Olive View-UCLA MEDICAL CENTER

COUNTY OF LOS ANGELES
DEPARTMENT OF HEALTH SERVICES

Policy Title:	**CONSENT POLICY**		
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Distribution:	**Hospital-Wide** ☒	**If not Hospital-Wide, Other:**	

PURPOSE:

To ensure that the patient, or the patient's legal representative, is provided information necessary to enable him/her to evaluate a proposed treatment and/or procedure/operation before agreeing to the treatment and/or procedure/operation.

DEFINITION(S):

General Consent – A patient's consent to general medical treatment and services.

Informed Consent – A patient's right to decide whether or not to submit to a specific treatment and/or procedure/operation, after being reasonably informed of the nature and purpose of the proposed treatment, including the risks, expected benefits, potential complications as well as the alternatives and their expected risks and benefits.

Chemotherapy – For the purpose of this policy, chemotherapy is defined as medications which meet all of the following classes:

- Are given for the treatment of oncological or neoplastic conditions;
- Are of the following drug classes:
  - Cytotoxic drugs or
  - Immunotherapeutic agents which are conjugated to cytotoxic drugs
- Are administered by any of the following routes: PO, IV, IM, topical, intradermal, intrathecal, or into any body cavity by any means (including intraperitoneal therapy).

  For the purpose of this policy, the definitions of chemotherapy as contained in other handbooks, compendia, administration manuals, or listings do not apply.

Oncological Conditions – For the purpose of this policy, oncological conditions are those diagnosed as cancers or neoplasms, which follows the practices recommended by national organizations organized around the treatment of these diseases and disorders.

iMed Consent Program – The iMed Consent program is a web-based informed consent program that is found on the OVMC home page and via the electronic medical record. The iMed Consent program and associated printed forms shall be used whenever informed consent is required. The iMed Consent form itself is not informed consent, it is evidence for both the hospital and the physician or qualified medical practitioner that informed consent was obtained. The form is not a substitute for the role the physician or qualified medical

practitioner has in the informed consent process, which is to inform the patient of the risks, expected benefits, potential complications and alternatives of the proposed procedure as described more fully below.

Adult – For the purpose of making health care decisions, an adult is a person who has reached the age of 18, or a minor who has entered into a valid marriage, who is on active duty with the armed forces of the USA, or who has been declared emancipated pursuant to Family Code Section 7122.

Patient's representative – An adult person who is acting or speaking as a surrogate and is a member of the patient's family, the patient's domestic partner or if no family or partner is available, an individual (adult, relative or close friend) who is believed to be able to speak to the wishes of the patient.

Legal representative or agent – An individual designated in a power of attorney for health care form (or Advanced Directive) to make a health care decision for a patient.

Capacity – A person's ability to understand the nature and consequences of a decision and to make and communicate a decision. This includes, in the case of a proposed health care, the ability to understand its significant risks, benefits, alternatives and potential complications.

Health Care Provider – an individual licensed, certified or otherwise authorized by California law to provide health care (including specific procedures and treatments) in the ordinary course of business.

Witness – Witness to signature of the patient. A "professional employee for the facility" (admitting personnel, RN, LVN, ward clerk, or other hospital employee of similar responsibility) may act as a witness to the patient's signature. The surgeon CANNOT witness his/her own surgical consent. A witness is recommended not required, except in the instances set forth in **Section II, D**, **#2 Telephonic Consent** and **Section II, M, Patient physically unable to sign but can leave their mark.** A witness should be 18 years of age or over, not related to the patient, and understands the role of the witness. The witness should be present when the form is signed by the patient or the patient's legal representative or agent and should indicate he or she witnessed the signing by placing their own signature in the designated witness space. A signature without a witness is acceptable, and treatment should not be delayed for lack of the signature of a witness.

POLICY:

Except in medical emergencies, no medical care shall be provided at Olive View- UCLA Medical Center (OVMC) unless appropriate consent has been obtained from the patient or the patient's legal representative. The verbalized information on the proposed course of treatment and/or procedure/operation provided during the consent process should be in the language that the patient understands (preferred language).

