Informed Consent

POLICY 6.02.02
Patient Care
Informed Consent
Issued: 10/1991
Last Approval: 10/2022

Office of Origin: Risk Management

I. PURPOSE

To define the Informed Consent process that establishes a mutual understanding between the Patient and the healthcare provider about the care, treatment, and services that the Patient receives in accordance with federal and state laws and regulations and The Joint Commission.

II. REFERENCES

California Health and Safety Code § 1645, The Paul Gann Blood Safety Act

California Probate Code § 4658

California Probate Code § 3200

Conditions of Participation for Hospitals 42 CFR § 482.13 (b)(2)

The Joint Commission Standards, RI.01.03.01

UCSF Medical Center Administrative Policies:

- 6.02.03 Patient Right to Refuse Treatment
- 6.02.04 Transfusion Information Form and Consent to Blood Transfusions
- 6.02.05 Terms and Conditions of Service
- 6.04.01 Advance Healthcare Directives/POLST (Physician's Order for Life Sustaining Treatment)
- 6.04.15 Universal Protocol-Perioperative/Pre-Procedure Verification
- 6.06.04 Interpreting, Translation and Language Access Services

III. DEFINITIONS

Patient: For the purpose of consent, "Patient" refers to a Patient with Capacity to Make Healthcare Decisions.

Informed Consent: Agreement or permission accompanied by full notice about the care, treatment, or service that is the subject of the consent. A patient must be apprised of the nature, risks, and alternatives of a medical procedure or treatment before the physician or other health care professional begins any such course. After receiving this information, the patient then either consents to or refuses such a procedure or treatment.

Treatment Authorization Consent: Patients receiving care at UCSF provide a general Treatment Authorization Consent (distinguishable from a separate Informed Consent), which is obtained and documented by a Patient or Surrogate Decision Maker's signature on the "Terms and Conditions of Service." This authorization provides consent for routine and common procedures that have minimal risk. Examples include but are not limited to IV line placement, EKG, Chest X-ray, medication administration.

Treatment Requiring Separate Informed Consent: Treatment or procedures that require Informed Consent are considered "complex" and include: significant diagnostic, therapeutic, or surgical procedures, including all major or minor surgical procedures, those involving general anesthesia or moderate/deep sedation, and non-operative procedures that involve more than a

slight risk of harm or change body structure. Examples of treatments requiring Informed Consent can be found in section V. H below.

Surrogate Decision Maker: A Surrogate Decision Maker can be orally designated by the patient, an agent appointed in an advance health care directive, a durable power of attorney for health care, or a court appointed conservator of the person. When patients without such an agent or conservator lose Capacity to Make Health Care Decisions, a family member, domestic partner, or persons with whom the patient is closely associated may be considered to act as Surrogate , Decision Makers related to health care decisions.

Capacity to Make Healthcare Decisions: The ability to understand the significant benefits, risks and alternatives of a proposed healthcare procedure or treatment, understand the nature and consequences of a decision to proceed or forgo, and communicate that decision. A Patient's physician should determine if a Patient has Capacity to Make Healthcare Decisions (Probate Code section 4658). Conditions for which psychiatric or psychological treatment may be required does not equate to a lack of Capacity to Make Health Care Decisions.

Emancipated Minor: A minor who has received a court order of emancipation and who holds a Department of Motor Vehicles identification card indicating that the minor is emancipated. Emancipated Minors with capacity have the right to consent to their own care and treatment.

Medical Center Staff: For purposes of this policy, Medical Center Staff include nurses and non-privileged or credentialed APPs, Residents and Fellows.

Credentialed Healthcare Provider: For purposes of this policy, a Credentialed Healthcare Provider includes an Attending Physician, or an APP who is credentialed and privileged to perform the proposed procedure.

Demonstrated Competency: A Resident or Fellow may be designated as having Demonstrated Competency for independent performance of a procedure based on a formal competency assessment completed as part of evaluation process done through their residency or fellowship program, and as determined by the Chair or designee.

IV. POLICY

A. It is the policy of UCSF Medical Center to ensure that Patients or their Surrogate Decision Makers are provided with necessary information so that they can make an informed decision about undergoing procedures or treatments that require Informed Consent. (See section V.H. below for examples)

B. The Patient has a legal right to be informed of the nature of the proposed care, treatment, services, or procedures, including potential benefits, risks, and potential problems during recuperation or other complications, as well as alternative forms of treatment, including the possible results of not receiving care, treatment, and services, in language the Patient or their Surrogate Decision Maker can understand

C. Absent an emergent situation, no procedure or treatment requiring Informed Consent will be performed without the Attending or Credentialed Healthcare Provider having an Informed Consent discussion about the planned diagnostic, therapeutic or surgical procedure, and there being a consent form signed by the Patient or their Surrogate Decision Maker.

