SUNY DOWNSTATE MEDICAL CENTER

DEPARTMENT OF PATHOLOGY
POLICY AND PROCEDURE

☒ UNIVERSITY HOSPITAL OF BROOKLYN ❑ BAY RIDGE

Subject: PROCEDURES FOR DOCUMENTING PHYSICIAN-PATIENT DISCUSSION PRIOR ELECTIVE TRANSFUSION AND FOR DOCUMENTING PATIENT CONSENT OR REFUSAL TO ELECTIVE TRANSFUSION OF BLOOD COMPONENTS / PRODUCTS

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Policy No.: BLB-2A

No. of Pages (including this page): 5

Original Issue Date: 08/92

Supersedes: 02/10

Effective Date: 02/11

NYS CLEP Standards:
CAP Standards:
JC Standards:

Issued by: Regulatory Affairs
Related Policies:

Review Date	Revisions		Director	Designee	Comments / Revisions
	No	Yes			

Discontinuation Date: _____

I. POLICY: The following two types of transfusion-related documentation must be obtained prior to intended elective transfusion.

1. The transfusing physician, prior to an intended elective transfusion episode, must discuss with the patient (or patient surrogate) the transfusion indications, known and unknown risks, alternatives, possible risks of no transfusion, possible need for multiple transfusions, and the fact that the choice to undergo transfusion belongs to the patient alone. The patient or surrogate must have the opportunity to ask questions. **This physician-patient conversation or notification, must be documented, dated, signed by the physician, and charted.**

2. The patient (or patient surrogate) must consent to, or refuse an elective transfusion episode. **Documentation of consent or refusal must be signed by the patient, or patient surrogate, witnessed, dated and charted.**

3. The preferred mechanism for documenting these separate types of transfusion-related documentation is the two sided form: **(Side I) DOCUMENTATION OF PATIENT NOTIFICATION BY THE TRANSFUSING PHYSICIAN REGARDING TRANSFUSION OF BLOOD COMPONENTS/PRODUCTS; (SIDE II) TRANSFUSION NOTIFICATION/ CONSENT/REFUSAL FORM (SD002N). (See copies of Side I and Side II respectively. An instruction sheet is attached to the form for reference.**

4. Alternatively, a chart note signed by the physician may serve as documentation of the physician-patient conversation regarding transfusion, although not for documentation of patient consent/refusal.

II. PROCEDURE

GENERAL:

1. The following is the procedure for using the two sided form:

A. The form should be obtained from the nursing station. The patient demographics should be stamped or written in the space provided on both sides.

B. An elective (in other than life-threatening circumstances) transfusion episode may be considered to include all transfusions occurring during a single hospital inpatient admission or a single outpatient visit. **An episode is defined as one or more than one closely spaced transfusion given to attain a desired hematocrit or other effect. If the indication for inpatient transfusion changes, a new form must be generated**.

C. The transfusion physician may be either a house staff or attending physician caring for the patient.

D. The transfusing physician has the responsibility for assuring the completion of both types of transfusion-related documentation, and for appropriate referral to the Non Blood Management Program (NBMP), if transfusion is refused.

E. The nursing and other categories of New York State (NYS) approved staff assisting in starting an elective transfusion have the responsibility for making sure that prior to obtaining blood components/products from the blood bank both types of completed transfusion-related documentation are in the chart.

2. **THE DOCUMENTATION OF PATIENT NOTIFICATION REGARDING TRANSFUSION (Side I)** should be used as follows:

A. The **DOCUMENTATION OF PATIENT NOTIFICATION** side of the form should be signed and dated by the transfusing physician prior to each elective transfusion episode, following the outlined discussion with the patient. The patient (or patient surrogate) does not need to sign this form. The terms in parentheses are intended as examples of language which may be understandable to some patients; for others, simpler words will be needed.

B. A signed, dated chart note by the transfusing physician, summarizing such a decision, may be used in lieu of the **DOCUMENTATION OF PATIENT NOTIFICATION** side of the form.