PROCEDURE:

I. GENERAL CONSENT

A. Inpatient General Consent is valid for the entire period of hospitalization and terminates upon discharge. Outpatient General Consent is valid for one year except for those visits to the Emergency Room and the Pediatric Clinic where a General Consent is signed at every encounter. A General Consent should be obtained at the time of registration for all inpatient visits, once a year for outpatient visits, and at the time of presentation for an outpatient procedure. The General Consent Emergency Medical Treatment Conditions of Admission part 1 is obtained upon arrival for care in the Emergency Room and General Consent Emergency Medical Treatment Conditions of Admission part 2 is obtained after the Medical Screening Exam (MSE) has been completed. When patients are brought to the Emergency Room on a 72-Hour Psychiatric Hold (5150), a signature on the General Consent form is not necessary. The words “On 72-Hour Hold” take the place of the signature; it is then witnessed in the usual fashion. Patients on a 72-Hour Psychiatric Hold (5150) require other paperwork demonstrating need for hold, patient notification of hold, and consent for psychotropic medications.

B. Treatment of Minors:
If the patient is a minor with no legal authority to consent, one of the following must be met:

1. The general consent shall be obtained from the patient’s legal guardian or patient’s authorized representative. Minors of divorced parents may have consent from either parent. If there is a conflict between the parents, the one who has court ordered custody has the final authority.

2. If special circumstances such as distance, etc., make it impossible for the parents of a minor to give written consent, telephone consent may be given so long as there is a second party, such as a nurse listening when the parent/guardian gives consent for treatment. Both the caller and listener (witness) will sign the consent form.

3. The mother has legal authority to consent to medical treatment for a minor born to unwed parents. The father of the minor also has the legal authority to consent to medical treatment however, where there is reason to doubt the status of someone claiming to be the child’s father, a copy of the birth certificate or court judgment should be requested before accepting consent.

4. A minor parent may validly consent to medical or surgical treatment for his or her child. However, the minor parent must demonstrate capacity, which is the ability to understand the nature of the treatment, its risks and benefits, and any alternatives to the treatment, as with any situation requiring informed consent.

5. If consent is obtained from a non-parent adult relative or caregiver, the minor must be living with the adult relative or caregiver who may authorize medical care for the minor by signing a **Caregiver’s Authorization Affidavit form** (T-HS0103141AE). The affidavit is valid for only one year from the date of

signature. The affidavit becomes invalid when the health care provider learns that the minor no longer lives with the caregiver. The adult must be at least 18 years of age or older and must be a qualified relative, which is defined in the law as a spouse, parent, step-parent, brother, sister, half-brother, half-sister, uncle, aunt, nephew, niece, first cousin or any person denoted by the prefix "grand" or "great", or the spouse of any of the persons specified in the definition, even after the marriage has been terminated by death or dissolution. The adult must advise the parent of the proposed medical treatment and the parent must have no objection thereto; or the adult must be unable to contact the parents.

6. Adoptive parents, who have legally adopted by order of the court, may consent. A stepparent who has not legally adopted a minor does not have the authority to consent to treatment on the minor's behalf without written authorization from the natural parent or guardian or a valid **Caregiver's Authorization Affidavit**. Foster parents do not have legal capacity to consent to medical treatment unless they have been authorized by the agency having legal custody of the minor.

7. If the child is ill or injured during regular school hours, reasonable medical treatment may be provided without parental consent if the minor's parent(s) or guardian cannot be reached. This does not apply if the parent(s) or guardian has filed with the school district a written objection to any medical treatment other than first aid. Treatment is limited to medical treatment that is "reasonable" under the circumstances. This does not include procedures involving significant risk or invasiveness.

8. The court may consent to medical treatment for a minor who is a ward of the court.

9. Absent special circumstances, social workers and probation officers do not have the authority to consent to treatment on behalf of minors in their custody. Upon recommendation of the attending physician, a social worker or probation officer may authorize necessary medical treatment provided that he or she first notifies the parent, guardian or other person who is authorized to give consent. If such person objects, treatment can be provided only upon order of the court.

10. Minors who are at least 15 years of age may make an Anatomical Gift with the written consent of a parent or guardian.

