Government of Newfoundland and Labrador

Department of Health and Community Services
Provincial Blood Coordinating Program

CONSENT OR REFUSAL TO ADMINISTRATION OF BLOOD COMPONENTS AND PLASMA PROTEIN AND RELATED PRODUCTS	NLBCP-023

Office of Administrative Responsibility	Issuing Authority
Medical Advisor to the Provincial Blood Coordinating Program	Dr. Lucinda Whitman
Manager, Provincial Blood Coordinating Program	Daphne Osborne
Author	Melissa Dawe
Effective Date	2023-07-30
Version	4.0
Review Due Date	2025-07-30

Overview

Transfusion of blood components and/or administration of plasma protein and related products (PPRP) is a medical treatment that is not without risks. Legal and ethical requirements for informed consent ensure that recipients are aware of the risks versus benefits of treatment and that they are making an informed decision. The recipient has the right to accept or refuse transfusion.

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. **Informed Consent**: A person's agreement to transfusion of blood components and/or PPRP that contains human plasma 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 responsibility of the authorized prescriber 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 responsibility of the authorized prescriber to obtain informed consent and ensure the appropriate form – Consent Form for the Administration of Blood Component(s) and/or PPRP – 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.
5. **Mature Minor**: A minor assessed and deemed mature by a qualified physician, a qualified psychologist or an advanced nurse practitioner to understand the nature, consequences and associated risks of a required medical procedure and deemed capable of making a specific treatment decision.
6. **Patient**: For the purpose of this document, patient shall refer to a patient, a resident and/or a client.
7. **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 responsibility of the authorized prescriber to inform the patient of the risks involved in refusal. The appropriate form – Refusal of Treatment with Blood Components and/or PPRP – must be signed by the patient or substitute decision maker and placed on the patient's health record.

8. **Series of Treatments:** A pre-determined sequence of related interventions, specific to a plan of care that may be either inpatient and/or outpatient.
9. **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. The Provincial Health Authority (PHA) shall have a policy to ensure that patients are appropriately informed before receiving blood components and PPRP that contain human plasma. The policy must state that patients will be given information on the specific blood component or PPRP 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 refusal of transfusion. All information should be provided 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 responses.
2. Informed consent is intended to provide the patient with sufficient information and respects the right of patients to decide about medical treatment based on the relative advantages and disadvantages, and to protect the authorized prescriber from liability.
3. The PHA should have policies in place guiding authorized prescribers on documentation 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 declined.
4. The PHA shall have policies in place to ensure inpatients are informed of all blood components and PPRP that contain human plasma administered.
5. The PHA should have a process in place to audit consent process, every one to two years.
6. The audit process should include:
    6.1. A description of the blood component or blood product was given;
    6.2. The risks and benefits, including life-threatening risks, were explained;
    6.3. Alternatives, with risks and benefits, were given; and,
    6.4. Patient consent was obtained (signed).

Guidelines

The PHA 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, communication, 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 tone nor content of communication.
2. Consent is required from the patient or substitute decision maker/guardian for all blood components and PPRP that contain human plasma administered.
3. The authorized prescriber is responsible to obtain the consent.
4. 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 authorized prescriber should obtain consent from the applicable person outlined in the Advance Health Care Directives Act.
5. Health care providers are responsible to know which PPRP are human plasma derived as administration of these products requires consent.
6. The patient has the right to provide 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 authorized prescriber 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 PPRP. Therefore, all Jehovah's Witness patients should be interviewed to determine their specific beliefs so that the best care is provided 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 a child has been deemed a mature minor, they may provide informed consent.
9. In cases where a child does not appear to understand the material and significant risks, the parent may consent or refuse to 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, a judge may grant an order to authorize the recommended treatment with no liability placed on the health care professionals providing such treatment. A manager or social worker who has been granted a continuous custody order may consent to medical treatment.
11. The authorized prescriber 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 PPRP that contain human plasma (e.g. Rh immune globulin, intravenous immune globulin).
2. The health care provider proposing the transfusion of blood component or PPRP that contains human plasma must explain to the patient or substitute decision maker the indication 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 authorized prescriber prior to signing the Consent for Administration of Blood Components and/or Plasma Protein and Related Products form. If the patient is unable to read, there shall be a mechanism in place to provide 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 Plasma Protein and Related 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 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 authorized prescriber must be informed.
10. Consent is valid for one year for patients requiring continued outpatient transfusion support or home infusion. (e.g. Intravenous Immune Globulin).

Refusal of Consent

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

2. When a patient refuses a proposed treatment requiring the transfusion of blood components and/or PPRP that contain human plasma, the patient must sign a Refusal for Treatment with Blood Components and/or Plasma Protein and Related 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 PPRP that contain human plasma does not constitute refusal for all treatments.

