

UC Riverside School of Medicine Policies and Procedures**Policy Title:** Informed Consent**Policy Number:** 950-02-017

Responsible Officer:	School of Medicine Compliance and Privacy Officer
Responsible Office:	SOM Compliance
Origination Date:	4/2019
Date of Revision:	N/A
Scope:	SOM and UCR Health Faculty Practice Locations

I. Policy Summary

Care is provided to patients of UCR Health based on the medical judgment of the treating provider and the informed consent of the patient. Patients will be given information concerning the medical necessity, benefits, possible risks, and known alternatives to procedures prior to the initiation of care, unless the emergent nature of the patient's condition precludes such a discussion. It is the policy of UCR Health to respect patient autonomy as evidenced through obtaining the patient's consent, before initial examination, medical treatment, tests, or procedures are performed.

II. Definitions

Refer to Standard Definitions Guide.

III. Policy

All patients seen at a UCR Health clinic or treated by a UCR Health clinical faculty member (provider) will be provided with information regarding their care, treatment and the benefits, risks, side effects of an invasive procedure, and its alternatives and will be explained in a language the patient understands. This will be evidenced by a signed Informed Consent form.

IV. Responsibility

All clinical faculty and staff.

V. Procedure**A. Who May Obtain Informed Consent**

Only the treating licensed physician, or provider properly credentialed to perform the procedure requiring consent, will provide the verbal discussion, written materials and/or audio/video recordings in order to impart the information to the patient necessary to obtain the informed consent. The provider will be available for, and qualified to answer questions regarding the procedure.

B. Defining Consent

Providers must obtain valid consent before treatment is provided. For consent to be valid, it must be voluntary and informed, and the person consenting must have the capacity to make the decision. These terms are explained below:

1. Voluntary – the decision to either consent or not to consent to treatment must be made by the individual patient, or authorized representative and must not be influenced by pressure from medical staff, friends or family.

2. Informed – the patient or authorized representative must be given all of the information in terms of what the treatment involves, including the benefits and risks, whether there are reasonable alternative treatments and what will happen if treatment doesn't proceed.
3. Capacity – the patient must be capable of giving consent, which means they understand the information given to them, and they can use it to make an informed decision.

Consent may need to be revisited after it has been obtained if there are any significant changes in the patient (e.g., their health status, health care needs, specific circumstances, capacity, etc.) or treatment (e.g., the nature, expected benefits, material risks, and material side effects, etc.). The passage of time may increase the risk that these changes will arise and that consent may need to be obtained again.

Patients and their authorized representative can refuse or withhold consent to a treatment or procedure. In addition, consent can be withdrawn at any time prior to the treatment or procedure.

In emergencies, treatment can only be provided without consent when in a medical doctor's judgement it is necessary for either:

- a. Prevention of serious bodily injury or death.
- b. Alleviation of serious pain.

C. Who May Consent

If a patient is capable with respect to a treatment, the provider must obtain consent from the patient directly.

If a patient is incapable of consenting to a treatment, the physician must obtain consent from the authorized representative, who will give or refuse consent on the patient's behalf.

D. Capacity

A patient has capacity to consent to a treatment if they he/she is able to understand the information that is relevant to making a decision about the treatment and able to appreciate the reasonably foreseeable consequences of a decision or lack of decision. The capacity to consent to a treatment varies according to the individual patient and the complexity of the decision at hand.

Providers are entitled to presume that a patient is capable with respect to a treatment unless there are reasonable grounds to believe otherwise. For example, there could be something in a patient's history or behavior that would make a physician question the patient's capacity to consent to the treatment.

Capacity must be considered at various points in time and in relation to the specific treatment being proposed. Capacity is fluid, it can change over time, and depends

on the nature and complexity of the specific treatment decision. A patient may be incapable of consenting to a treatment at one time and capable at another, and be incapable of consenting to some treatments and capable with respect to others.

When capacity is in question any licensed physician may make a determination on capacity and may do so by performing a directed examination. This must be documented in the patient's medical record.

There will be a waiting period to obtain consent after giving a narcotic of four to six hours. A clinical evaluation of the patient's alertness and to assess for impaired decision making will be conducted by a physician after this waiting period.

E. Authorized Representative

There are five categories under which health care decision making may be made for patients lacking capacity, as follows:

1. Durable power of attorney for health care
2. Living will
3. Statutory surrogacy
4. Court-appointed conservator
5. Court authorized medical treatment for adults without conservators

If there is no authorized representative and the patient is incapacitated the closest available relative (following the California Hospital Association Table) will have authority to consent.

