Saskatoon Health Region	**POLICY** Number: 7311-50-004 Title: INFORMED CONSENT FOR BLOOD COMPONENTS AND/OR PLASMA PROTEIN PRODUCTS, INCLUDING TISSUE GRAFT TRANSPLANTATION
Authorization [ ] President and CEO [X] Vice President, Finance and Corporate Services	Source: Chair, SHR Transfusion Committee Cross Index: 7311-50-002 Date Approved: June 11, 2010 Date Revised: February 3, 2017 Date Effective: February 9, 2017 Date Reaffirmed: Scope: SHR

DEFINITIONS

Allogeneic Component(s) means cellular or plasma components donated from another individual.

Autologous Component means a blood component donated by the patient, for use by the patient.

Blood Components means:
- Packed red blood cells (RBC)
- Platelets (PLT)
- Plasma, including fresh frozen plasma(FFP), frozen plasma(FP), cryosupernatant plasma (CSP)
- Cryoprecipitate (CRYO)
- Granulocytes (does not include hematopoietic stem cells).

Capacity means the ability to understand information relevant to a health care decision, the ability to appreciate the reasonably foreseeable consequences of making or not making a health care decision, and the ability to communicate the decision.

Cell Saver Blood means autologous red cells collected by suction of the surgical field, which is then centrifuged and washed by a cell saver machine for transfusion back to the patient.

Course of Treatment means a series or sequence of similar treatments administered to a person over a period of time for a particular health problem.

Plasma Protein Product means any product manufactured from human plasma.

Most Responsible Health Practitioner (MRHP) means the health practitioner who has the responsibility and accountability for the specific treatment/procedure(s) provided to a patient and who is authorized by Saskatoon Health Region (SHR) to perform the duties required to fulfill the delivery of such a treatment/procedure(s) within the scope of their practice.

Substitute Decision Maker (SDM) means a person who, pursuant to *The Health Care Directives and Substitute Decision Makers Act*, is entitled to make health care decisions on behalf of the subject individual (see SHR Policy: *Consent/Informed Consent*, Appendix A).

Tissue Graft means tissue (skin, bone, tendon or amniotic membrane) that is donated from another person. This tissue may have been acquired from a living or deceased donor.

Transplantation means the action of implanting a human tissue graft from a living or deceased donor into a patient accepting of this tissue.

Transfusion means any administration of a blood component(s) or plasma protein product given by intravenous, subcutaneous or intramuscular route.

Transfusionist means a qualified individual skilled in administering transfusions. This may include Nurses, Physicians and others who are trained in blood components and plasma protein product administration.

1. PURPOSE

The purpose of this policy is to ensure patient recipients of transfusions and tissue grafts are informed of the reason for a blood component and/or plasma protein product transfusion or tissue graft transplantation, and understand the risks, benefits and any alternative therapies that are available.

2. PRINCIPLE

Patients have the right to decide whether they wish to receive a blood component, plasma protein product and/or tissue graft.

3. POLICY

Consent

3.1 A valid written consent shall be obtained from the patient or SDM before administration of blood components and/or plasma protein products.

3.2 The consent must be obtained by the MRHP who has knowledge of the proposed blood/blood component and/or plasma protein product.

3.2.1 Health care professionals authorized to obtain informed consent for transfusion include:

- Physicians,
- Resident physicians, if obtaining consent for transfusion of blood component(s) or plasma protein product(s) falls within their training and expertise. Should it fall outside the scope of practice, they can take part in the consent process through the treating Physician remains responsible for ensuring the consent process is appropriate, complete and documented,
- Medical students(JURSIs) may participate in the consent process only if directly supervised by an MRHP,
- Registered midwives if obtaining informed consent for transfusion of blood components and plasma protein products falls within their training, expertise and in accordance with their clinical privileges granted by SHR,
- Registered Nurse Practitioners [RN(NP)] if obtaining consent for transfusion of blood components or plasma protein products is a practice for which he/she is currently competent and this is necessary within his/her chosen specialty area,
- Registered Nurses utilizing a RN clinical protocol for specific plasma protein product(s) prescription (e.g. Public Health Nurses).

3.3 The consent shall remain in effect for a maximum of one year during the course of treatment for which consent is obtained and must be documented within the patient's current health record.

3.3.1 In the case of multiple transfusions, the qualified transfusionist administering the transfusion will verbally reconfirm with the adult patient their agreement of the treatment.

- If the patient has any questions at that time, the patient is referred to the MRHP for further explanation and discussion.