D. If the Patient is non-English speaking or they have Limited English Proficiency (LEP) and state that their preferred language is not English, or they are speech or hearing impaired, interpretation services must be provided via an in-person, video or telephone interpreter.

E. The Attending Physician or Credentialed Healthcare Provider who will perform a surgery, procedure, or treatment, shall disclose to the Patient any financial interests related to the procedure, use of a medical device or equipment, that the physician may have related to a proposed surgery or procedure beyond compensation for the surgery or procedure.

F. A Patient or Surrogate Decision Maker may withdraw consent for a procedure or treatment at any time.

V. PROCEDURE

A. Physician or Credentialed Healthcare Provider's Responsibility for the Informed Consent Discussion

1. It is the responsibility of the Attending Physician, or other credentialed healthcare provider, who is knowledgeable about the specific surgery, procedure, or treatment, to have an Informed Consent discussion with the Patient or their Surrogate Decision Maker. The Informed Consent discussion cannot be delegated away to other Medical Center Staff and must be completed by the provider who will perform the surgery, procedure, or treatment.

    a. If the procedure or treatment is one that a resident or fellow has demonstrated and documented competency to perform, as determined by their Chair or designee, then the resident or fellow may have the Informed Consent discussion with the Patient or their Surrogate Decision Maker.

2. The Attending Physician or Credentialed Healthcare Provider who will perform the surgery, procedure or treatment must document the initial Informed Consent discussion in a note, in the Patient's medical record prior to the surgery or procedure, and will document that the following were discussed:

    a. Diagnosis (the reason for which the procedure is being proposed);

    b. Nature of the proposed care, treatment, services, medications, interventions, or procedures;

    c. Material risks, benefits, side effects, including potential problems that occur during recuperation, and likelihood of success of the proposed intervention;

    d. Reasonable alternative options, if any, including the possibility of not receiving care, treatment and services, as well as the risks, benefits and likelihood of success of the alternatives;

    e. An indication that the Attending Physician or credentialed healthcare provider has responded to questions about the procedure from the person providing consent;

    f. Any financial interests that the physician may have related to the proposed surgery or procedure beyond compensation for the surgery or procedure performed.

3. A Resident, Fellow, or APP may augment the initial Informed Consent discussion previously conducted by the Attending Physician or Credentialed Healthcare Provider for the planned procedure, even if not credentialed for the procedure, if they have knowledge about the procedure.

    a. Augmentation provides further explanation and response to any questions the Patient or Surrogate Decision Maker may have after the initial Informed Consent discussion.

4. The process of obtaining a Patient or Surrogate Decision Maker's signature on the procedural consent form may be delegated by the Attending physician or Credentialed Healthcare Provider to medical center staff if the informed consent discussion for the procedure has already occurred (See V.B.1.)
5. If a Patient requests that they not be informed of the risks, etc. of a particular surgery or procedure, the physician will fully document in the medical record that the review of the risks, benefits, and alternatives was offered to the Patient who declined to have the discussion, and that the Patient had capacity to do so. The physician should document what information was disclosed to the Patient.
6. Generally, if possible, the Informed Consent discussion should occur with sufficient time allowed for the Patient to consider their decision.
    a. Common sense, reasonableness and good judgment should dictate whether the Patient's consent is timely in any given circumstance.
        i. If there have been changes in the indication for the procedure, the risks, the alternatives or the likelihood of success, a new consent must be obtained.
        ii. If there is any doubt, the Patient should be given as much information as necessary to obtain Informed Consent prior to the procedure beginning.
7. When it is not possible to obtain Informed Consent (e.g., an emergency), the reason that consent could not be obtained should be documented in the record. (See section V.G.)
8. Role of Anesthesia Provider: The Anesthesia or sedation provider shall discuss with the Patient/Surrogate Decision Maker the risks, benefits and alternatives to the proposed plan for anesthesia and document this discussion in the medical record.
9. Residents or Fellows with Demonstrated Competency for a bedside procedure (e.g. central line placement, lumbar puncture) should obtain Informed Consent for the planned procedure from the Patient or the Surrogate Decision Maker before performance of the procedure unless there is an emergency exception to the need for Informed Consent.

B. Medical Center Staff's Role in Informed Consent Process

1. Medical Center Staff cannot have the Informed Consent discussion with a Patient or their Surrogate Decision Maker about a proposed or planned procedure. Staff may assist in the completion of the consent form by collecting the signature of the Patient or their Surrogate Decision Maker.
2. Prior to collection of a Patient/Surrogate Decision Maker signature on a consent form, Medical Center Staff should verify that the Patient/Surrogate Decision Maker has talked to the Attending physician or credentialed provider who will perform the planned procedure or treatment, have no further questions, and authorize the procedure.
    a. If a Patient or Surrogate Decision Maker has further questions, the form should not be signed, and the appropriate physician or provider immediately notified.
    b. A Patient or their Surrogate Decision Maker may withdraw their consent for surgery or a procedure at any time. If consent is withdrawn, the form should not be signed and the physician or provider shall be immediately notified.
3. Medical Center Staff will ensure that the Attending Physician or Credentialed Healthcare Provider performing the surgery, procedure or treatment has documented the Informed

Consent discussion in the medical record prior to the commencement of the surgery or procedure. See Policy 6.04.15, Universal Protocol, Perioperative/Pre-Procedure Verification.)