F. Minors

Refer to Policy and Procedure *Confidentiality and Consent Requirements for Treatment of Minors* (Policy #950-02-018).

G. Initial Visit

All patients requesting services from a UCR Health provider must sign the Terms and Conditions of Service prior to seeing a provider. UCR Health Terms and Conditions of Service serve as consent to physicians and other health care professionals assisting in patient care for the following:

- Medical treatments
- Exams or procedures
- X-ray tests
- Blood draw
- Medications/injections
- Medical photography or videotapes
- Laboratory tests

The UCR Health Terms and Conditions of Service also serve as consent to the understanding that UCR Health is a Teaching, Research and Health Care Institution; How Medical Information and Specimens will be used; Practices regarding the Release of Medical Information; Patients' responsibility to pay and authorization to assign insurance benefits.

H. Consent for Invasive Procedure/Surgery

Elements of the Consent form will include:

1. Name of the facility where the procedure is to take place.
2. Name of the specific procedure for which consent is being given.
3. Name of the responsible practitioner who will be performing the procedure.
4. Statement that the procedure, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's legal representative. (Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity).
5. Signature of the patient or the patient's legal representative.
6. If there is an applicable law governing the content of the procedure specific informed consent form, then the consent form must also comply with those requirements (hysterectomy, sterilization, blood transfusion).
7. Name of the practitioner who conducted the informed consent discussion with the patient or the patient's representative.
8. Date, time, and signature of the person witnessing the patient or the patient's legal representative signing the consent form.
9. Indication or listing of the material risks of the procedure or treatment that were discussed with the patient or the patient's representative.
10. Statement, if applicable, that physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the facilities' policies as applicable and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner.
11. In exceptional cases, consent may be verbal (example: blind patient) but there must be at least 2 witnesses who attest (in writing) to hearing the consent.

I. Required Documentation

The physician must document in the medical record that a discussion was held with the patient and that Informed Consent was obtained. This documentation can be accomplished in a variety of ways – through a chart note in the progress notes of the patient's record, through a note in the patient's history and physical, through a certification provision on the consent form itself (if the form contains one), or through documentation provided from the physician's office (e.g., an Informed Consent form signed by both the patient and the physician).

J. Procedure-specific Consent Requirements

1. Hysterectomy

The provider will obtain both written and oral consent prior to the performance of a hysterectomy. The following information will be given verbally and in writing (UCR Health *Consent for Hysterectomy* (Attachment A))

- a. Advice that the patient can withhold or withdraw consent up to the time the hysterectomy is performed
- b. Type of procedure to be performed and alternatives
- c. Advice that the hysterectomy is irreversible and will result in sterilization

- d. Description of the risks and discomforts
- e. Description of the benefits and advantages
- f. Approximate hospital length of stay
- g. Approximate length of time for recovery
- h. Financial cost to the patient

Hysterectomies will not be performed on Medi-Cal patients for the purpose of sterilization.

2. Blood Transfusion

When there is a likelihood that the patient will need a blood transfusion during a procedure, the provider will discuss the matter beforehand and obtain the patient's Informed Consent. This discussion will include the risks and benefits of transfusion, the alternatives to transfusion and the possibilities of direct donation and autologous transfusions when this is feasible and available. This discussion will happen, whenever possible, to allow the patient adequate time for pre-donation. In addition, the patient must be provided "A Patient's Guide to Blood Transfusion" (Attachment B).

3. Elective Sterilization

Elective Sterilization is performed for the primary purpose of rendering the patient incapable of reproduction as apposed as a Secondary Sterilization, which is a side-effect of an otherwise necessary procedure. (Should be discussed as a risk of the procedure in the Informed Consent discussion).

Physician or qualified delegate (licensed to perform the procedure) must inform patient of risks, benefits, and alternatives and obtain Informed Consent.

The consent requirements are different based upon a patient's payer status. There are 2 different groups, each with its own rules, as follows:

- a. Medi-Cal/"Federally Funded": Includes all Medi-Cal and Family PACT beneficiaries (including secondary), though it does not include Medicare or Tricare
 - Patient must be provided with state-mandated information booklet (Attachment D)
 - Patient must be informed of 30-day waiting period
 - Patient must be advised of the name of the operating physician
 - Informed consent form must be signed by patient and witnessed by a person of the patient's choosing
 - The 30-day waiting period starts after the patient signs the consent form
 - Patient may not be in labor and must be at least 24 hours postpartum or 24 hours post abortion to consent
 - Must be at least 21 years old
 - Cannot be under any type of involuntary detention
 - Must sign consent form PM-330
 - Patient cannot be "mentally incompetent"
- b. Private Pay, which includes commercial insurance

