INFORMED CONSENT - ELECTIVE AND NON-ELECTIVE STERILIZATION

The purpose of this document is for the clarification of the legal requirements in obtaining informed consent for sterilization procedures.

A) ELECTIVE STERILIZATION

An elective sterilization is for the purpose of rendering a person (male or female) incapable of reproducing.

State and Federal regulations mandate special informed consent requirements for elective reproductive sterilizations. The regulations apply to elective sterilizations only. Title 22 governs elective sterilizations performed in a licensed acute care hospital, regardless of the source of payment.

PRIVATE PAY (Title 22, CCR, Sections 70037.1, 70707.1-70707.8 & 70736)

Medicare and TRICARE patients should be treated under the private pay rules applicable to hosp performed procedures.

MEDI-CAL or other federally funded programs (Family PACT). (Title 22, CCR 51163, 51305.1-51305.7& 70707.6, 42 CFR Sections 50.201-50.210)- additional requirements and restrictions which do not apply to private pts, and govern sterilizations performed in both inpt and outpt settings.

I) AGE & PAYOR STATUS

1. PRIVATE PAY

Must be 18 yrs of age to consent to sterilization.

Exception: Under 18 if one of the following:

a) Entered into marriage whether or not dissolution
b) Active duty with armed services
c) 15 y.o. who lives apart from parents/guardians etc. and manages own financial affairs.
d) Emancipated Minor

Although, in certain limited circumstances a minor may request sterilization, if you do receive a request from a minor to perform a sterilization procedure, please contact Risk Management before consenting to discuss the potential issues involved. This scenario would be rare, if ever.
2. **MEDI-CAL or other federally funded programs (Family PACT)**

   Must be 21 yrs of age to consent to sterilization.

**II) OBTAINING INFORMED CONSENT**

There are 2 steps to the consent process.

**Step#1:** The patient must be provided with certain information at the time the patient signs the consent:

1) Person obtaining consent for sterilization must provide the individual with the special consent form and the pamphlet on sterilization published by the DPH. There are 2 forms, one for Medi-Cal/Federally Funded (PM 330) & Non-Federally Funded (PM 284).

2) Person obtaining consent must offer to answer any questions the individual may have concerning the procedure.

3) Must provide **orally**:
   a) patient is free to withhold or withdraw consent at any time before the procedure without any ramifications.
   b) description of available alternatives
   c) sterilization procedure is considered irreversible
   d) through explanation of the procedure to be performed
   e) description of discomforts & risks including possible effects of anesthesia
   f) description of benefits and advantages of sterilization
   g) approximate length of hospital stay
   h) length of recovery
   i) financial costs
   j) established or new procedure
   k) procedure will not be performed for at least 30 days, except for certain circumstances
   l) name of the physician performing the procedure.

4) Must ensure the patient understands the above info.

5) Sterilization must be requested without fraud, duress, or undue influence.

The consent form must be signed and dated by the patient being sterilized, interpreter if any used, physician or physician’s designee obtaining the consent.

**Person obtaining consent must certify:**

- *Advised the patient of the above listed information prior to the pt signing the consent form.*

- *That advised pt that no federal benefits will be withdrawn if decides against sterilization.*

- *Certification of oral explanation of the above requirements for informed consent*
Determination that the individual appeared to be mentally competent and understands the content and nature of the informed consent process and knowingly and voluntarily consented.

If an interpreter is used, the interpreter must certify that transmitted the information as presented orally to pt, read consent form and explained to pt, to the best of interpreter’s knowledge and belief that the pt understood.

Step#2: Within 72 hrs prior to the patient receiving any pre-op medication, the consent is verified by and signed by the physician who actually performs the procedure and certifies that:

- Advised the pt that federal benefits will not be withheld if pt decides to not proceed with the procedure.
- Physician or physician’s designee orally explained the requirements for informed consent.
- Determined that to best of physician knowledge the pt appeared mentally competent and knowingly and voluntarily consented.
- The appropriate waiting period has passed since the pt signed the consent form (unless there is an exception to the waiting period).

A copy of the sterilization consent must be given to the patient and a copy for the physician and hospital and attached to all claims for sterilization procedures.

III) WAITING PERIOD

30 days (but not more than 180 days) must pass after the sterilization consent form has been signed. The 30 days starts the day after the consent is signed. Private Pay patients may request in writing that procedure be performed in less than 30 days. Medi-Cal patients cannot request in writing to have the sterilization performed in less than 30 days.

Exceptions:

Emergency ABD surgery:
A sterilization procedure may be performed at the time of an emergency abdominal surgery if pt has given written informed consent at least 30 days before intended to be sterilized. At least 72 hrs have passed since gave written informed consent.
EX: Pt signed sterilization consent on 7/1/09 with a planned date of surgery for 8/31/09. Patient presents to the ED on 7/15/09 in need of emergency abdominal surgery and wishes to have the tubal ligation at the same time. In this case, pt gave written informed consent 30 days prior to intended date of procedure and it has been over 72 hrs since pt signed consent form so may proceed.