C. The completed, signed consent form will be utilized as part of the pre-procedure verification process (See Policy 6.04.15, Universal Protocol, Perioperative/Pre-Procedure Verification.)The Surgical/Procedural Consent Form

1. A Surgical/Procedural consent form must be completed and signed by the Patient or their Surrogate Decision Maker prior to a surgery or procedure taking place unless an exception applies. (See section V. G below).
2. For planned procedures, the consent form may be signed by the Patient or their Surrogate Decision Maker before the day of the surgery or procedure during an out Patient clinic visit and be present in the Patient's electronic medical record before the day of the surgery or procedure.
3. If a Patient presents to the pre-operative or pre-procedural area without a completed, signed consent form being present in the medical record, the Patient or Surrogate Decision Maker's signature should be collected upon arrival.
4. A Patient should not be provided with any sedating medications or move into the operating or procedure room until the form is signed.
5. A signed consent form for a procedure is valid as long as the Patient's condition does not change, and the surgery or procedure to be done remains the same.
    a. Special care should be taken to review those consents that were obtained more than one month prior to the proposed surgery or procedure. Several weeks may not be unreasonable, provided the Patient's condition has not changed, and the nature of the risks and benefits remains the same. (Note: there are no strict rules governing how far in advance of the procedure a consent discussion can or should occur.)
    b. For information related to the duration of a consent for blood transfusion, see Policy 6.02.04, Transfusion Information Form and Consent to Blood Transfusions.
    c. A consent form for an inpatient who requires multiple wound debridement and/or negative wound pressure therapy (i.e. wound vac) procedures during a single hospital admission, will be valid if the patient's condition has not changed and the procedure to be done is the same.
6. Verbal Consent
    a. If a Patient lacks Capacity to Make Healthcare Decisions and cannot consent on their own behalf, a Surrogate Decision Maker can consent on the Patient's behalf. In this situation when the Surrogate Decision Maker is not physically present to sign the form, then telephone or verbal consent for the procedure may be obtained from the Surrogate Decision Maker.
        i. Consent by telephone shall be witnessed by Medical Center Staff or another member of the medical team who will remain on the line during the consent conversation and hear the Surrogate Decision Maker give their consent to proceed.
        ii. The provider shall complete the consent form, and the form should note that the consent was verbal and include the name of the patient's Surrogate Decision

Maker providing consent.

iii. Both the provider and the witness should sign the consent form.

b. If the Patient has capacity but is physically unable to sign the form, verbal consent is acceptable.

i. The Patient's verbal consent shall be witnessed by Medical Center Staff or another member of the medical team, and the reason the Patient is unable to physically sign documented in the record.

ii. The provider shall complete the consent form, and the form should note that the consent was verbal.

iii. Both the provider and the witness should sign the consent form.

7. If an interpreter is utilized during the Informed Consent process, all documentation should reflect the use of an interpreter. (For information related to requesting language interpreters, and services for speech or hearing-impaired Patients, see Policy 6.06.04, Interpreting and Translation Services.)

a. Family members should not serve as an interpreter absent an inability to provide a certified medical interpreter.

D. Multi-Panel Surgical Procedure: If a Surgeon is consenting a patient for a procedure that involves other surgeons performing an aspect of that procedure, so long as the Surgeon can explain the risk/benefits and alternatives, and the second surgeon's procedure is inherent to the main procedure, then one consent is appropriate. (Example: one surgeon performing the approach for another surgeon's spine surgery)

1. A second consent is necessary if a second procedure is truly separate and not inherent to the main procedure.

E. Patient Information Sheets or other material used to augment the Informed Consent process: Each clinical service may develop patient information sheets or other informational tools such as audiotapes and videotapes, such as educational videos, that contain some or all the information related to Informed Consent. This material may augment, but not replace, the use of the consent form and the occurrence of an Informed Consent discussion. This material should contain a written acknowledgement of receipt by the Patient and be placed in the medical record.

