



A. IDENTIFICATION

1. Patient name, Social Security Number and Date of Birth:

Name: Last, First, Middle

Social Security Number

Date of Birth

2. Decision-making capacity:

 The patient HAS decision-making capacity (skip to item 3). The patient DOES NOT HAVE decision-making capacity. Enter surrogate name and relationship to the patient. (If the patient's surrogate is not established or available, refer to Handbook 1004.1 for guidance.)

Name: Last, First, Middle

Relationship

3. Name of the treatment(s)/procedure(s):

4. Part of the body on which the treatment/procedure will be performed: (Correct site includes the correct side [i.e., left or right] and the precise anatomical part, such as a specific finger. DO NOT ABBREVIATE.)

5. Practitioner obtaining consent:

Name: Last, First, Middle

6. Supervising practitioner: (if applicable)

Name: Last, First, Middle

7. Additional practitioner(s) performing or supervising the treatment/procedure: (if not listed above)

B. INFORMATION ABOUT THE TREATMENT/PROCEDURE

8. Reason for the treatment/procedure (diagnosis, condition, or indication):

9. Brief description of the treatment/procedure:

10. Potential benefits of the treatment/procedure:

11. Known risks and side effects of the treatment/procedure: (Include potential problems related to recuperation.)

12. Alternatives to the treatment/procedure:

13. Anesthesia / Moderate Sedation (CHECK ONE):

Neither anesthesia nor moderate sedation will be used in this treatment/procedure.

Moderate sedation will be used. Medications will be administered to decrease anxiety and discomfort during the treatment/procedure. These medications will be administered by a qualified practitioner. Patient response to some of these medications varies. Patients are expected to remain aware and responsive during the treatment or procedure. Minor risks of moderate sedation include temporary amnesia or forgetfulness and drowsiness. Moderate sedation can interfere with your ability to drive, operate machinery, or make important decisions for up to 24 hours. Medications used for moderate sedation can cause allergic reactions, respiratory depression (this is when your breathing slows down and may stop), low blood pressure, and a slow or irregular heart beat. In rare instances these complications can cause death. Tell your health care team if you do not want to receive moderate sedation.

Anesthesia will be administered. A member of the anesthesia care team will visit you before your treatment to discuss the type(s) of anesthesia you may need and to give you more information about anesthesia. It may become necessary to alter your anesthesia care plan after this discussion. Devices may be applied to your body and placed in your veins and arteries to monitor you during your anesthesia. All forms of anesthesia involve some risk. Minor (not life-threatening) risks include: nausea, vomiting, and pain where an injection is given. Although rare, severe complications include: injury to blood vessels, drug reactions, bleeding, blood clots, loss of sensation or limb function, infection, paralysis, stroke, brain damage, heart attack, and death.

Here is a basic description of the major types of anesthesia including their risks in addition to those described above:

General anesthesia involves drugs that are injected into the bloodstream or breathed into the lungs. A tube or other device may be inserted into your airway to help you breathe. The expected benefit is that you will be totally unconscious and you will not feel pain during the procedure. Additional risks include: injury to the teeth, throat, eyes, or lung. In less than one case in a thousand, patients may be aware of activities during their surgery.

Spinal or epidural analgesia/anesthesia involves a drug being injected through a needle or catheter placed into the spinal canal. The expected benefit is a temporary decreased feeling in the area of surgical incision, allowing surgery to proceed without pain. Additional risks include: headache, backache, convulsions, persistent weakness and or numbness, abnormal heart rhythms, and incomplete pain relief during the operation that may require general anesthesia.

Major/minor nerve block involves a drug being injected near nerves providing loss or reduction of sensation and movement to the area. The expected benefit is a temporary loss of feeling and/or movement of a specific limb or area of your body. Additional risks include: convulsions, persistent weakness and or numbness, and incomplete pain relief during the operation that may require general anesthesia.

