A. POLICY:

1. Informed consent must be obtained and available in the patient's chart for all elective operative and/or special procedures prior to moving the patient to the procedure room, except in areas where the patient is directly admitted to the procedure room or in emergency situations (see below for criteria) and prior to the patient being given any preoperative medication. The consent must be obtained whenever the planned procedure meets any of the following criteria:
   
a. Any surgical procedures and/or procedures requiring anesthesia
   
b. Any procedure involving high radiation exposure
   
c. For any diagnostic or therapeutic procedure or other medical treatment which involves significant material risk
   
d. For any use of a drug with a significant, material risk of an adverse reaction
   
e. Any other procedures which pose a significant and material risk which would reasonably require a specific explanation to the patient.

B. PROCEDURE:

1. The treating physician/practitioner has primary responsibility for obtaining consent. The written consent serves as a memorandum of understanding between the patient and the practitioner. The practitioner should personally explain the treatment to the patient and, whenever possible, sign the form as a witness (or check the box “Witnessed by Provider below”). The practitioner who explained the treatment to the patient must sign the attestation on the form. When appropriate, other witnesses may sign the form in addition to the practitioner. The purpose of the witness is to confirm the signing of the consent by the patient and the patient's competence to sign.

2. When appropriate and in the best interest of the patient, consent may be obtained by another physician/practitioner or a Non-Physician Provider (NPP) under the supervision of the treating physician/practitioner, with complete knowledge of the procedure. At Evergreen, NPPs include Advanced Registered Nurse Practitioner (ARNP), Physician’s Assistant Certified (PA-C), Certified Registered Nurse Anesthetist (CRNA), and Certified Nurse Midwife (CNM). In addition, a certified Genetic Counselor may obtain consent for genetic testing; the performing provider must also sign the consent prior to the procedure.

3. Under Washington State law, physicians are responsible for the acts of Non-Physician Providers (NPPs) under their supervision. Qualified medical practitioners who are not physicians who will perform important parts of the surgery or administration of anesthesia may perform only those tasks that are within their scope of practice, as determined under Washington State law and regulation, and for which they have been granted privileges by the hospital.

4. The treating practitioner(s) must have the patient, or his or her legal representative, sign an informed consent form prior to moving the patient to the procedure room, except in areas where the patient is directly admitted to the procedure room or in emergency situations (see below for criteria). For scheduled/elective procedures, consents should be completed prior to the patient being admitted. A copy of the signed consent should be given to the patient at time of signing. Practitioners should verbally describe any information which they or their professional specialty feel is significant in
the proposed treatment or procedure, and make a note either in the patient's medical record or on the consent form itself concerning the content of the discussion with the patient.

5. Anesthesiologists should make every effort to personally discuss with the patient the risks involved in anesthesia. Proper notation of the discussion should be entered in the anesthetic record, the patient's medical record or on a separate informed consent form.

6. One copy of the completed and signed form should be retained by the treating provider, hospital, and patient.

7. A consent is considered valid for no more than 90 days after the form is signed and dated. A consent form is not considered valid after the procedure consented for has been performed or after discharge from the hospitalization for which the consent was given, unless consent was clearly for continuing treatment.

8. Informed consent forms and admission orders should be faxed to the Health Information Management (HIM) Department prior to the patient's admission to the hospital for scheduled/elective procedures.

9. A certified medical interpreter or translated version of the form must be used when the patient is non-English speaking and the use of an interpreter must be documented on the consent form.

C. CONTENT OF THE CONSENT FORM:

1. A valid consent form must contain the following information, in language that the patient could reasonably be expected to understand:

   a. Name of the hospital where the procedure is to take place
   b. Name of the specific procedure for which consent is being given, in both medical and lay language
   c. Name of the responsible practitioner who is performing the procedure
      i. If a Healthcare Industry Representative will be present in the OR or procedure room
   d. That the provider discussed the benefits, risks, complications, side effects and alternative forms of treatment
   e. The date and time the consent was signed by the patient, practitioner, and witness

2. NOTE: The preferred consent form is based on the Washington State Hospital Association (2010) model informed consent form.