F. Individuals Who May Consent to Medical Care/Treatment

1. Adults

a. An Adult with Capacity to Make Healthcare Decisions or an Emancipated Minor may consent to their own treatment. In general, an adult Patient requesting or presenting themself for treatment can be presumed competent to consent, unless there is evidence to the contrary.

b. A Surrogate Decision Maker (inclusive of an agent designated under a validly executed Advance Healthcare Directive or durable power of attorney for the person) may consent to treatment for a Patient who lacks Capacity to Make Healthcare Decisions. (See Policy 6.04.01, Advance Healthcare Directives/POLST (Physician's Order for Life Sustaining Treatment) for more information about advance directives.)

i. When a Patient without an agent or conservator loses Capacity to Make Healthcare Decisions, a family member, domestic partner, or persons with whom the Patient is closely associated may be considered to act as Surrogate Decision Maker related to healthcare decisions.

c. A conservator may grant consent only if the letters of conservatorship state that the Patient lacks the capacity to consent to medical treatment.

d. A parent or legal guardian of a minor Patient may consent to treatment of the minor.

i. Generally, the consent of only one parent is required.

ii. If a minor's parents are divorced or legally separated and have joint legal custody, both parents must consent if specified by court order. Consult Risk Management at (415) 353-1842 when these circumstances apply.

e. Disputes between family members regarding healthcare decisions may require an ethics consult or risk management review. Please contact Risk Management at (415) 353-1842 for assistance. In the event legal review is necessary, please contact Legal Affairs at (415) 476-5003.

f. If a family member cannot reasonably be contacted or refuses to participate in a Patient's care, efforts should be undertaken to have a conservator appointed on a Patient's behalf. Contact Social Work at (415) 353-1504.

g. If a Patient has no Surrogate Decision Maker of any kind to participate in the Patient's care, and the appointment of a conservator cannot be completed in a timely manner to ensure Patient safety, then a court order may be considered pursuant to Probate Code Section 3200. Contact the Office of Legal Affairs at (415) 476-5003 for assistance with this process.

h. If a Patient is capable to grant consent and provides an informed refusal to the medical care recommended, treatment cannot be initiated. There should be ongoing discussion with the Patient about the risks of not proceeding with the recommended medical care with documentation of those discussions in the Patient's medical record.

2. Minors

a. Minors (Patients younger than 18 years old) cannot be treated without the consent of a parent or guardian except under the circumstances listed below.

i. If the minor is age 15 or older, lives apart from parent or guardian and manages own financial affairs;

ii. If the minor is emancipated (requires the granting of a court petition);

iii. If the minor is on active duty with the US armed forces; or

iv. If the minor is married or in a registered domestic partnership.

b. Minors may consent to the following care and treatment:

i. Care related to pregnancy or the prevention of pregnancy (any age);

ii. Pregnancy Termination, under limited circumstances, but not sterilization (any age);

iii. Treatment of a reportable or sexually transmitted disease (age 12 or older);

iv. Treatment of rape or sexual assault (age 12 or older);

v. Outpatient mental health treatment or counseling, excluding ECT, psychosurgery or psychotropic drugs (age 12 or older);

vi. Treatment of a drug or alcohol-related problem if treating physician deems and documents that parental involvement is not appropriate and excluding narcotic replacement drugs (age 12 or older).

c. Minors who are parents may consent to care and treatment for their children.

G. Emergency Exception to Informed Consent Requirement

1. A healthcare provider may proceed with necessary medical care and treatment without obtaining Informed Consent if waiting to obtain Informed Consent would result in serious disability or death of the Patient. Under these circumstances the healthcare provider should document in the medical record the nature of the emergency and any efforts to obtain consent.

2. If the Patient is incapable of granting consent (unconscious, altered consciousness), the provider should:

a. Weigh the possibilities of obtaining consent against the possibility that delay would jeopardize the health of the Patient;

b. The involved provider should consult with another physician to determine whether an emergency exists;

c. Document the emergency, efforts made to obtain consent, and the inability to obtain consent in the medical record, and

d. Treat only the emergency condition.

H. Types of Treatment Requiring Informed Consent: significant diagnostic, therapeutic or surgical procedures require that a Patient's written consent be obtained prior to the subject procedure. Examples include:

1. All major or minor surgery or procedures which involve an entry into the body either through an incision or through the use of natural openings;

2. Any procedure involving general anesthesia, or moderate or deep sedation, whether or not entry into the body is involved;

3. All non-operative procedures which involve more than a slight risk of harm to Patient, or which involve the risk of a change in Patient's body structures;

4. All procedures where radium, x-rays, or isotopes are used in the therapy of Patient;

5. Sterilization;

6. HIV testing;

7. Blood transfusions: See Administrative Policy 6.02.04, Transfusion Information Form and Consent to Blood Transfusion;

8. Administration of investigational drugs;

9. Participation in clinical research protocols.

VI. RESPONSIBILITY

Questions about the implementation of this policy should be directed to Medical Center Risk Management (415-353-1842).

