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<th>Office of Administrative Responsibility</th>
<th>Issuing Authority</th>
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Overview

Transfusion of blood components and/or administration of blood products is a medical treatment that is not without risks. Both legally and ethically, there are requirements for informed consent to ensure that recipients are aware of the risks versus benefits of this treatment and that they are making an informed decision to consent to or refuse it. The Newfoundland and Labrador Blood Coordinating Program (NLPBCP) has developed this policy to provide guidance and resources to the Regional Health Authorities (RHAs) in the development of their region specific policies and documents.

Definitions

1. **Episode of Care**: A period of hospitalization (inpatient or outpatient) in which care was received for a presenting problem beginning with registration and ending with discharge.

2. **Explicit Consent**: The patient or guardian states a willingness to accept specific intervention(s). Explicit consent may be written or oral.

3. **Guardian**: A person lawfully invested with the power and charged with the duty of taking care of the person and managing the property and rights of another person.

4. **Health Care Provider**: Physicians, nurses, laboratory technologists, physiotherapists, social workers, and others who provide professional health care to the patient.

5. **Informed Consent**: A person’s agreement to transfusion of blood components and/or blood products is based on a full disclosure of facts needed to make the decision. Information given to the patient must include a description of the blood component and/or products being discussed and potential alternative therapies, if applicable, and the benefits and risks associated with each treatment option. It is the physician’s (or physician’s delegate) responsibility to inform the patient of the risks, benefits, and alternatives to transfusion. The patient must be given the opportunity to ask questions and receive answers to ensure understanding of all information that is given. It is the physician’s (or physician’s delegate) responsibility to obtain informed consent and ensure the appropriate form – Consent Form for the Administration of Blood Component(s) and/or Blood Products – is signed by the patient or substitute decision maker and becomes a part of the patient’s health record. In addition, the patient’s conduct indicates a willingness to submit to medical treatment.

6. **Mature Minor**: A minor assessed and deemed mature by a physician to understand the nature, consequences and associated risks of a required medical procedure and deemed capable of making a specific treatment decision.

7. **Patient**: For the purpose of this document, patient shall refer to a patient, a resident and/or a client.

8. **Physician’s delegate**: A qualified and suitably licensed health care professional who is authorized to perform specific medical acts under the general supervision of a physician.

9. **Refusal of consent**: A competent adult and a mature minor patient may refuse any intervention, even though such refusal may endanger life or health. No other person has
the right to refuse intervention on behalf of a mentally competent adult or mature minor. It is the physician’s (or physician’s delegate) responsibility to inform the patient of the risks involved in refusal. The appropriate form – Refusal of Treatment with Blood Components and/or Blood Products – must be signed by the patient or substitute decision maker and placed on the patient’s health record.

10. **Series of Treatments**: A pre-determined sequence of related interventions, specific to a plan of care that may be either inpatient and/or outpatient.

11. **Substitute Decision Maker**: The person appointed by the maker of an advance health care directive to make health care decisions on his or her behalf or appointed by the court to do so. Where there is no appointment, the decision maker should be determined in accordance with section 10 of the Advance Health Care Directives Act.

**Policy**

1. RHAs shall have a policy to ensure that patients are appropriately informed before receiving blood components and blood products. The policy must state that patients will be given information on the blood component or blood product and the diagnosis that it is treating, the purpose of the transfusion, the risks and benefits of transfusion, alternatives to transfusion including the risks and benefits, and the risks associated with transfusion refusal. All information should be given in terminology that the patient will understand. The policy shall describe the process of obtaining informed consent from the patient including the opportunity for the patient to ask questions and receive satisfactory answers. The recipient has the right to accept or refuse transfusion.

2. Informed consent is intended to provide the patient with sufficient information and asserts the right of patients to decide about medical treatment based on the relative advantages and disadvantages, and to protect the physician (or physician’s delegate) from liability.

3. RHAs should have policies in place guiding physicians on document requirements of the consent process. This should include what was discussed with the patient in terms of risks and benefits of the transfusion, alternate treatments including risks and benefits, as well as the risks if treatment is refused or declined.