3.4 Consent for receipt of a tissue graft shall be obtained by the surgeon, as a part of the *Consent to Surgery*.

3.4.1 The surgeon shall document the type of tissue graft to be used during surgery on the *Consent to Surgery* Form.

3.5 Consent for transfusion of blood components and/or plasma protein products or tissue graft transplantation may be withdrawn by the patient at any time.

Criteria for Valid Consent

3.6 The patient/SDM shall be legally competent and mentally capable of giving consent to the transfusion of a blood component(s) and/or plasma protein product(s) or tissue transplantation. The MRHP shall determine capacity of the patient on an individual basis (see SHR Procedure: *Consent/Informed Consent*).

3.6.1 The consent must be given voluntarily, and not obtained through undue inducement, pressure or with an element of force, fraud, deceit, duress or coercion.

3.6.2 The patient/SDM must receive an adequate disclosure of information from the MRHP about the proposed blood component(s) and/or plasma protein product(s), transfusion or tissue transplantation, including:

- the nature and purpose of the proposed transfusion or transplantation
- the probable risks and benefits
- reasonable alternatives to treatment, if any exist
- the risks and benefits of the alternatives
- the impact of treatment on the patient's lifestyle
- the consequences for refusing treatments or tests.

3.6.3 The patient/SDM must have an opportunity to ask questions and to receive understandable answers.

Who may Give Consent

3.7 Staff shall comply with SHR Policy: *Consent/Informed Consent* (including, but not limited to, the requirements regarding: emergency situations and authority to obtain and give consent (see SHR Policy: *Consent/Informed Consent*).

Consent for Autologous Transfusion

3.8 Eligibility for autologous transfusion shall be determined by the MHRP, together with the Transfusion Medical Director. Consent for transfusion of autologous blood shall be obtained and maintained on the patient's current health record.

3.8.1 If the autologous donor wishes only to receive autologous component(s) and declines consent of allogeneic component transfusion, this refusal of consent must be documented on the patient's current health record.

3.9 Consent for receipt of cell saver blood shall be obtained by the surgeon, as a part of the consent to surgery.

3.9.1 The patient/SDM shall be informed post operatively if cell saver blood has been infused.

Refusal of Transfusion

3.10 Refusal for the administration of a blood component(s) and/or plasma protein product(s) shall be documented.

3.10.1 If the patient/SDM refuses to sign the consent, the reason for refusal, shall be documented on the current health record.

3.10.2 The patient/SDM may indicate refusal of specific components or products and acceptance of others which must be documented before any transfusion is to take place.

3.10.3 In cases where parents or guardians of minor children refuse a necessary transfusion the MRHP, shall contact the appropriate child protective services if refusal of transfusion is reasonably considered to be detrimental to the child's well-being (see SHR Policy: *Suspected Child Abuse*, see definition of Child Abuse).

3.10.4 Refusal of transfusion can be withdrawn by the patient or SDM at any time.

4. ROLES AND RESPONSIBILITIES

4.1 MRHP

4.1.1 Obtain informed written consent or the refusal of consent (and exceptions thereof) from the patient/SDM for the patient's course of treatment.

4.1.2 Determine capacity of the patient to provide consent, which includes an age of understanding.

4.1.3 Provide the patient/SDM with information regarding the risks, benefits and alternatives of transfusion. It is preferable for the MRHP to obtain the signature on the consent form during this discussion.

4.2 Transfusionist

4.2.1 Ensure the appropriate consent form has been completed and signed by the MRHP and the patient prior to administering treatment. If there is no current valid consent form, the Transfusionist must contact the MRHP and make arrangements to obtain consent from the patient.

4.2.2 Ensure the valid consent form is present on the patient's health record.

4.2.3 Confirm verbally with the patient/SDM before every transfusion that the patient is still in agreement for transfusion. If the consent is not signed, the patient/SDM has further questions or the consent is over one year old the MRHP shall be notified and the transfusion will not occur.

5. POLICY MANAGEMENT

The management of this policy including policy education, monitoring, implementation and amendment is the responsibility of the Chair, SHR Transfusion Committee or designate.

6. NON-COMPLIANCE/MISUSE

Non-compliance with this policy may result in disciplinary action up to and including termination of employment and/or privileges.

Non-compliance of this policy will result in the incident being brought forward to Practitioner Advisory Committee for review and action by the Senior Medical Officer (or designate).