VII. HISTORY OF POLICY

Approved April 2002 by Mark R. Laret, CEO

Revised September 2004 by Mari Siebold, Legal Affairs

Revised November 2005 by Virginia Fleming, Risk Management

Reviewed November 2005 by Policy Steering Committee

Approved November 2005 by Executive Medical Board, Governance Advisory Committee and Chancellor J. Michael Bishop

Revised November 2006 by Tatiana Schultz, Risk Management, Susan Alves-Rankin, Patient Relations, and Ann Sparkman, Legal Affairs

Reviewed November 2006 by Adrienne Green, MD, Associate Chief Medical Officer

Reviewed December 2006 by Policy Steering Committee

Approved December 2006 by Executive Medical Board, Governance Advisory Council and Chancellor J. Michael Bishop

Reviewed November 2014 by Susan Penney, Risk Management and Ann Sparkman, Office of Legal Affairs

Reviewed November 2014 by Risk Management Committee

Reviewed October 2015 by Policy Steering Committee

Reviewed and Approved October 2015 by Executive Medical Board and Governance Advisory Council

Reviewed and Approved with no changes February 2019 by Susan Penney, Risk Management

Reviewed and Approved with no changes February 2019 by Policy Steering Committee

Reviewed and Approved February 2019 by Executive Medical Board and Governance Advisory Council

Reviewed and Revised June 2022 by Kimberly Dimino, Executive Director Medical Center Risk Management

Reviewed and Approved August 2022 by Policy Steering Committee

Reviewed and Approved October 2022 by Executive Medical Board and Governance Advisory Council

VIII. APPENDIX

A. Procedural Consent Form

B. eConsent Form Exemplar

Appendix A

UCSF Health

UNIT NUMBER
PT. NAME
BIRTHDATE
LOCATION
DATE

PROOF VERSION #08
10-18-2022

AUTHORIZATION FOR SURGERY, SPECIAL DIAGNOSTIC OR THERAPEUTIC PROCEDURE, BLOOD TRANSFUSION, AND ADMINISTRATION OF ANESTHETICS (Page 1 of 3)

Proceduralist(s): _____

Procedure(s): _____

_____

_____

The risks, benefits, and alternatives of the procedure were discussed. This discussion included, but was not limited to: _____

_____

_____

_____

as well as the risk of bleeding, infection, damage to anatomical structures, need for reoperation, scarring, pain, risk related to anesthesia as discussed by your anesthesia provider, or even death. The patient and/or the patient's medical decision maker understands, has had all of his/her questions answered, and desires to proceed as documented in this informed consent. **OR**

Date of note in Electronic Health Record with informed consent documentation: _____

PATIENT AUTHORIZATION

1. I authorize the surgeon(s)/provider(s) and associates to perform the operation(s) and/or procedure(s) as shown above.

   I understand that UCSF Medical Center is a teaching institution and that associates or assistants involved in the operation(s) or procedure(s) may include residents, fellows, medical students or other allied healthcare professionals. I authorize that such associates or assistants may perform or observe portions of the operation(s) or procedure(s) under the direction of the physician(s) identified in paragraph 1 above. That physician may be out of the operating or procedural room for some of the surgical tasks done by the associates and assistants if the physician(s) identified in paragraph 1 determines it is safe to do so.

   I understand that the primary surgeon(s) will be present during their key portions of the procedure or surgery and at all times will be immediately available or will ensure another qualified surgeon is immediately available. I will be advised if the surgeon is scheduled to perform surgery in 2 operating rooms at the same time.

2. I authorize the administration of anesthesia and/or sedation as may be considered necessary or advisable. I have been advised that there are certain risks associated with anesthetics that may include allergic reactions, and/or drug intolerances, and dental, mouth or throat damage, discomfort or soreness. I understand that the explanations that I have received may not be exhaustive or all-inclusive and that other more remote risks may be involved.

5-00-0823A (Rev. 10/22) ORIGINAL – MEDICAL RECORD COPY; YELLOW – PATIENT COPY

AUTHORIZATION FOR SURGERY OR SPECIAL DIAGNOSTIC OR THERAPEUTIC PROCEDURE (Page 1 of 3)

UCSF Health

UNIT NUMBER

PT. NAME

BIRTHDATE

PROOF VERSION #08
10-18-2022

LOCATION DATE

AUTHORIZATION FOR SURGERY, SPECIAL DIAGNOSTIC OR THERAPEUTIC PROCEDURE, BLOOD TRANSFUSION, AND ADMINISTRATION OF ANESTHETICS (Page 2 of 3)

3. I authorize the use of pathology and radiology services if necessary. I understand that any tissue removed will be disposed of at the discretion of the hospital pathologist or designee. I authorize the pathologist to retain, preserve, use or dispose of any tissues, organs, bones, bodily fluid or medical devices that may be removed during the operation(s) or procedure(s). I understand that such specimens may be used for research, as permitted by federal and state law. I understand that I have no property ownership or interest in such specimens or data derived from these specimens and no right or entitlement in any research or research project using or derived from the specimens.