Requirements are the same as above with the following exceptions:

- Patients must be at least 18 years old, OR have ever entered into a valid marriage (do not need to be presently married); on active duty with any branch of the U.S. Armed Services; greater than 15 years old, living apart from parents and managing own finances ("Self-Sufficient Minor"); declared emancipated by a court ("Emancipated Minor")
- 30-Day waiting period can be shortened to 72 hours in the event of an emergency abdominal surgery or premature delivery
- Private Pay patients only may reduce to 72 hours, thus waiving the 30-day requirement. The request must be made in writing
- Not required for private pay patients if the procedure is performed in a physician's office (vasectomy)

Consent may be obtained via fax—though if from a patient representative they must also send supporting documents, sufficient to prove identity.

Gender – Consent requirements apply equally to both men and women.

K. Duration of Informed Consent

A consent remains effective until the patient revokes it or until circumstances change so as to materially affect the nature of, or the risks of the procedure and/or the alternatives of the procedure to which the patient consented.

Sterilization Consent Form PM 330 (Attachment C) will expire 180 days from the date of Signature.

A copy of all signed consent forms will be provided to the patient and will be maintained in the patients' medical record.

VI. Forms and Attachments

Consent for Hysterectomy (Attachment A)

"A Patient's Guide to Blood Transfusion" (Attachment B)

Sterilization Consent Form PM 330 (Attachment C)

State Mandated Permanent Birth Control Booklet (Attachment D)

VII. Related Information

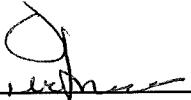
Not Applicable

VIII. Revision History

New Policy


Approval(s):

APPROVED BY CHAIR OF COMPLIANCE COMMITTEE (04/24/19)



PAUL HACKMAN, J.D., L.L.M.
CHIEF COMPLIANCE AND PRIVACY OFFICER
SCHOOL OF MEDICINE

05-13-19
DATE



DEBORAH DEAS, M.D., M.P.H.
DEAN, SCHOOL OF MEDICINE
CEO, CLINICAL AFFAIRS

5/13/19
DATE

Attachment A



Consent for Hysterectomy

DO NOT SIGN THIS FORM UNTIL YOU HAVE READ IT AND FULLY UNDERSTAND ITS CONTENTS

Patient's Name _____

The following has been explained to me in general terms and I understand that:

A hysterectomy involves removal of the uterus through an incision into the abdomen or through the vagina, or may involve the use of a laparoscope.

The reason for the hysterectomy is: _____

A hysterectomy is generally very safe, but with any major surgery comes the risk of complications.

Risks associated with a hysterectomy include, but are not limited to the following:

- Blood clots
- Infection
- Excessive bleeding
- Adverse reaction to anesthesia
- Damage to your urinary tract, bladder, rectum or other pelvic structures during surgery, which may require further surgical repair
- Earlier onset of menopause even if the ovaries aren't removed
- Rarely, death

I understand that it is not possible to list all possible risks and complications that may arise in any procedure or surgery.

I understand that, barring unforeseen complications, I will be in the hospital approximately zero (0) to three (3) days and that I will not be fully recovered from this surgery for approximately six (6) to twelve (12) weeks.

I understand that a hysterectomy is permanent and not reversible. I understand that I will not be able to become pregnant or bear children if I undergo this procedure. I understand that I have the right to seek consultation from other physicians.

I understand that the physician, medical personnel and other assistants will rely on statements about my condition, medical history, and other information in determining whether to perform the procedure or the course of treatment for my condition and in recommending the above procedure.

I understand the practice of medicine is not an exact science and that **NO GUARANTEES OR ASSURANCES HAVE BEEN MADE TO ME** concerning the results of this procedure.

I also consent to diagnostic studies, tests, anesthesia, x-ray examinations, biopsies and other treatment or courses of treatment relating to the diagnosis or procedures described herein.

By signing this form, I acknowledge that I have read or had this form read and/or explained to me, that I fully understand its contents, and that I have been given ample opportunity to ask questions and that any questions have been answered satisfactorily. All blanks or statements requiring completion were filled in before I signed this form. I have received the additional information listed below related to the hysterectomy. **I UNDERSTAND THAT I HAVE THE RIGHT TO WITHDRAW MY CONSENT UP TO THE TIME OF SURGERY.**

I voluntarily consent to allow Dr. _____ or any physician designated or selected by him or her and all medical personnel under his/her direct supervision and control and all other personnel who may otherwise be involved in performing such procedures to perform the hysterectomy as described.