C. This documentation should be completed and charted regardless of the patient's or patient surrogate's consent to, or refusal of transfusion.

3. **THE PATIENT CONSENT OR REFUSAL TO PERMIT TRANSFUSION (side II)** should be used as follows:

A. The **PATIENT CONSENT OR REFUSAL** side of the form should be signed by patients, with the capacity to understand, including by patients under 18 years of age, following the discussions with the physician regarding transfusion, and prior to each elective transfusion episode, as defined above.

It also should be signed by the parent or legal guardian of a patient under 18 years of age, as well as by the surrogate of a patient older than 18 years, who does not have the capacity to understand.

B. The **PATIENT CONSENT OR REFUSAL** side of the form allows the patient to sign either to consent to, or to refuse transfusion. Patients under 18 years of age with capacity to understand should sign in the space for child assent. A parent or legal guardian also must sign for a patient under 18 years of age. A surrogate must sign for a patient older than 18 years, who does not have the capacity to understand.

C. The **PATIENT CONSENT OR REFUSAL** side of the form should be co-signed and addressed by a witness, but does not require physician signature.

D. If the patient (or his/her surrogate) refuses any or all of the transfusion options, he/she should be referred to the Non Blood Management Program (NBMP). Such patients will be provided the opportunity to sign additional, more inclusive and specific forms.

Note: For Novoseven, the **TRANSFUSION NOTIFICATION/CONSENT/REFUSAL FORM** has been edited to reflect it's off label use with the corresponding risks. A **FACT SHEET/PROTOCOL FOR NOVOSEVEN** is also handed out with the **TRANSFUSION NOTIFICATION/CONSENT/REFUSAL FORM.**

III. ATTACHMENTS

IV. REFERENCES

Refer to BLB-2
CAP Transfusion Medicine Checklist, 7/11/11
AABB Standards, 27th Edition, 2011
NYS Department of Health Regulations, Subpart 58-2, 9/07
NYS Department of Health Standards, 1/08

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FACT SHEET/PROTOCOL FOR NOVOSEVEN-RECOMBINANT ACTIVATED FACTOR VII (rFVIIa)

I. If NovoSeven (rFVIIa) is being given for an off-label indication (the only FDA-approved indications are for: factor VII or factor IX deficiencies with inhibitors: acquired factor VIII inhibitors in nonhemophiliacs congenital factor VII deficiency), the transfusing physician should discuss the indications, risks, benefits and alternatives for its use with the patient (or his/her surrogate), The risks include the very rare occurrence of thromboembolic phonomena, the rare occurrence of antibodies to factor VII (in patients with congenital factor VII deficiency) and very rare allergic or anaphylactic reactions. The discussion, including side effects, and the patient's or surrogate's consent, MUST be documented on the attached hospital consent form, filled out specifically for off-label use of NovoSeven (rFVIIa). In an emergency situation, consent can be obtained after administration.

PATIENTS WITH A HISTORY OF CURRENT OR PAST THROMBOEMBOLIC EVENTS OR ATHEROSCHEROSIS MAY BE AT INCREASED RISK FOR THROMBOEMBOLIC SIDE EFFECTS OF NOVOSEVEN (rFVIIa).

II. A Physician's Order should be written in the chart as for any product or any medications.

III. A Physician's Order should be entered into the hospital computer system as for any Blood Bank product.

IV. When treating the microvascular coagulopathy of massive transfusion, in general, the least one therapeutic round of thawed plasma, cryoprecipitate and platelets should be given it appropriate, and the platelet count optimized, before administering NovoSeven (rFVIIa).