STOP

My tissue:

☐ **May be used in medical research**

☐ **May NOT be used in medical research**

4. The nature and purpose of the procedure or operation, the likelihood of benefits, risks, complications and side effects of the procedure or operation and its alternatives, possible alternative methods of treatment (including the risks related to not receiving the operation or procedure) and potential problems that might occur during recuperation have been explained to me by my surgeon listed above. My consent is given with the understanding that any operation or procedure involves risks and hazards some of which can be serious and possibly fatal. I understand that risks may vary depending on the operation or procedure for which I am consenting. I am aware that the practice of medicine and surgery is not an exact science and no guarantee has been made as to the results or cure. I understand that the explanations that I have received may not be exhaustive or all-inclusive and that other more remote risks may be involved.

5. Transfusion Consent. My provider has discussed with me that there is a reasonable possibility that a transfusion of blood or blood products may be necessary. I have received a copy of the transfusion information form describing my transfusion options (unless I have a life-threatening emergency or medical contraindications). My provider has discussed the risks, benefits, and alternatives of the transfusion of blood and blood products with me. I have also learned about the option of pre-donating my own blood and have had the opportunity to discuss this matter with my provider.

   The patient has been given the information form based on medical indication.

STOP

By signing this consent form:

☐ **I DO** ☐ **I DO NOT (check one) consent to the transfusion of blood or blood products, as my doctor may order, in connection with the operation(s) or procedure(s) discussed in this form.**

6. I understand that I have the right to refuse any proposed operation or procedure any time before it is performed. During surgery, additional procedures which are in addition to, or different from those set forth in paragraph 1 may be carried out as considered necessary for my well-being by my physician or surgeon for conditions not known at the time the operation or procedure commenced.

590-3603B (Rev. 10/22) ORIGINAL – MEDICAL RECORD COPY, YELLOW – PATIENT COPY

AUTHORIZATION FOR SURGERY OR SPECIAL DIAGNOSTIC OR THERAPEUTIC PROCEDURE (Page 2 of 3)

UCSF Health

UNIT NUMBER
PT. NAME
BIRTHDATE
LOCATION
DATE

PROOF VERSION #08
10-18-2022

AUTHORIZATION FOR SURGERY, SPECIAL DIAGNOSTIC OR THERAPEUTIC PROCEDURE, BLOOD TRANSFUSION, AND ADMINISTRATION OF ANESTHETICS (Page 3 of 3)

PATIENT AUTHORIZATION Continued

7. I understand that there may be a health care industry representative or other visitors present, with the approval of UCSF, during my operation or procedure for purposes of medical observation or to provide technical support.
8. I acknowledge that I have the right to be informed if my physician has any economic interest related to the performance of the operation(s) or procedure(s) beyond the compensation for the surgery or procedure performed.
9. In the event of an accidental exposure to my blood or bodily fluids to a physician, contractor or employee of the facility, I consent to testing for HIV, Hepatitis or other bloodborne pathogens.
10. I have had full opportunity to ask question concerning my condition, the authorized procedure(s) and/or surgery(s), the alternatives, and the risks and consequences associated with it. All the questions I have asked have been answered.

My signature is my acknowledgement that I have read, understood, and agreed to the above, that I have received all the information I desire regarding the operation/procedure, and that I specifically agree to the performance of the operation or procedure.

Date: _____ Time: ____:____ M. Patient's Signature: _____

☐ Patient is a minor and patient's parent / conservator / guardian (circle one) signed.

☐ Patient is incompetent and patient's conservator / guardian (circle one) signed.

☐ Patient is unable to sign because _____

Consent obtained in: ☐ English ☐ Spanish ☐ Cantonese ☐ Mandarin ☐ Other: _____

Source ***required:*** ☐ Certified bilingual ☐ In person ☐ Telephone ☐ Video

Interpreter Name and/or ID Number ***required*** (please print): _____

_____

Provider:

I have discussed the risks, benefits, and alternatives with the patient or the patient's decision maker as noted above.