Quality Control

1. Informed consent for administration of blood components and/or PPRP forms or refusal for treatment with blood components and/or PPRP forms are part of a patient's transfusion record.
2. All transfusion records shall be maintained in accordance with Provincial Blood Coordinating Program's Records Retention policy found here.

Key Words

Consent, blood components, PPRP

Supplemental Materials

1. Pamphlet "Information for Patients, Residents and Clients" http://www.health.gov.nl.ca/health/bloodservices/pdf/patient_information.pdf
2. Pamphlet "Information for Health Care Provider" http://www.health.gov.nl.ca/health/bloodservices/pdf/physician_information.pdf

Appendices

Appendix A: Consent Form for Administration of Blood Components and/or Plasma Protein and Related Products (PPRP)
Appendix B: Refusal of Treatment with Blood Components and/or Plasma Protein and Related Products (PPRP) Form

References

AABB. (2022). *Standards for Blood Banks and Transfusion Services.* (33rd ed.). Bethesda, Maryland: AABB Press.

Canadian Society for Transfusion Medicine. (2021). *CSTM standards for hospital transfusion services.* Version 5. Markham, ON: Author.

Canadian Standards Association. (2020).*Blood and blood components, Z902-20*. Mississauga, ON: Author.

College of Registered Nurses of Newfoundland and Labrador. (2019). *Standards of Practice for Registered Nurses and Nurse Practitioners*. Retrieved from https://crnnl.ca/site/uploads/2021/09/standards-of-practice-for-rns-and-nps.pdf

Capen, K. (1995). Informed consent and blood transfusions: What does Krever's Interim Report mean to doctors? *Canadian Medical Association Journal, 152*(10), 1663-1665.

Capen, K. (1998). There's more to Krever's report than the blood issue- much, more. *Canadian Medical Association Journal*, *158*(1), 92-94.

Government of Newfoundland and Labrador. (1995). *Advance health care directives act*. Retrieved from http://www.assembly.nl.ca/legislation/sr/statutes/a04-1.htm

Government of Newfoundland and Labrador. (2010). *Children and youth care and protection act*. Retrieved from http://www.assembly.nl.ca/legislation/sr/statutes/c12-2.htm

Garner, B. A. (Ed.). (2009). *Black's Law Dictionary*. (9th ed.). St. Paul, MN: West Publishing Company.

Peppin, P. (2011, May). Informed consent. In J. Downie, T. Caulfield, & C. M. Flood (Eds.) *Canadian Health Law and Policy* (4th ed., pp.153-194). Markham, ON: LexisNexis Canada Inc.

Smith, M. L. (2004). Jehovah's Witness refusal of blood products. In S. Post (Ed.), *Encyclopedia of Bioethics* (3rd ed., Vol. 3, pp. 1341-1346). New York: Macmillan Reference USA. Retrieved from https://epdf.pub/encyclopedia-of-bioethics8d77f4080b1b5e061a72d370a324a6be99022.html

The College of Physicians and Surgeons of Newfoundland and Labrador. (2019). *Consent to Treatment: Standard of Practice (June 2019)*. Retrieved from

https://cpsnl.ca/wp-content/uploads/2022/09/Consent-to-Treatment-2019.pdf

Appendix A:

Consent Form for Administration of Blood Components and/or Plasma Protein and Related Products (PPRP)

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 six 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.
- Consent is valid for one year for patients requiring continued outpatient transfusion support or home infusion of PPRP that contain human plasma.

Patient Statement:

I, _____ hereby consent to the administration of:
Blood components and/or PPRP manufactured from donor blood

_____
(Specify blood components or PPRP)

I have read the information/the information has been communicated as contained in the transfusion information pamphlet entitled "Information for Patients, Clients and Residents" 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 _____
Authorized Prescriber'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	Print Name	Date (DD/MONTH/YYYY)
_____	_____	_____
Signature of Witness	Print Name	Date (DD/MONTH/YYYY)

Authorized Prescriber 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	Print Name	Date (DD/MONTH/YYYY)

Appendix B:

Refusal of Treatment with
Blood Components and/or Plasma Protein and Related Products (PPRP)

Hospital Site:	

Patient Statement:

I, _____ refuse treatment by the administration of blood components and /or PPRP.

I have read the transfusion information pamphlet entitled "Information for Patients, Clients and Residents".

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
Authorized Prescriber's Name
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), from any responsibility for any untoward outcomes due to my refusal to permit the use of blood components and / or PPRP that contain human plasma.

_____	_____	_____
Signature of Patient or Substitute Decision Maker	Print Name	Date (DD/MONTH/YYYY)
_____	_____	_____
Signature of Witness	Print Name	Date (DD/MONTH/YYYY)

Authorized Prescriber 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)