific) reason for consent (Sample B) (general form with transfusion as procedure)

An integrated progress note (IPN) should contain details of the consent discussion which may include specific individualized risks and alternatives discussed.

In the event of an emergency situation where a patient cannot provide consent and no SDM is available, an emergency treatment/transfusion may be given without consent. However, consent must be obtained as soon as the patient or SDM is able to render an informed decision. The details of the situation and subsequent discussion should be clearly documented in the patient's health record.

Upon discharge from hospital, the patient shall be provided with written notification regarding their transfusion of blood, blood components, and/or blood products. Refer to Appendix 3 Notification Card Sample.

1.4 Materials

- Consent form
- Refusal of treatment form
- Integrated progress note

1.5 Quality Control

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 blood products through random patient and health care record audits and/or other quality improvement mechanisms. Health Care Facilities/Service Delivery Organizations should implement a quality improvement system facilitated through the Transfusion Practice Committee to monitor compliance.

1.6 Procedure

Routine (non-emergency)

Action	Key Points
Authorized health practitioner determines need or potential need for blood, blood component, or blood product.	**When possible, the discussion regarding the need or potential need for blood, blood products, or blood components should take place as early as possible prior to the surgical procedure or blood therapy.**
Authorized health practitioner obtains consent for transfusion by having a conversation with the patient/SDM that encompasses all necessary standards for informed consent. The standards state that informed consent *must*: • Have up to date information regarding the blood, blood component, or blood product • Include a description of the blood, blood product, or blood component to be transfused • Involve discussion regarding risk and benefits of: ○ Transfusion vs. no treatment	**Please refer to your site's policy regarding informed consent (for procedures, treatments, and investigations) for all details and scenarios regarding informed consent.**

○ 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	

Emergency situations (no consent)

Action	Key Points
The authorized health practitioner may order a transfusion *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.	**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.**

1.7 Notes/Special Considerations

Duration of Consent

Informed consent is valid 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 shall be reviewed. The informed consent process must be reviewed at least every 12 months for patients with chronic conditions.

A new consent form shall be completed in any of the following situations:

- The consent form for one course of treatment on the patient's health record is greater than 12 months after the date of signing.
- The patient's condition and/or indication for transfusion has changed.
- The medical knowledge surrounding the patient's condition or treatment has changed.
- There has been a change in what the patient does/does not consent to receive (example: patient originally refuses a blood transfusion but did accept other blood components/products. Now patient will accept all blood, blood products, and blood components).

Interpreters

WRHA Interpreters can be available on a 24/7/365 basis, in-person, over the phone, or via MbTelehealth. Health care providers shall make every effort to obtain services of an interpreter for discussions regarding consent. Ad hoc interpreters (i.e. non-WRHA staff) may be used in the event a WRHA interpreter will not be available within a reasonable time frame.

Pediatrics

In Manitoba, a person who is 16 years of age or older, and has the mental capacity to make health care decisions, has the right to consent, or refuse to consent, to medical treatment.

Refer to Guideline 11 for additional details for pediatric patients.

Telephone Consent

In an emergent situation, where the patient/resident/client is unable to provide informed consent and the substitute decision maker is available only by telephone, the authorized prescriber may obtain informed consent by telephone. Along with the authorized prescriber, there shall be a witness to whom the substitute decision maker repeats his or her informed consent. The witness shall sign the consent form. Whenever possible, the substitute decision maker's written consent should be obtained as soon as possible thereafter.

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 consent process the discussion with the patient should include the number of transfusions in the treatment plan. The number of transfusions should be clearly written on the consent form. Example: A patient requires IVIG therapy for 12 months. The conversation and the form should specify multiple infusions over 12 months. A review of patients' understanding and available alternatives should be ongoing.