11. Minors 17 years of age or older may make a donation of blood. Minors between the ages of 15 and 17 may consent to blood donation, but the blood bank may accept such donation only with the written consent of the minor's parent(s) or guardian and the written authorization of a physician.

If a minor requires treatment and the emergency exception is not applicable, or the minor may not consent pursuant to any of the statutory exceptions discussed above,

and no "Caregiver's Authorization Affidavit" form has been signed (or the signed form is not available), communication with the parent(s), guardian, or caregiver by telephone or fax to obtain the necessary consent must be vigorously pursued. If the communication is unsuccessful, case-by-case exceptions may be granted by Medical Administration.

If the parent or guardian refuses to give consent for emergency treatment, call 1-800-540-4000, Department of Children and Family. Administration and OVMC Risk Management should be notified. There are certain conditions under which a minor may give consent to medical care. One of the following must apply:

1. A minor 14 years of age or older may petition the court for emancipation. If the court grants the minor's request, the Department of Motor Vehicles will issue an identification card that states that the minor is emancipated. (Family Code Section 7120).

2. Minors under 18, who have entered into a valid marriage, whether or not such marriage was terminated by dissolution or death of the spouse (Family Code Section 7002).

3. When a minor 15 years of age or older is living separate and apart from his or her parent(s) or legal guardian, whether living with or without the consent or acquiescence of his or her parent(s) or legal guardian and manages his or her financial affairs, regardless of source of income, the minor is capable of giving a valid consent for medical care without parental or guardian consent knowledge or financial liability.

4. A minor 12 years or older is consenting for services related to the testing and treatment for reportable communicable or infectious diseases, including STI/STD/HIV, drug and alcohol abuse diagnosis and treatment, outpatient mental health services and rape and sexual assault-related services. A minor at any age may consent for the prevention and treatment of pregnancy. However, this law does not apply to sterilization.

5. Any minor, regardless of age, while serving on active duty with any branch of the U.S. armed services may consent to medical, dental, or psychiatric care without parental consent, knowledge, or liability.

In the absence of evidence to the contrary, Olive View-UCLA Medical Center providers may reasonably believe that the affirmations made in the form are correct without independent verification.

Minors over the age of 14, who are to receive follow-up medical care in the outpatient setting, will be evaluated by a physician by seeing the minor in the Pediatric Clinic with a parent present. Upon evaluation, if it is determined that the minor will require further/frequent follow-up visits pertaining the same medical issue; the physician will obtain a consent for follow-up treatment to be done with or without

a parent present for future visits. The treatment modality and the physician will determine the duration of the consent. The consent must be initiated and completed by the physician. Education regarding treatment plan and follow up care is to be performed and documented by Medical and Nursing Staff. The following criteria must be met for using follow-up treatment consent:

1. Minor must be 14 years of age or above
2. Minor must have a non-acute, non-critical event
3. An initial treatment consent must be signed as well as a follow-up consent
4. If the condition changes, a new consent must be signed
5. Additional medical procedures and/or treatment not specified in first consent, requires a parent/guardian to be present.

Common medical issues that require continued follow-up care are, but not limited to:

1. Suture removal
2. Wound check
3. Dressing changes
4. Repeated lab draws
5. Skin disorders
6. Weight management

C. If an adult is not able to consent due to **lack of capacity**, the general consent shall be obtained from the patient's representative or legal representative. The determination of **lack of capacity** shall be made by a physician and usually does not require a psychiatric consultation or a court hearing.

1. Although it is preferable that a legal representative's consent be secured, if the patient does not have a legal representative, it is acceptable to rely upon the consent given by the patient's family, domestic partner.

2. The condition of lack of capacity may be temporary (at the point of presentation) or permanent.

D. Consent for HIV testing is covered by the general consent for medical care, and does not require specific mention in the general consent. When any licensed test to diagnose HIV infection is ordered, the ordering health care provider is responsible for informing the patient of the intent to perform the test and that they have the right to refuse the test. The patient will also be informed that there are treatment options for HIV, and risk reduction strategies to prevent HIV transmission if the test is positive. If the patient refuses HIV testing, this must be documented in the medical record.