Premature delivery:
If pt gave written informed consent 30 days prior to the expected date of delivery (EDC), at least 72 hrs passed after pt gave consent.

EX: Pt EDC is 9/1/09. Pt signed sterilization consent on 7/1/09. Pt goes into premature labor on 7/2/09. Although, the pt signed the consent 30 days prior to the EDC, it has not been 72 hrs since the consent was obtained.

IV) COMPETENCY TO GIVE INFORMED CONSENT FOR ELECTIVE STERILIZATION (Applicable to Private Pay & Medi-Cal Patients)

- Patient understands content and nature of the informed consent process
  
  (Persons with mental retardation are not necessarily incompetent)

- Pt must not be in a mentally altered state: under the influence of alcohol or other substances.

- Pt must not be in labor and not less than 24 hrs postpartum or post abortion.

- Consent must not be during the period of time the decision being made for obtaining an abortion or during the procedure. If a pt is consented for sterilization and later wishes to obtain an abortion, the procedures may be performed concurrently (waiting requirements apply).

- Additional criteria for Medi-Cal & certain other federally funded pts:

  - Must not be deemed mentally incompetent by a court unless the pt has been declared competent for specific purposes such as ability to consent to sterilization.

  - Must not be an institutionalized individual (involuntary confined in a correctional or rehab facility including a mental health facility.

  - Must not be confined under a voluntary commitment in a mental health facility.

An incompetent person may be sterilized pursuant to a court order under certain circumstances. Is such a request is made, please contact Risk Management to discuss before proceeding.
B) HYSTERECTOMIES

Health & Safety Code Sections 1690-1691; Title 22, CCR Sections 51305.6 & 70707.5 govern Hysterectomies. Physicians must obtain verbal and written informed consent before performing a hysterectomy on any patient (H&S Code Section 1690).

Elective Sterilization (rare if ever done anymore for this purpose):

- If performed for sterilization purposes, then the eligibility & consent requirements are the same as for any other “elective sterilization” procedure.

- Will not be reimbursed under Medi-Cal or certain other federally funded programs if performed as an “elective sterilization” procedure.

- If performing a hysterectomy is not for purpose of sterilization but is medically necessary then all the usual consent requirements will apply (i.e. competent pt may consent and surrogate decision makers may consent for incompetent patients).

Informed Consent and Documentation:

- Informed Consent must be verbal and written.

- Provider must inform the patient and patient’s representatives that the hysterectomy will result in permanent sterility of the patient.

- Patient and pt’s representative, if any, sign the written acknowledgement that they are in receipt of this information.

- Patient must be informed of the right to seek a second opinion.

- *If patient sterile prior to the hysterectomy, the provider must discuss the previous sterility with the pt and document in the record to include the cause of the previous sterility.*

- Informed consent to include risks, benefits, etc. of the hysterectomy procedure.

H&S Code Section 1690: Additional Physician Requirements re: some overlapping with Title 22 Acute Care Hospitals requirements:

Verbal and written consent required with following elements:

- Pt free to withhold or withdraw consent at any time prior to surgery without affecting pt’s right to future care or treatment without loss of any state or federal benefits otherwise entitled to.
• Description of types of surgery & other procedures involved in hysterectomy, any known available and appropriate alternatives to hysterectomy

• Hysterectomy irreversible and infertility will result (unless the pt was previously sterile or postmenopausal)

• Description of discomforts and risks associated with surgery and anesthesia.

• Benefits/advantages to expect as a result of a hysterectomy.

• Approx length of stay in the hospital

• Approx length of recovery time.

• Financial costs for physician and surgeons fees.

• Pt must sign a written statement prior to surgery attesting that she has read and understood this information and that this info was discussed with her.

Exception: Informed Consent is not required in emergencies but physician must prepare and sign a statement in own handwriting, certifying the nature of the emergency.

Physicians must obtain verbal and written informed consent before performing a hysterectomy on any patient (H&S Code Section 1690). The information that must be provided verbally and in writing is set forth in the sample Hysterectomy form attached.

C) NON-ELECTIVE STERILIZATION

Non-elective sterilizations are secondary to or a side effect of an otherwise necessary medical procedure that will result in sterility. These types of procedures are not subject to the regulations governing elective procedures.

Examples of procedures which would be considered medically necessary:

  Breast Cancer patient undergoing oophorectomy as a preventive measure
  Tumor debulking procedures

However, when obtaining informed consent for these types of medically necessary procedures, the consenting of these patients must include that these procedures will result in sterility.