I understand that in additions to my physician's fee for the Hysterectomy there will be other charges such as the hospital, facility or laboratory costs, anesthesia charges and possible other physician fees.

THE NATURE AND PURPOSE OF THE HYSTERECTOMY HAS BEEN EXPLAINED BY MY PHYSICIAN INCLUDING THE RISKS, COMPLICATIONS AND EXPECTED BENEFITS OF THE HYSTERECTOMY. THE THERAPEUTIC ALTERNATIVES TO THE HYSTERECTOMY AND THE RISKS AND BENEFITS OF THESE ALTERNATIVES HAVE ALSO BEEN EXPLAINED

Person Giving Consent (Print)

Signature

Date _____ Time _____

Witness (Print)

Signature

Relationship to patient if not the patient _____

Patient unable to sign because: _____

Physician Signature

Additional materials used, if any, during the informed consent process for this procedure: _____

If Consent required interpretation:

Interpreter Signature

Or

CYRACOM ID#

Attachment B

References:

- Circular of Information for the Use of Human Blood and Blood Components. AABB. Nov 2013 (revised April 2014)
- AABB Technical Manual. 18th Edition.



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.

This brochure is provided as a source of information and is not considered a replacement for the Informed Consent process prior to the transfusion of blood.



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Revised 06/2016

A Patient's Guide to Blood Transfusion



California
Department of Health Services

June 2016

This document provides written information regarding the benefits, risks, and alternatives of transfusion of blood products (including red blood cells, plasma, platelets, or others) collected from the patient (autologous) or another person. This material serves as a supplement to the discussion you have with your physician. It is important that you fully understand this information, so please read this document thoroughly. If you have any questions regarding the procedure, ask your physician prior to consenting to receive a transfusion.

■ Information about the treatment

Transfusions of blood products are provided to increase the amount of blood components in your body when they are below a reasonable level for your health. The transfusion may be made up of red blood cells, plasma, platelets or other specialized products made from blood. Your physician will decide on the right amount and type of blood product based on your medical condition or diagnosis.

■ Potential benefits of the treatment

Transfusion of blood products may be necessary to correct low levels of blood components in your body, and may also make you feel better. In some cases, failure to receive transfusion(s) may result in death.

■ Risks of the treatment

Known risks of this treatment include, but are not limited to:

- Irritation, pain, or infection at the needle site
- Temporary reaction such as a fever, chills, or skin rashes.

Other rare but more serious complications include severe allergic reactions, heart failure due to fluid overload, acute pulmonary edema (fluid leaking into the lungs), hemolysis (destruction of red blood cells), shock, or death.

Transfusion of blood products carries a very small risk of transmission of infectious diseases such as HIV (about 1 in 1.5 million), Hepatitis C (about 1 in 1.2 million), and Hepatitis B (about 1 in 1 million). Other significant infections may also be transmitted by transfusion, but overall this risk is low.

■ Treatment Options/Alternatives

If you need blood you have several options. Most patients requiring transfusion receive blood products donated by volunteer community donors. These donors are extensively screened about their health history and undergo numerous blood tests as mandated by state and federal regulations in order to ensure the safest possible blood supply. Alternatives to transfusion with blood products from volunteer community donors include:

- Pre-operative autologous donation (using your own previously donated blood), see below for more information
- Directed donation (blood donated by people who you have asked to donate for you), see below for more information
- Intra-operative autologous transfusion/Hemodilution (collecting your own blood during surgery to be given back to you)

- Medications (certain medications may increase blood volume prior to surgery or reduce active bleeding to lessen the need for transfusion)

These options may be available only if your health, time, and procedure permit. They may not be available at all locations or for all patients. You may also choose not to receive blood transfusion; however this decision may hold life-threatening consequences.

Pre-operative autologous donation is not appropriate for all patients. Autologous donation involves collecting your own blood prior to a planned surgery for storage in the hospital blood bank. It is important to discuss with your physician if it is safe for you to donate and the likelihood of needing a transfusion based on your surgery and current transfusion guidelines. Receiving your own blood may reduce, but will not eliminate, the risk of transfusion-related complications. Insurance company policies may vary regarding reimbursement for this service. Overall, although autologous donation is an option to consider for those who qualify, the number of autologous donations in the United States has significantly decreased in the last few decades mainly due to major advances in blood safety and efforts to decrease unnecessary blood transfusions.

Directed donation refers to blood collected from "directed donors" who are donating blood for a specific patient by request. Directed donors are often family and friends of the patient. Directed donors go through the same qualification process as volunteer donors. Directed donations are not considered to be safer than the general blood supply.