7. REFERENCES

See end of Procedure

PROCEDURE Number: 7311-50-004 Title: INFORMED CONSENT FOR BLOOD COMPONENTS AND /OR PLASMA PROTEIN PRODUCTS , INCLUDING TISSUE GRAFT TRANSPLANTATION	
Authorization [ ] President and CEO [X] Vice President Finance and Corporate Services	Source: Chair, SHR Transfusion Committee Cross Index: Date Approved: June 11, 2010 Date Revised: February 3, 2017 Date Effective: February 9, 2017 Date Reaffirmed: Cross Index: Scope: SHR

1. PURPOSE

The purpose of this procedure is to facilitate effective communication between the Physician, healthcare providers and the patient as it relates to the safe transfusion and informed consent of blood components, plasma protein products and receipt of tissue grafts.

2. PROCEDURE

2.1 The MRHP meets with the patient/SDM to discuss the benefits, risks and alternatives to transfusion or tissue graft transplantation.

2.2 The MRHP provides the patient/SDM with an opportunity to ask questions regarding their transfusion or tissue graft transplantation.

2.2.1 In the event of an emergent/life threatening circumstance the MRHP and another Physician who determines the transfusion necessary, document the emergency on the consent form. As soon as the patient/SDM is capable of providing consent, the MRHP ensures the document is completed and placed on the patient's health record.

2.2.2 If a transfusion is recommended the MRHP presents the patient/SDM the *SHR Consent for Administration of Blood Components and/or Plasma Protein Products* form for signature (see SHR Form #101479 *(link inserted)*).

2.2.3 If a tissue graft is recommended, the surgeon shall present the patient with the SHR *Consent for Surgery Form* (see form #100362 *(link inserted)*), which shall include the type of tissue to be transplanted, for signature.

2.3 Provide the patient/SDM the *SHR Blood Transfusion Information for Patients Handbook (link inserted)* or applicable patient information handouts (see *Supporting Documents* below) prior to signing of the informed consent form.

2.4 Obtain written consent and provide a copy of the signed SHR *Informed Consent for Administration of Blood Components and/or Plasma Protein Products* form or *Consent to Surgery Form*.

2.5 Attached the consent form to the health record.

2.5.1 If the patient/SDM refuses consent for a blood component and/or plasma protein product transfusion or withdraws consent, the MRHP discusses the risks of this decision and outcome with the patient/SDM. MRHP documents the refusal using SHR Form #101330 *(link inserted)*. Place the signed refusal of consent form in the patient's permanent health record.

2.5.2 If the patient/SDM refuses or withdraws consent for tissue graft transplantation, the surgeon documents this decision and discussion in the patient's chart.

2.6 The Transfusionist verifies that a signed consent form exists on the patient's health record and that it is in effect prior to each blood component and/or plasma protein product transfusion.

3. PROCEDURE MANAGEMENT

The management of this procedure including procedures education, monitoring, implementation and amendment is the responsibility of the Chair, SHR Transfusion Committee or designate.

4. NON-COMPLIANCE/BREACH

Non-compliance with this procedure may result in disciplinary action up to and including termination of employment and/or privileges.
Non-compliance of this procedure will result in the incident being brought forward to Practitioner Advisory Committee for review and action by the Senior Medical Officer (or designate).

5. REFERENCES

Bloody Easy 3. Blood Transfusions, Blood Alternatives and Transfusion Reactions. A third edition. Sunnybrook and Woman's College Health Sciences Center 2011. JL Callum, MD, FRCP and PH Pinkerton, MD, FRCPC, FRCPath.

Canadian Law of Consent to Treatment. Rozovsky, Lorne E. and Fay A., 1990.

Clinical Guide to Transfusion.https://professionaleducation.blood.ca/enwww.transfusionmedicine.ca (Accessed November 2016)

CSA Z902-15 Regulations Blood and Blood Components, December 2015

CSTM Standards for Hospital Transfusion Services. Version 3- September 2011

Health Care Consent Act, 1996 (Last amendment, 2007)

The Adult Guardianship and Co-decision-making Act, Saskatchewan

The Age of Majority Act, Saskatchewan

The Children's Law Act, Saskatchewan

The Child and Family Services Act, Saskatchewan

The Health Care Directives and Substitute Decision Makers Act, Saskatchewan

6. RELATED and SUPPORTING DOCUMENTS

SHR Forms:

- Informed Consent for Administration of Blood Components and/or Plasma Protein products SHR Form #101479
- Refusal of Consent for the Administration of Blood Components and/or Plasma Protein Products, # 101330
- Consent to Surgery, Diagnostic and Treatment Procedures, #100362

Patient Information:

- LSM 901 Heading Home After a Transfusion, December 2016
- LSM 902 Rh Immune Globulin (WinRho) Information for Patients and Families, December 2016
- LSM 903 Immune Globulin for Post Exposure Infection Prevention, December 2016
- LSM 905 Information for Patients about Blood Transfusion and Tissue Transplantation Version 2, December 2016