I. PURPOSE:

The purpose of this policy is to outline physicians' obligation to:

A. Provide patients with information about transfusion options prior to a medical treatment or surgical procedure for which there is a reasonable possibility that a transfusion may be necessary, pursuant to the Paul Gann Act
B. Obtain informed consent for transfusion of blood products
C. Document any refusal to consent to transfusion of blood products

II. POLICY:

Medical staff members are responsible for informing each patient of the risks, benefits, and alternatives for transfusions of blood products, and to provide required written information regarding the options for blood transfusion, pursuant to the Paul Gann Act.

III. PROCEDURE:

A. Obtaining Informed Consent for Transfusion of Blood Products
    1. The Medical Staff Rules and Regulations require that providers obtain informed consent for blood transfusions. See *Informed Consent* policy for situations where informed consent is not required, such as in an emergency. Physicians should discuss the risks, benefits and alternatives of blood transfusion with patients.
    2. Frequency of obtaining consent for transfusion of blood products; consent must be obtained:
        a. When there is a reasonable possibility that blood transfusion may be necessary as a result of a medical treatment or surgical procedures.
            i. Inpatients: The consent will be valid for transfusions of blood products during the medical treatment or surgical procedure and as part of the ongoing course of treatment during the patient's hospitalization.
            ii. Outpatients: Once per year for outpatients undergoing medical treatment or procedures that require continued, ongoing transfusions of blood products.
        b. Whenever a patient's circumstances change, such that they materially affect the nature of the risk of the most recent consent a new consent should be obtained. This may also include new admissions and/or unrelated treatment courses where consent for transfusion of blood products has not already been obtained.
    3. Documentation of informed consent
        a. Patients or their legally designated representative for making healthcare decisions sign Documentation of Gann Act) (see section III.C.4.a below)
        b. The provider should document the consent discussion in the patient's medical record.
B. Patient refusal to consent for blood transfusion -- See Blood Transfusion Refusal policy in the SHC Patient Care Manual for more information. In summary:
    1. Patients or their legally designated representative for making healthcare decisions may refuse to consent for transfusion of blood products. If a patient refuses to consent for transfusion of blood products, the patient documents this refusal by signing the Refusal to Permit Blood Transfusion form (Form 15-19), or checking the refusal box on the Consent Blood Transfusions, Blood

Products and Gann Act form (Form #15-2671). The provider documents his/her discussion with the patient or legal designated representative regarding the risks and consequences of refusing a blood transfusion in the medical record (informed refusal).

2. Minors – if the treating physician has determined that medical treatment is necessary to sustain life or prevent lifelong disability of a minor patient, and parents or legal guardians have been contacted and refuse to provide consent, the provider, in collaboration with a hospital social worker should immediately contact Child Protective Services (CPS) for consultation and possible court order.
3. Dependent adults - if the treating provider has determined that medical treatment is necessary to sustain life or prevent lifelong disability of a dependent adult patient, and the legally designated representative has been contacted and refuses to provide consent, the provider, in collaboration with a hospital social worker should immediately contact Adult Protective Services (APS) for further action (e.g., consultation, investigation, and possibly a court order if indicated).

C. Paul Gann Blood Safety Act. Whenever there is a reasonable possibility that a blood transfusion may be necessary for a patient (inpatient or outpatient) as a result of a medical or surgical procedure, the provider who makes the determination that the reasonable possibility exists must do all of the following:

1. Directly or APP (i.e., a nurse practitioner, certified nurse midwife, or a physician assistant), who is licensed in the state and authorized to order a blood transfusions provide the patient with the California Department of Health Services (CDHS) brochure titled A Patient's Guide to Blood Transfusion which informs the patient of the risks and benefits of receiving autologous blood and blood from designated or community blood donors. Found online at: https://www.mbc.ca.gov/Publications/Brochures/Blood_Transfusions.aspx
    a. In a life threatening emergency, the Gann Act brochure does not need to be given, and the provider should document accordingly. on the appropriate consent form.
2. Allow adequate time before the medical procedure or surgery for autologous or designated blood donation to take place, unless the patient declines, there is a life-threatening emergency or where there are medical contraindications.
3. Frequently provide patients with Gann Act brochure.
    a. For inpatients, the Gann Act brochure must be given to patients once per admission.
    b. For inpatients or outpatients who are undergoing a serial course of treatment, which requires multiple admissions/treatments and blood transfusions, such as chemotherapy or apheresis treatments, the Gann Act brochure must be given once a year. If the Gann Act brochure is revised by CDHS during this period, a new brochure should be given to the patient.
4. Documentation of Gann Act
    a. Documentation of Gann Act can be found on the following consent form: *Consent Blood Transfusions, Blood Products and Gann Act (Form #15-2671).*

IV. COMPLIANCE:

A. All workforce members including employees, contracted staff, students, volunteers, medical staff, and individuals representing or engaging in the practice at SHC are responsible for ensuring that individuals comply with this policy.
B. Violations of this policy will be reported to the Department Manager and any other appropriate Department as determined by the Department Manager or in accordance with hospital policy. Violations will be investigated to determine the nature, extent, and potential risk to the hospital. Workforce members who violate this policy will be subject to the appropriate disciplinary action up to and including termination.