4. RHAs shall have policies in place to ensure patients are informed of all blood components and products administered including documentation of this process. The documentation should include the quantity of each component or product transfused.

**Guidelines**

The RHAs shall incorporate these policy guidelines as a minimum into existing documents where they exist.

1. Consent to treatment is a process that involves legal, ethical, communications, cultural and religious aspects. The health care provider must act in the best interest of the patient. They must remain neutral and not influence the patient decision by what they state, how they state it including the tone and choice of wording.
2. If the patient is deemed incapable of providing informed consent to treatment, consent may be obtained from the patient’s substitute decision maker. If no substitute decision maker has been appointed, the physician should obtain consent from the applicable person outlined in the Advance Health Care Directives Act.

3. It is the attending physician’s responsibility to acquire consent from the substitute decision maker/guardian for the patient who is to receive blood components or blood products during an episode of care or series of treatments. The attending physician may delegate responsibility to acquire consent to another physician including a resident or nurse practitioner (i.e. physician delegate).

4. Health care providers are responsible to know which blood products are human based as administration of these products requires consent.

5. Consent is required from the patient or substitute decision maker/guardian for all blood components and blood products administered.

6. The patient has the right to give or refuse consent. The written document is not the consent. The presentation of the form to be signed may lead to the conversation and education between the physician (or physician delegate) and patient which reflects true informed consent has been obtained. The document is part of the evidence that the process has occurred. Notification in the patient’s health record verifies that the information exchange has occurred. Signed informed consent forms or refusal to consent become a permanent part of the patient’s health record. Records are to be maintained as per facility policy.

7. Jehovah’s Witness leadership allows some individual judgement in terms of blood products. Therefore, all Jehovah’s Witness patients should be interviewed to determine what their specific beliefs are so that the best care is provided to them without opposing their views. Jehovah’s Witness patients wishing to have the support of the Hospital Liaison Committee may contact the Hospital Liaison Committee at 1-905-873-1006 (24 hour access).

8. If the child has been deemed a mature minor, he or she may provide informed consent.

9. In cases where the child does not appear to understand the material and significant risks, the parent may consent or refuse consent on behalf of the child.

10. If a manager or social worker believes a child is in need of protective intervention due to parent refusal to permit medical treatment that is being recommended by a qualified health professional, the judge may grant an order to authorize the recommended treatment with no liability placed on the health care professionals providing such treatment. Only if the manager or social worker has been granted a continuous custody order may they consent to medical treatment.

11. The physician (physician delegate) may treat a patient without parental consent in an emergency life threatening situation in accordance with common law.
Procedure

1. The patient/substitute decision maker must be adequately informed of the potential risks associated with blood components (e.g. red blood cells, frozen plasma) and manufactured blood products (e.g. Rh immune globulin, intravenous immune globulin).

2. The health care provider proposing the transfusion of blood component or blood product must explain to the patient or substitute decision maker the need for treatment, the risks and benefits, side effects, alternative treatment and the associated risks and benefits as well as the risks of not having the treatment. Refer to Information for Healthcare Providers.

3. To facilitate the transfer of information, all patients including those having any pre-transfusion testing preoperatively should receive a copy of Information for Patients, Residents, and Clients.

4. The patient should read the information and obtain answers to questions or concerns from the physician (physician delegate) prior to signing the Consent for Administration of Blood Components and/or Blood Products form. If the patient is unable to read, there shall be a mechanism in place that provides the patient with the relevant information so that an informed decision can be made by the patient.

5. The Consent for Administration of Blood Components and/or Blood Products form must be signed by the patient or substitute decision maker.

6. Consent is required for each episode of care or series of treatments. A new consent form must be completed for each episode of care or series of treatments.

7. Consent may be obtained within thirty (30) days prior to treatment. If more than 30 days has passed before the intervention commences the patient must sign the consent form to indicate that there has not been a change in the patient’s medical condition.

8. Consent is valid for six (6) months for the particular hospitalization/outpatient period with the exception of the following:
   8.1. consent is revoked by the consent giver.
   8.2. a change is made in the planned and consented to intervention. or
   8.3. the patient indicates the medical condition has changed.