V. AN APPROPRIATE SINGLE DOSE OF NovoSeven (rFVIIa) HAS BEEN ISSUED FROM BLOOD BANK, FOLLOWING REVIEW OF THE REQUEST BY A BLOOD BANK PHYSICIAN. ADMINISTER ALL OF THE VIALS, WHICH WERE ISSUED FOR THIS DOSE. *IF THIS DOSE IS NOT INFUSED WITHIN 30 MINUTES, IT MUST BE RETURNED TO THE BLOOD BANK IMMEDIATELY?* THIS PRODUCT MUST BE RECONSTITUTED WITH *STERILE WATER FOR INJECTION, USP.,* THE DILUENT PROVIDED BY THE MANUFACTURER. DO *NOT* USE NORMAL SALINE. MINISTER INTRAVENOUSLY. SEE PACKAGE INSERT FOR ADDITIONAL INFORMATION.

VI. The administration of NovoSeven (rFVIIa) MUST be documented in the chart progress notes, including date, time, and response or lack of response (in terms of bleeding). Any possible adverse effects related to this product should be reported to the Blood Bank.

**It is to be expected that the prothrombin time will be shortened to below normal level and the activated partial thromboplastin time also may be shortened, but to a lesser extent. However, there is no laboratory test which can be uses to assess the efficacy of this drug. The efficacy must be assessed clinically.*

NOVOSEVEN MUST BE RECONSTRUCTED WITH STERILE WATER FOR INJECTION USP. DO NOT USE NORMAL SALINE. SEE PACKAGE INSERT FOR ADDITIONAL INFORMATION.

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Page 2 has been modified for rFVIIa (NovoSeven)

TRANSFUSION NOTIFICATION/CONSENT/REFUSAL FORM PHYSICIAN INSTRUCTIONS

SIDE I

DOCUMENTATION OF PATIENT NOTIFICATION BY THE TRANSFUSING PHYSICIAN REGARDING TRANSFUSION OF BLOOD COMPONENTS/RELATED PRODUCTS

Prior to requesting blood products for an elective (other than life-threatening circumstances) transfusion episode, the transfusing physician should have a discussion similar to that outlined on Side I, with the patient (or surrogate), using language understandable to him/her. **The transfusing physician may be either a house staff or attending physician caring for the patient, who discusses the transfusion(s) with the patient. Side I of this form** can serve as documentation and **should be completed by the transfusing physician and entered into the medical record prior to elective tansfusions,** including both homologous (donor and recipient different) and autologous (donor and recipient the same) transfusions of blood components/products. If a transfusion episode requires a number of units of blood products, this form should be completed once, before the first unit is transfused. **An episode is defined as one or more closely spaced transfusions given during the same hospital admission for the same medical indication. If the indication for transfusion changes, a new form must be generated**. A new form also must be completed for each hospital admission and outpatient visit during which transfusion will occur. Use of the form may be retroactive, if transfusion is necessary to immediately sustain life in emergency situations. **A dated note, in the patient's record, signed by the physician, is an acceptable alternative to completion of Side I of this form**. **The patient consent/refusal form on the reverse side must be completed, by the patient, prior to each elective transfusion episode, consisting of one or more transfusions as defined above**. Patients who refuse transfusion should be referred to the Coordinator for the Non-Blood Management Program (who can be reached through the telephone operator), and their refusal must be documented on Side II of this form, as well as in the progress notes of the patient's record.

SIDE II

PATIENT CONSENT OR REFUSAL TO PERMIT TRANSFUSION OF BLOOD COMPONENTS/RELATED PRODUCTS

The patient (or surrogate) consenting to transfusion must complete **Parts I and III** prior to each elective transfusion episode. A legally appropriate surrogate must complete Part III for patients under 18 years of age and for patients of any age who cannot understand. If a transfusion episode requires a number of blood products, this form should be completed once, before the first unit is transfused. A new form must be completed on the occasions noted above for Side I. **Part 1B is for off-label transfusions only and Blood Bank will fill in the product and risk spaces for those. The patient (or surrogate) refusing** transfusion must complete **Parts II and II** and should be referred to the Coordinator for the Non-Blood Management Program. The patient (or surrogate) may choose IIA, refusal of all blood products **or** IIB, acceptance of only certain blood products. **The transfusion notification form on Side I must be completed by the transfusing physician**. **For refusal of transfusion, the physician should complete the notification form and write a progress note in the patient's record, documenting transfusion discussion and refusal.**

PLEASE REMOVE AND DISCARD THIS INSTRUCTION SHEET BEFORE COMPLETION OF THE ATTACHED FORM. THIS SHEET IS NOT PART OF THE MEDICAL RECORD.