II. Informed Consent

Written informed consent should be obtained for major therapeutic and diagnostic treatments or procedures where disclosure of significant medical information, including risks, benefits, and alternatives would assist the patient in making an educated decision whether to undergo the proposed treatment or procedure. The consent cannot be obtained from the patient through the exercise of duress or coercion. There is no duty to

make disclosure of the risks when the patient requests that he/she not be so informed, however; the patient's refusal should be documented, or where the procedure is simple and the danger remote and commonly understood to be remote. Likewise, there is no duty to discuss minor risks inherent in common procedures when such procedures very seldom result in serious ill effects.

A. A signed General Consent is sufficient for the following procedures:
   1. Any component of a physical examination
   2. Arterial puncture for blood gas
   3. Venipuncture for blood
   4. IV/IO placement
   5. Therapeutic injection of medication (except chemotherapy)
   6. Post-operative wound exploration
   7. Dressing changes
   8. Removal of staple, sutures, drains, wires, arch bars, etc.
   9. Removal of corneal or conjunctival foreign body
   10. Lacrimal system irrigation
   11. Insertion of Foley catheter or nasogastric tube
   12. Closed reduction of fracture
   13. Tissue expander injection
   14. Diagnostic radiological examinations without a diagnostic agent
   15. Application of cast/splint
   16. Local nerve block
   17. Superficial wound debridement
   18. Suturing not requiring a surgical consultation
   19. Incision and drainage not requiring a surgical consultation
   20. EMG and Evoked Potentials
   21. Skin shave or punch biopsies, not involving face or hands

B. All competent adult patients shall give informed consent for themselves. If the adult patient lacks capacity, the authority to consent is transferred to the patient's legal representative, designated surrogate decision maker, or next closest relative/friend who can speak to the wishes of the patient. In the case of a medical emergency, a physician may proceed with lifesaving procedures under the theory of implied consent. The provider must document the nature of the emergency in the Medical Record. If it is not a medical emergency, Clinical Social Work Department should be contacted to identify next of kin or available decision maker. If no one can be identified, refer to Policy #2372: "Health Care Decisions for Unrepresented Patients."

C. Upon giving informed consent, the patient will be made aware that he/she may reverse his/her decision at any time up until the actual procedure is initiated, and that his/her refusal of consent or reversal of decision for informed consent does not trigger process of termination of medical care of follow-up. The reversal of decision for informed consent will be documented in the progress notes in the medical record by a physician.

D. Telephone Consent:
OVMC recognizes that there may be occasion when informed consent to treatment cannot be obtained in person; e.g., obtaining informed consent from the parent of a minor who is an inpatient. Therefore, a telephone informed consent to treatment may be obtained.

1. This method of informed consent shall be reserved for those instances where time/or condition of the patient do not allow for informed consent to be obtained in person.

2. A conference call shall be set up with physician or qualified medical practitioner, a registered nurse, and the party who is giving informed consent. The discussion, as outlined on the iMed **Authorization for and Informed Consent to Surgery or Special Diagnostic or Therapeutic Procedures** under **Telephonic Consent to Operation and Rendering of Other Medical Services**, shall be performed by the physician or qualified medical practitioner with the registered nurse acting as the employee witness. If the patient's language is other than English and the provider obtaining informed consent does not speak the patient's primary language, a translator will be utilized who will act as a witness. If a translator/interpreter is used, the **Interpreter Attestation during Informed Consent** (Form HS-1001) must be completed and retained with the informed consent.

E. Emergency Treatment Exception:
In the case of a medical emergency, indicated diagnostic and therapeutic interventions may be pursued without the patient's consent provided there is no evidence that the patient, or the patient's legal representative, would refuse such interventions. A medical emergency exists when immediate interventions are required for the alleviation of severe pain or for the immediate diagnosis and/or treatment of medical conditions that could lead to serious disability or death if not immediately addressed [Business and Professions Code section 2397(c)(2),(3)]. In such cases, the emergency exception rule can and should be invoked. This rule does not require two physician signatures. However, in such instances, precise documentation in the medical record of the rationale for performance of the emergency interventions is required. Diagnostic or therapeutic interventions exceeding that needed for effective management of the emergent condition may not be performed without patient or the patient representative's consent.