Date: _____ Time: ____:____ M. Provider Signature: _____

5/20-082/0C (Rev. 10/22) ORIGINAL – MEDICAL RECORD COPY, YELLOW – PATIENT COPY

AUTHORIZATION FOR SURGERY OR SPECIAL DIAGNOSTIC OR THERAPEUTIC PROCEDURE (Page 3 of 3)

Appendix B

8/31/2022 Chris Optime 80005865

UCSF Health | UCSF Benioff Children's Hospital Oakland | UCSF Benioff Children's Hospital San Francisco

Authorization for Surgery, Special Diagnostic or Therapeutic Procedure, Blood Transfusion, and Administration of Anesthetics

Optime, Chris
80005865
Male
41 y.o. (6/24/1981)

Procedure(s) and Procedualist(s)

Panel 1 Procedure(s): LAPAROSCOPIC NISSEN FUNDOPLICATION; POSSIBLE OPEN (N/A)
Kimberly S. Kirkwood, MD

This consent is for Panel 1

DOCUMENTATION OF INFORMED CONSENT BY PROVIDER
The risks, benefits, and alternatives of the procedure were discussed. This discussion included, but was not limited to:

Risk and Benefits discussed with patient.

as well as the risk of bleeding, infection, damage to anatomical structures, need for reoperation, scarring, pain, risk related to anesthesia as discussed by your anesthesia provider, or even death. The patient and/or the patient's medical decision maker understands, has had all of his/her questions answered, and desires to proceed as documented in this informed consent.

OR

See informed consent discussion in progress notes of 8/8/2022

8/31/2022 Chris Optime 80005865

PATIENT AUTHORIZATION

1. I authorize the surgeon(s)/provider(s) and associates to perform the operation(s) and/or procedure(s) as shown above.

   I understand that UCSF Medical Center is a teaching institution and that associates or assistants involved in the operation(s) or procedure(s) may include residents, fellows, medical students or other allied healthcare professionals. I authorize that such associates or assistants may perform or observe portions of the operation(s) or procedure(s) under the direction of the physician(s) identified in paragraph 1 above. That physician may be out of the operating or procedural room for some of the surgical tasks done by the associates and assistants if the physician(s) identified in paragraph 1 determines it is safe to do so.

   I understand that the primary surgeon(s) will be present during their key portions of the procedure or surgery and at all times will be immediately available or will ensure another qualified surgeon is immediately available. I will be advised if the surgeon is scheduled to perform surgery in 2 operating rooms at the same time.

2. I authorize the administration of anesthesia and/or sedation as may be considered necessary or advisable. I have been advised that there are certain risks associated with anesthetics that may include allergic reactions, and/or drug intolerances, and dental, mouth or throat damage, discomfort or soreness. I understand that the

   explanations that I have received may not be exhaustive or all-inclusive and that other more remote risks may be involved.

3. I authorize the use of pathology and radiology services if necessary. I understand that any tissue removed will be disposed of at the discretion of the hospital pathologist or designee. I authorize the pathologist to retain, preserve, use or dispose of any tissues, organs, bones, bodily fluid or medical devices that may be removed during the operation(s) or procedure(s). I understand that such specimens may be used for research, as permitted by federal and state law. I understand that I have no property ownership or interest in such specimens or data derived from these specimens and no right or entitlement in any research or research project using or derived from the specimens.

My Tissue may be used in research:

Yes

Yes
No
Not Applicable

4. The nature and purpose of the procedure or operation, the likelihood of benefits, risks, complications and side effects of the procedure or operation and its alternatives, possible alternative methods of treatment (including the risks related to

8/31/2022 Chris Optime 80005865

not receiving the operation or procedure) and potential problems that might occur during recuperation have been explained to me by my surgeon listed above. My consent is given with the understanding that any operation or procedure involves risks and hazards some of which can be serious and possibly fatal. I understand that risks may vary depending on the operation or procedure for which I am consenting. I am aware that the practice of medicine and surgery is not an exact science and no guarantee has been made as to the results or cure. I understand that the explanations that I have received may not be exhaustive or all-inclusive and that other more remote risks may be involved.

5. Transfusion Consent (Not Applicable)

My provider has discussed with me that there is a reasonable possibility that a transfusion of blood or blood products may be necessary. I have received a copy of the transfusion information form describing my transfusion options (unless I have a life-threatening emergency or medical contraindications). My provider has discussed the risks, benefits, and alternatives of the transfusion of blood and blood products with me. I have also learned about the option of pre-donating my own blood and have had the opportunity to discuss this matter with my provider.

The patient has not (not applicable) been given the information form based on medical indication.

STOP	I consent to the transfusion of blood or blood products, as my provider may order, in connection with the operation(s) or procedure(s) discussed in this form: **Not Applicable**

6. I understand that I have the right to refuse any proposed operation or procedure any time before it is performed. During surgery, additional procedures which are in addition to, or different from those set forth in paragraph 1 may be carried out as considered necessary for my well-being by my physician or surgeon for conditions not known at the time the operation or procedure commenced.

7. I understand that there may be a health care industry representative or other visitors present, with the approval of UCSF, during my operation or procedure for purposes of medical observation or to provide technical support.

8. I acknowledge that I have the right to be informed if my physician has any economic interest related to the performance of the operation(s) or procedure(s) beyond the compensation for the surgery or procedure performed.

9. In the event of an accidental exposure to my blood or bodily fluids to a physician, contractor or employee of the facility, I consent to testing for HIV, Hepatitis or other bloodborne pathogens.