SUNY DOWNSTATE Medical Center
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TRANSFUSION NOTIFICATION/ CONSENT/REFUSAL FORM

DOCUMENTATION OF PATIENT NOTIFICATION BY THE TRANSFUSING PHYSICIAN REGARDING TRANSFUSION OF BLOOD COMPONENTS/RELATED PRODUCTS

DISCUSSION: The following **should be** explained to the above patient (or surrogate): (a) the transfusion indication, (b) the possible benefits, (c) **the risks** (**including but not limited to the following and those listed in the table below as well as other as yet unknown risks**): transfusion reaction; infection; HIV disease, hepatitis C, hepatitis B, HTLV-I/II infections; other as yet unknown ill effects; and the possibility of a fatal side effect, (d) **the alternatives**: preoperative autologous (by the patient for him/herself) donation, directed (e.g. by friends and relatives, for a specific patient) donation, intraoperative or postoperative blood salvage, agents to stimulate red cell production if appropriate (e.g. iron, erythropoietin, folic acid, vitamin B12), volume expanders (e.g., crystalloids, albumin), hemostatic agents, (e) **the risks of no transfusion** (including but not limited to, shock, heart attack and failure, stroke, respiratory arrest, bleeding and death), (f) **the possible need for multiple transfusions,** (g) **the fact that the choice to undergo transfusion belongs to the patient alone**. Also, **if transfusion of a product not approved for the indication is proposed, the "off-label" status of the transfusion must be explained as well as all of the above items, with specific reference to the product**.

RISKS OF BLOOD TRANSFUSION PER UNITS TRANSFUSED*

Urticaria (itchy rash)	1:500	Hepatitis B infection	1:63,000
Fever with or without chills	1:1,000-1:10,000	Hepatitis C infection	1:1,6 million
Acute lung injury	1:5,000>1:100,000	HIV infection	1:1.9 million
ABO blood group incompatibility	1:38,000	Bacterial contamination:	
Hemolysis, fatal	1:250,000-1:600,000	Platelets	1:900-1:2,000
		Red blood cells	<1:1,000,000
HTLV infection	1:641,000	All other**	<1:1,000,000

*These statistics do not apply to plasma derivatives, e.g. albumin. See package inserts for side effects of those.
**Includes: Infectious diseases like malaria, West Nile Fever, cytomegalovirus infection, Chagas disease; situations in which patient factors are critical such as graft vs. host disease (transfused lymphocytes attack recipient's tissues), and other events such as volume overload, hyperkalemia (high potassium), hypothermia (decreased body temperature, immune suppression (decreased resistance to infection and tumors).

I have discussed all of the above with the patient/surrogate. The patient/surrogate was given the opportunity to ask questions concerning the proposed transfusion(s) and I have answered those questions. The patient/surrogate also verbalized his/her understanding of the information given to him/her.

I understand that I have to document the discussions regarding any refusal of transfusion in the progress notes of the patient's record, as well as by completion of this form.

COMMENTS: _____
_____
_____

_____ _____
SIGNATURE OF THE TRANSFUSING PHYSICIAN (may be any physician caring for the patient) **DATE/TIME**

_____ _____
PRINT NAME OF THE TRANSFUSING PHYSICIAN **HOSPITAL ID NUMBER**

NOTE: The signature of the physician who discusses the transfusion with the patient is **mandatory**. It should be placed on the above signature line for the transfusing physician.

—PLEASE TURN OVER—