F. The physician or qualified medical practitioner must explain to the patient all information about the proposed treatment and/or procedure/operation including:

1. Nature and purpose of the treatment and/or procedure/operation to be rendered

2. Expected benefits or effects of the procedure

3. Likelihood of achieving treatment goals

4. Possible risks, complications or particular discomfort, including potential problems related to recuperation (there is no duty to discuss minor risks inherent in common procedures when such procedures very seldom result in serious ill effects)

5. Alternative to the treatment and/or procedure/operation

6. Likely outcome if treatment and/or procedure/operation is declined

7. Who will conduct the surgical intervention and administer anesthesia

8. Whether physicians other than the performing/operating practitioner, including but not limited to residents, will be performing important tasks related to the treatment and/or procedure/operation in accordance with the hospital's policies

9. Whether, as permitted by State Law, qualified medical practitioners who are not physicians will perform important parts of the treatment and/or procedure/operation or administer the anesthesia, and if so, the types of tasks each type of practitioner will carry out, and that such practitioners will be performing only tasks within their scope of practice for which they have been granted privileges by the hospital.

10. The authorization by the patient for the pathologist to use his or her discretion in the disposition or use of any member, organ, or other tissue removed from the patient's person during the operation(s) or procedure(s) identified in the consent and during the informed consent discussion

11. Any potential conflicting interests (such as research or financial interests) the physician or qualified medical practitioner may have.

G. For surgeries in which residents will perform important parts of the surgery, discussion will include the following:

1. That the facility maintains personnel and facilities to assist providers in the performance of the operation or procedure recommended

2. Providers other than the operating practitioner, including but not limited to residents, will perform important tasks related to the surgery, in accordance with the facility's policies.

3. Participating residents involved in the post-graduate training programs will be selected at the time of surgery based on availability, level of skill, and competence

4. Residents will be under the supervision of the responsible practitioner and he/she may not be physically present

5. Qualified medical practitioners who are not physicians may perform important parts of the surgery or administer anesthesia within their scope of practice, as determined under state law, and for which they have been granted privileges by the facility

H. Vendors who are involved in a patient's care during surgery must be acknowledged in the informed consent as giving care to the patient in the operating room.

I. The person preparing the consent will be prompted by the iMed Consent program to specify whether an interpreter will be used. If the patient's preferred language is other than English, and the provider does not speak the patient's preferred language, an interpreter shall be utilized in the informed consent process. In such cases, the person preparing the informed consent shall mark "yes" on the iMed consent when prompted to provide a response.

A separate **Interpreter Attestation during Informed Consent** (Form HS-1001) (available within the iMed Consent program as a separate document under LADHS Consents and Forms) shall be completed where the interpreter's name and signature shall be recorded.

If a telephone interpretation service is utilized, section III of Form HS-1001 should be filled out, noting language, Telephone Operator ID number, date and time. If a video modality interpretive service (e.g., internet-based video conference system) is used, section III should also be used, noting language, interpreter ID number, date and time.

If the physician or qualified medical practitioner obtaining consent speaks to the patient in their preferred language, "provider" will be marked when prompted by the iMed Consent Program and asked if an interpreter will be used. In this instance, the physician or qualified medical practitioner does not need to complete the **Interpreter Attestation during Informed Consent** (Form HS-1001).

If both, the physician or qualified medical practitioner obtaining consent and the patient speak the same language, an interpreter is not required and the person preparing the informed consent shall mark "no" when prompted by the iMed Consent program.

J. Prior to commencing surgery (except in the case of emergency), the presence of the signed Informed Consent for the proposed procedure will be verified by the person responsible for administering anesthesia. If anesthesia is not to be administered, the physician or qualified medical practitioner will do this verification process. A notation shall be made in the medical record attesting to this verification. It is the responsibility of the surgeon to see that the patient is properly consented before surgery takes place.

K. Except as otherwise mandated, an Informed Consent is valid until either revoked by the patient or at such time as there are changes in the patient condition and the

course of treatment that would materially affect the nature, risks, benefits and alternatives to the procedure for which the patient originally gave consent. A new consent must be obtained for each procedure. The consent for sterilization is only valid for 180 days.