9. If the patient indicates that there has been a change in the medical condition, the attending physician (physician delegate) must be informed.

10. Consent is valid for 6 months for patients requiring continued transfusion support. (e.g. Intravenous Immune Globulin).

Refusal of Consent

1. Patients have the right to refuse transfusions of blood components and blood products.

2. When a patient refuses a proposed treatment requiring the transfusion of blood components and/or blood products, the patient must sign a Refusal for Treatment with Blood Components and/or Blood Products form.
3. Documentation should include the treatment offered including the risks of not having the treatment, any treatment alternatives discussed, and the patient decision (refusal, choice of alternative therapy).

4. Refusal to receive blood components and blood products does not constitute refusal for all treatments.

**Quality Control**

1. Informed consent for administration of blood components and/or blood products forms or refusal for treatment with blood components and/or blood products forms are part of a patient’s transfusion record.

2. All transfusion records shall be maintained in the patient’s health record in accordance with the health care facility’s policy.

**Key Words**
Consent, blood components, blood products

**Supplemental Materials**

1. Pamphlet “Information for Patients”

2. Pamphlet “Information for Physicians”

**Appendices**

Appendix A: Consent Form for Administration of Blood Components and/or Blood Products
Appendix B: Refusal of Treatment with Blood Components and/or Blood Products Form
References


Appendix A:

Consent Form for Administration of Blood Components and/or Blood Products

Hospital Site: 

- Consent is required for each episode of care or series of treatments
- Consent may be obtained within thirty (30) days prior to treatment.
- Consent is valid for 6 months or for the particular hospitalization/outpatient period unless revoked by the consent giver, or a change is made in the planned and consented to intervention or the patient indicated their medical condition has changed, or if there is a change in the patient’s physical or mental status.

Patient Statement:

I, _____________________________ hereby consent to the administration of:
Blood components and/or Blood products manufactured from donor blood
___________________________

(Specify blood components or blood products)

I have read the information/the information has been communicated as contained in the transfusion information pamphlet entitled “Information for Patients” as provided to me by my health care provider.

I acknowledge that the nature of the treatment(s), expected benefits, material risks, material side effects, alternative course of action and the likely consequences of not having treatment(s) have been discussed with me by __________________________

Physician’s Name

I have had opportunities to ask questions regarding this treatment and all questions have been answered to my satisfaction.

______________________________
Signature of Patient or Substitute Decision Maker

______________________________
Signature of Witness

Physician Statement:

I confirm that I have explained the nature of the treatment(s), the expected benefits, material risks, material side effects, alternative course of action and the likely consequences of not having treatment(s) to the above patient/substitute decision maker and answered all questions.

______________________________
Signature of Physician

______________________________
Signature of Witness
Appendix B:

**Refusal of Treatment with Blood Components and/or Blood Products**

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**Patient Statement:**

I, __________________________________ refuse treatment by the administration of blood components and/or blood products.

I have read the transfusion information pamphlet entitled “Information for Patients”.

I acknowledge that the nature of the treatment(s), expected benefits, material risks, material side effects, alternative course of action (including bloodless surgery) and the likely consequences of not having treatment(s) have been discussed with me by __________________________ and all questions have been answered to my satisfaction. I understand that such treatment in the opinion of the attending physician or assistants may be deemed necessary to preserve life or promote recovery. I therefore understand and accept any and all consequences and risks of refusing such treatment.

I release the attending physician, all hospital personnel, the hospital __________________________ (hospital name) (RHA), from any responsibility for any untoward outcomes due to my refusal to permit the use of blood components and/or blood products.

______________________________ _________________________ __________________
Signature of Patient or Substitute Decision Maker Print Name Date (DD/MONTH/YYYY)

______________________________ _________________________ __________________
Signature of Witness Print Name Date (DD/MONTH/YYYY)

**Physician Statement:**

I confirm that I have explained the nature of the treatment(s), the expected benefits, material risks, material side effects, alternative course of action and the likely consequences of not having treatment(s) to the above patient/substitute decision maker and answered all questions and the treatment has been refused.

______________________________ _________________________ __________________
Signature of Physician Print Name Date (DD/MONTH/YYYY)