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10. I have had full opportunity to ask question concerning my condition, the authorized procedure(s) and/or surgery(s), the alternatives, and the risks and consequences associated with it, All the questions I have asked have been answered,

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My signature is my acknowledgement that I have read, understood, and agreed to the above, that I have received all the information I desire regarding the operation/procedure, and that I specifically agree to the performance of the operation or procedure.

Relationship to Patient: Self
Surrogate Name and Relationship to Patient: Not Applicable
Reason patient unable to sign: Not Applicable

Language: English
Interpreter: Not Applicable
Interpreter Source: Not Applicable
Interpreter Name/Id: Not Applicable

Patient/Patient Decision Maker Signature:

Patient or Representative: Please sign below

Electronically signed at 8/31/2022 02:11 PM

Time & Date (if not signing electronically): _____

Provider Signature:

I have discussed the risks, benefits, and alternatives with the patient or the patient's decision maker as noted above.

Electronically signed at 8/31/2022 02:11 PM

Time & Date (if not signing electronically): _____

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A Patient's Guide to Blood Transfusion
California Department of Health Services
June 2006

If you need blood, you have several options, These options include receiving blood from the community, using your own blood (autologous), or blood from donors that you have selected (designated donors). Your options may be limited by time and health factors, Although you have the right to refuse a blood transfusion, this decision may hold life-threatening consequences.

It is important to weigh the risks, costs and benefits of donating your own blood before surgery. Many elective surgeries do not require blood transfusion. If you have questions about transfusion needs or options, please ask your provider. Check with your insurance company about your costs for donations. If you choose not to donate your own blood, or if more blood is required than expected, you may receive blood other than your own,

Community Donors. Hospitals maintain a supply of blood from volunteer (unpaid) community donors to meet transfusion needs, Community blood donors are screened by a through medical history, and then tested with the most accurate technology available.

Our nation's blood supply is very safe and high in quality, Nothing in life is risk free; however, the risks associated with blood transfusion are very small. The chance that a unit (pint) will transmit hepatitis B is less than 1 in 200,000 [1*]. Although the risk for other serious infections exist, that risk is much less than the annual risk of dying in a motor vehicle accident in the United States (1 in 7,000)[2].

Using your own blood – Autologous Donation, Using your own blood (autologous) can minimize the need for transfusion with donor blood. Using own blood will reduce, but not eliminated, the risk of transfusion-related infections and allergic reactions.
Patient who donate their own blood before surgery have lower blood levels at the time of surgery and, therefore, have a greater chance of needing transfusions during or after their surgeries. Autologous blood donations are not an option for all patients. It may not be safe for you to donate, Ask your provider if autologous donation is appropriate for you,

Donating BEFORE Surgery. Blood banks can draw your blood and store it for your use. This process usually is performed for planned surgery, Blood can be stored for only a limited period of time, so coordinating the donations with the date of surgery is important.

Donating DURING Surgery and/or After Surgery. Immediately before surgery, your provider may be able to remove some of your blood and replace it with other fluids. After surgery, the blood that was removed may be returned to you.

In addition, the surgeon may be able to recycle your blood during surgery. Blood that normally is shed and discarded during surgery could be collected, processed, and returned to you. A large volume of your blood can be recycled in this way.

Blood that is lost after surgery may be collected, filtered, and returned to you.

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Designated Donors. Although the blood supply today is very safer, some patients prefer to receive blood from people they know – "designated (or directed) donors. " This blood is not safer than blood from volunteer community donors. In some cases it may be less safe because donors known to the patient may not be truthful about their personal history. Blood donated by someone who was recently exposed to HIV or other infections could pass the screening tests, and infect you.
Designated donors must meet the same requirements as community donors. Several days notice is required for additional processing of designated donors.

If you have additional questions about your options for blood transfusion, please ask your provider. Information also can be obtained by calling your local community blood center or hospital blood bank.

References:

1. Stramer SL, Glynn SA, Kleinman SH et al. "Detection of HIV-1 and HCV infections among antibody-negative blood donors by nucleic acid-amplification testing. " New England Journal Medicine vol 351, pp.760-768, August 2004.

*The risk estimates were adjusted to include first time and repeat blood donors.

2. U. S. Department of Transportation's Fatality Analysis Reporting System website 2003 data:
http://www.hwysafety.org/research/fatality_facts/general.html.

This brochure is provided as source of information and is not to be considered a replacement for the informed consent process prior to the transfusion of blood.
This brochure was developed by the California Department of Health Services
Laboratory Field Services
850 Marina Bay Parkway
Richmond, CA 94804
In partnership with the Medical Technical Advisory Committee of the Blood Centers of California.
For information about brochure contents, please call Laboratory Field Services
(213)620-6574
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