V. RELATED DOCUMENTS / PROCEDURES:

A. Informed Consent
B. Health Care Decisions for Patients Who Lack Capacity
C. Health Care Decisions For Patients Who Lack Capacity and Lack Surrogates
D. Blood Transfusion Refusal
E. Interpreter and Translation Services

VI. APPENDICES

A. Appendix A: Consent Blood Transfusions, Blood Products and Gann Act
B. Appendix B: Consent Refusal to Permit Blood Transfusion

VII. DOCUMENT INFORMATION:

A. Legal References / Regulatory Requirements:
   1. Joint Commission Hospital Accreditation Manual 2019
   2. Health and Safety Code 1645
   3. California Hospital Association Consent Manual 2012
B. Original Document:
   1. Owner: Risk Management
   2. Author, date: Risk Management, June 2007
C. Distribution and Training Requirements:
   1. This policy resides in the Administrative Manual.
   2. New documents or any revised documents will be distributed to Administrative Manual holders. The department/unit/clinic manager will be responsible for communicating this information to the applicable staff.
D. Review and Renewal Requirements:
   1. This policy will be reviewed and/or revised every three years or as required by change of law or practice.
E. Review and Revision History:
   1. 07/2007 Transfusion Committee, SHC
   2. 10/2007 Continuous Quality Improvement Committee, SHC
   3. 09/2007 Operating Room Committee, SHC

4. 2013 Risk Management, March
5. 06/2016 Dana Orquiza, Risk Management
6. 07/2016 Transfusion Committee, SHC
7. 11/2019 Kevin Burson, Risk Management; Ann Weinacker, MD, Chief Physician Executive, The Risk Authority
8. 09/2019, 11/2019 Consent Forms Review: Dominique Watt, Director Perianesthesia Services; Anh Hoang, Patient Care Manager, Interventional Platform Pre/Post; Lisa Newton, Manager, IP Perianesthesia; Christie Davis, Director, Clinic Operations

F. Approvals:
1. 07/2008, 03/2013 Quality, Patient Safety & Effectiveness Committee
2. 08/2008, 04/2013 Medical Executive Committee; SHC Board Credentials, Policies and Procedures Committee
3. 7/2016 Transfusion Service
4. 09/2016 Policy Steering Committee; Quality, Patient Safety & Effectiveness
5. 10/ 2016 SHC Medical Executive Committee; SHC Board Credentials, Policies & Procedures Committee
6. 2020 Medical Executive Committee (MEC), Policy & Procedure Steering Committee, SHC Hospital Board Credentials, Policies and Procedures Committee

Stanford HEALTH CARE

Appendix A: Consent Blood Transfusions, Blood Products and Gann Act

Stanford HEALTH CARE

Appendix A: Consent Blood Transfusions, Blood Products and Gann Act

Medical Record Number

Patient Name

Addressograph or Label - Patient Name, Medical Record Number

STANFORD HEALTH CARE
STANFORD, CALIFORNIA 94305

CONSENT • BLOOD TRANSFUSIONS, BLOOD PRODUCTS AND GANN ACT

I understand that the medical provider believes that a blood transfusion(s) and/or the use of blood components may be needed:

- ❑ During this admission; OR
- ❑ As part of an ongoing course of treatment. I understand that if treatment requires ongoing blood transfusions and/or use of blood components, this consent for blood transfusions and/or use of blood components will remain valid for one year from the date of signature below.

I acknowledge that the medical provider has explained the risks, benefits and alternatives to transfusion and/or the use of blood components. I understand that the risks associated with transfusion and/or use of blood components include reactions, transmission of disease, and unforeseeable risks including death.

By my signature below, I confirm that:

- ❑ Yes, I authorize the use of blood transfusions and/or use of blood components during this hospitalization or as part of an ongoing course of treatment.
- ❑ No, I request that no blood or blood components be administered to the patient during this hospitalization or course of treatment. I hereby release Stanford Health Care, its personnel, the medical provider, and any other person participating in the patient's care from any responsibility whatsoever for unfavorable reactions or any untoward results, which include permanent disability and or death, due to my refusal to permit the use of blood or its components. The possible risks and consequences of such refusal on my part have been fully explained to me by the medical provider and I fully understand that such risks and consequences may occur as a result of my refusal.