Monitored anesthesia care involves monitoring of the heart and lungs to make sure that they are functioning adequately during your procedure. A local anesthetic will be injected to prevent pain, and the anesthesia care provider may use drugs to help you relax, and lessen any pain. You may remain conscious throughout your procedure, or you may be given medications that will make you unconscious. The expected benefit is that you will be comfortable during your operation with a minimum amount of anesthesia. This may result in a shorter stay in the hospital. Additional risks include: incomplete pain relief during the operation that may require additional anesthesia. Convulsions from the injected drug are a rare but serious complication.

14. Blood products (CHECK ONE)

It is not expected that blood products will be used in this treatment/procedure.

It is anticipated that blood products may be needed in this treatment/procedure and:

I CONSENT to the use of blood products during this treatment/procedure if they are needed to improve my overall condition or save my life. I understand that my consent for use of blood products is valid during the treatment/procedure and during the recovery period after the treatment/procedure. My provider will determine when this recovery period ends. I will be asked again for my consent for use of blood products if this consent form expires, my treatment plan changes, or if blood products are needed for a reason that is unrelated to this treatment/procedure. I understand that common risks of using blood products include (but are not limited to) infection or irritation where the needle is placed, fever, chills, and skin rashes. Other rare but more serious complications may occur such as allergic reactions, heart failure due to fluid overload, acute pulmonary edema (fluid leaking into the lungs), shock, or death. I also understand that transfusions of blood or blood products involve a small risk of transmission of diseases such as Hepatitis B (1 in 137,000), Hepatitis C (1 in 1,000,000), and HIV/AIDS (1 in 1,900,000). There is also a small risk of bacterial infection when blood products are transfused. Alternatives to blood or blood products may be available if my health, time, and procedure permit. These alternatives may include auto-donation (using my own previously donated blood) and intra-operative salvage (my own blood collected during surgery). In addition, medications may be used to reduce the need for blood products. (Please note exceptions to consent in the "Comments" section of the consent form.)

I DO NOT CONSENT to the use of blood products and I do not wish them to be used even if it is determined that they are needed to improve my overall condition or save my life. Alternatives to blood or blood products may be available if my health, time, and procedure permit. These alternatives may include auto-donation (using my own previously donated blood) and intra-operative salvage (my own blood collected during surgery). In addition, medications may be used to reduce the need for blood products.

15. Additional information

VA hospitals are teaching facilities, and trainees may participate in or observe this treatment/procedure. In certain circumstances, the presence of a vendor representative (company representative) is important to the success of the procedure. Prior to the procedure the representative will sign an agreement to strictly adhere to VA's privacy rules. The representative may provide technical advice but will not physically participate in the procedure. The representative will be closely monitored by the VA treatment team.

16. Comments

C. SIGNATURES

Practitioner obtaining consent:

- All relevant aspects of the treatment/procedure and its alternatives (including no treatment) have been discussed with the patient **(or surrogate) in language that s/he could understand. This discussion included the nature, indications, benefits, risks, side effects, and likelihood of success of each alternative.**
- The patient (or surrogate) demonstrated comprehension of the discussion.
- I have given the patient (or surrogate) an opportunity to ask questions.
- I did not use threats, inducements, misleading information, or make any attempt to coerce the patient/surrogate to consent to this **treatment/procedure.**
- I have offered the patient (or surrogate) the opportunity to review a printed copy of the consent form.

Signature _____ Date and Time _____

Patient or surrogate:

- Someone has explained this treatment/procedure and what it is for.
- Someone has explained how this treatment could help me and things that could go wrong.
- Someone has told me about other treatments/procedures that might be done instead, and what would happen if I have no **treatment.**
- Someone has answered all my questions.
- I know that I may refuse or change my mind about having this treatment/procedure. If I do refuse or change my mind, I will not **lose my health care or any other VA benefits.**
- I have been offered the opportunity to read the consent form.
- I choose to have this treatment/procedure.

Signature _____ Date and Time _____

Witnesses: No witness is required if the patient or surrogate signs their name. Two witnesses are required only when the patient's signature is indicated with an "X" or some other identifying mark.

Witness name (please print) _____

Signature _____ Date and Time _____

Witness name (please print) _____

Signature _____ Date and Time _____