L. Authorization of photographs: the physician or qualified medical practitioner must ask the patient for their authorization if photographs are to be taken during the treatment, and/or procedure/operation. The patient will initial next to "yes" or "no" on the informed consent form.

M. Following the Informed Consent process, the physician or qualified medical practitioner shall obtain the patient's signature, initials, date and time on the Informed Consent form. The physician or qualified medical practitioner will print his/her last name, sign, date, and time, as well as write their provider number in the designated area on the form. The person who is the witness to the patient/conservator/guardian signature will sign in the designated area. If the patient or their legal representative is physically unable to write his or her name, the person's mark must be obtained. This is done by the physician or qualified medical practitioner first writing the person's name in full and then having the person place and "X" beneath it. Two people must witness the signer place his or her mark on the consent form. The physician or qualified medical practitioner obtaining the patient's Informed Consent shall also document in the medical record that a discussion was held with the patient and that Informed Consent was obtained.

N. The signed original Informed Consent should be placed in the patient's medical record and a photocopy of the signed consent should be given to the patient.

O. Handwritten notes on printed Informed Consents – Handwritten additions to a printed consent are discouraged. If handwritten notes are made, the addition must be dated, timed and initialed by the patient or legal representative and initialed by the physician at the time the note is written.

P. iMed Consent Downtime Procedure - In the event that internet access or the Dialog Medical website is not available, a downtime procedure has been instituted. The iMed Consent program has a folder labeled "LADHS Consents and Forms". This contains a generic blank "Downtime" consent form in English and Spanish. A copy of each should be printed and stored for use when necessary. Handwritten completion of all fields is necessary during computer downtime.

Q. For any special circumstances relating to Informed Consent, you may contact the Risk Manager for Olive View-UCLA Medical Center for guidance. Contact number is (747) 210-3026. If calling after hours, (4:30 p.m. – 8:00 a.m.) please call the Administrative Nursing Officer (ANO) at (747) 210-3170.

III. CHEMOTHERAPY

The chemotherapy consent form is available in the iMed Consent system and shall be used to consent patients prior to receiving chemotherapy.

Physician Role: It is the responsibility of the treating physician, or member of the treating physician's team, to obtain the Informed Consent prior to the administration of chemotherapy.

Nursing Role: It is the responsibility of the nurse (in both inpatient and outpatient care areas) administering the first cycle of chemotherapy to verify that the chemotherapy Informed Consent has been obtained. The nurse will document confirmation of current consent in the nursing note. A consent obtained and verified in one treatment area will suffice for all areas. Nursing staff administering cycles of chemotherapy subsequent to the first cycle of chemotherapy will not be required to re-confirm initial consent.

The chemotherapy Informed Consent shall be valid for the entire course of treatment or until there is a change in goals of therapy.

IV. Bevacizumab (AVASTIN)

For adult outpatients a written Informed Consent for the administration of Avastin for the treatment of ocular and retinal disease shall be obtained on a yearly basis.

Before the first administration of Avastin by intraocular injection for the treatment of ocular and retinal disease(s), the provider will review the risks, benefits, and alternatives with the patient and obtain a signed Informed Consent.

For subsequent administrations of Avastin for the same medical indication over the following 12 months, the initial written consent document will serve as formal Informed Consent. The provider will review the plan with the patient prior to each subsequent treatment and obtain verbal permission to proceed.

A new written Informed Consent shall be obtained each 12 months or when the patient condition changes treatment plan.

The Informed Consent should clearly indicate whether the treatment will be for one eye (left or right) or for both eyes.

ATTACHMENTS/FORMS:

None

REFERENCE(S)/AUTHORITY:

Title 22 California Code of Regulations (CCR) Sections 70707.1 – 70707.7, 70223 (d), 3 Patients' Rights Condition of Participation (CoP) at 42 CFR 482.13(b)(2); Medical Records CoP at 482.24(c)(2)(v); Surgical Services Cop at 482.51(b)(2)
California Hospital Association Consent Manual 2017
DHS policy #314, Informed Consent
DHS policy #314.1, Providing Care to Minors in the Absence of Parent or Legal Guardian
DHS policy #314.2, Documenting Use of Interpretation Services During Informed Consent

Discussion

APPROVED BY:

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