_____ _____ _____

Date Time SIGNATURE (Patient, Legal Designated Representative)

_____ _____

PRINT NAME RELATIONSHIP to Patient

If an interpreter participated in the informed consent discussion:

Print:_____ or _____

SHC in-person interpreter name Video TEL interpreter ID # Language

Stanford HEALTH CARE

Appendix A: Consent Blood Transfusions, Blood Products and Gann Act

STANFORD HEALTH CARE
STANFORD, CALIFORNIA 94305

Medical Record Number

Patient Name

Addressograph or Label - Patient Name, Medical Record Number

CONSENT • BLOOD TRANSFUSIONS, BLOOD PRODUCTS AND GANN ACT

❑ Telephone Consent Obtained by Medical Provider

2nd Witness to Telephone Consent _____

Print Name and Title of Witness to Telephone Consent _____

MEDICAL PROVIDER ATTESTATION

I have discussed with the patient or properly designated representative that blood, blood components or blood components transfusion may be used in this hospitalization or during the patient's course of treatment. I have discussed the risks, benefits and alternatives of the transfusion and/or use of blood components.

❑ I have provided the patient/properly designated representative with the pamphlet "A Patient's Guide to Blood Transfusions" concerning the advantages, disadvantages, risks and benefits of autologous blood and/or direct and non-directed allogeneic blood from volunteers. I have allowed adequate time for the patient to arrange for pre-donation of blood for transfusion purposes except where there is a life threatening emergency, there are medical contraindications or the patient/properly designated representative has waived this right.

❑ The pamphlet "A Patient's Guide to Blood Transfusions" was not given to the patient/properly designated representative and consent was not obtained for the blood transfusion because a life threatening emergency existed, a properly designated representative was not available to provide consent, and the patient/properly designated representative's wishes with respect to blood transfusion were not known prior to the need for blood transfusion.

❑ The patient/properly designated representative refused consent for blood transfusion and/or blood components.

All questions were answered and the patient consents to the procedure.

Date	Time	Provider Signature/Title	Print Name

Stanford HEALTH CARE

Appendix B: Consent Refusal to Permit Blood Transfusion

Medical Record Number

Patient Name

Addressograph or Label - Patient Name, Medical Record Number

STANFORD HEALTH CARE
STANFORD, CALIFORNIA 94305

CONSENT • REFUSAL TO PERMIT BLOOD TRANSFUSION

I request that no blood or blood components be administered to_____ (name of patient) during this hospitalization. I hereby release the hospital, its personnel, the medical provider, and any other person participating in my care from any responsibility whatsoever for unfavorable reactions or any untoward results, which include permanent disability and death, due to my refusal to permit the use of blood or its components.

The possible risks and consequences of such refusal on my part have been fully explained to me by my medical provider and I fully understand that such risks and consequences may occur as a result of my refusal.

Date:_____

Time:_____

_____
SIGNATURE of Patient or Properly Designated Representative

_____
PRINT NAME

_____
RELATIONSHIP to Patient

_____
WITNESS

Spanish translation on reverse side

15-19 (08/14)

Stanford HEALTH CARE

Appendix B: Consent Refusal to Permit Blood Transfusion

Medical Record Number Patient Name Addressograph or Label - Patient Name, Medical Record Number	STANFORD HEALTH CARE STANFORD, CALIFORNIA 94305 CONSENT • REFUSAL TO PERMIT BLOOD TRANSFUSION

CONSENTIMIENTO. NEGACIÓN A PERMITIR TRANSFUSIÓN DE SANGRE

Solicito que no se me administre sangre ni ningún componente de la sangre a_____ (nombre del paciente) durante esta internación. Por este medio, libero al hospital, su personal, el profesional de salud, y a cualquier otra persona que participe en mi cuidado, de cualquier responsabilidad o reacción adversa, o resultado desfavorable, que incluye incapacidad permanente y muerte, debido a mi negación de permitir el empleo de sangre o sus componentes.

El profesional de salud me ha explicado los posibles riesgos y consecuencias de tal negación por mi parte, y entiendo plenamente que tales riesgos y consecuencias pueden ocurrir como resultado de mi negación.

Fecha:_____

Hora:_____

_____

SIGNATURE of Patient or Properly Designated Representative
FIRMA del Paciente o Representante debidamente designado

_____

Print name of Patient or Properly Designated Representative
Nombre del paciente o representante debidamente designado (en letra de molde)

_____

RELATIONSHIP to Patient
RELACIÓN con el Paciente

_____

WITNESS
TESTIGO