3. In the event an explanation of a planned surgery or procedure is handled over the telephone, the patient's (or their legal representative's) consent can be documented on the form and it must be witnessed by the practitioner and at least one other person. The fact that it is a telephone consent must be noted on the document.

4. Informed consents shall be signed by the patient if he/she is over 18 years of age and mentally competent. Consents must be signed before sedation is given. (NOTE: Consents from patients who are not competent, in severe pain, sedated, or in severe emotional distress are not valid.) If the patient is unable to sign or is not mentally competent, Washington State regulations regarding substituted consent must be followed. Please see Evergreen's policy on Informed Consent on Behalf of Incapacitated Patients for the list of surrogate decision-makers.
5. Informed Consent for minors shall follow Washington State regulations found in Evergreen’s policy Consent for Care of Minors.

6. If an informed consent is not obtained for any reason, the performing provider shall document the reason in the procedure note or progress note. Examples of reasons include:
   a. In the event of an emergency (see Emergency Cases below)
   b. Patient is unable to sign the consent and a legal representative is not available

D. Emergency Cases:

1. An emergency exists when immediate treatment is necessary to preserve life, or to prevent serious deterioration or aggravation of the patient’s condition. If the patient is unable to sign the consent, the practitioner should document on the progress note that he/she wishes to proceed with the needed surgery or procedure. If a family member is present at the hospital or can be contacted by telephone, consent should be obtained from the appropriate next of kin.

2. When no family member can be reached:
   a. The practitioner should obtain a second opinion or consult if the case is urgent, but could be delayed for 15-20 minutes or more. The second practitioner should document his/her assessment on the progress note.
   b. If the case is truly emergent, the practitioner should proceed with the procedure or surgery.

E. SPECIAL CONSENT RULES:

1. ABORTION:
   a. The hospital follows the Washington State Reproductive Privacy Act which states that “A physician may terminate a pregnancy, and a person acting under that physician’s general direction may assist, where a woman chooses to have an abortion prior to the viability of the fetus, or to protect her health or life.”
   b. Viability is defined in Washington State as “the point in the pregnancy when, in the judgment of such physician on the particular facts of the case before the physician, there is a reasonable likelihood of the fetus’s sustained survival outside of the uterus without the application of extraordinary medical measures.” The non-viability of the fetus, or the medical necessity of the abortion to protect the life or health of the woman, must be confirmed in writing by the treating physician; and that confirmation should be included in the medical record pursuant to procedures established by the hospital, including appropriate consultation.
   c. The patient’s prior informed consent is required. Spousal consent is not required, but is desirable if it can be readily obtained. Consent of parents or legal guardian of an unmarried minor is not required, assuming the minor is of sufficient maturity and mental competence to give an informed consent.

2. STERILIZATION:
   a. Federally/State Funded Sterilizations:
      i. Federal regulations require:
         1. A special informed consent form DSHS 13-364(x) (available from DSHS),
II. that patients be twenty-one (21) years of age or older and
mentally competent, and

III. a thirty (30) day waiting period.

ii. DSHS (Washington State Medicaid) regulations require that:

I. The client is at least eighteen (18) years of age at the time consent is signed;

II. The client is a mentally competent individual;

III. The client has voluntarily given informed consent using form DSHS 13-364(x); and

IV. At least thirty (30) days, but not more than 180 days, have passed between the date the client gave informed consent and the date of the sterilization.

b. Voluntary Sterilizations Not Funded Under Federal or State Programs:

i. There is no statute or case law in Washington State limiting the right of a competent patient to undergo sterilization. Informed consent by a competent adult for voluntary sterilization should follow the general consent rules for surgery and may recite the risk that pregnancy may occur despite the procedure. An emancipated minor likewise may consent to a sterilization procedure.

References

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Signed by

Jeff Tomlin, MD,
Medical Director
(04/13/2012 11:54AM PST)

Bob Malte,
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