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**Patient Medical Record (write in or apply sticker)**

Name: \_\_\_\_\_

Medical Record No. \_\_\_\_\_

DOB: \_\_\_\_\_

Admitting MD: \_\_\_\_\_

**Physician's Surgical Procedure Disclosure and Patient Consent: Bladder – Instillation of Bacillus Calmette Guerin (BCG)**

**TO THE PATIENT:** You have the right to be informed about your condition and the recommended surgical, medical, or diagnostic procedure so that you may decide whether or not to undergo the procedure after knowing the risks involved and any treatment alternatives available to you. This information is not meant to alarm you; it is an effort to make you better informed so that you may give or withhold your consent to the procedure. If you do not understand any of the information provided, ask your physician to explain it to you. You may have additional consent discussions regarding: anesthesia, the administration of blood or blood products, certain medications, or additional persons involved in the procedure you are consenting to.

REASON FOR PROCEDURE: I (we) voluntarily request my physician, \_\_\_\_\_, and such associates, technical assistants, and other health care providers as they may deem necessary, to treat my condition: **Bladder cancer.**

**PROCEDURE(S):** I (we) understand that the following surgical procedure(s) is planned for me on or about (month) \_\_\_\_\_ (day) \_\_\_\_\_ (year) \_\_\_\_\_. I voluntarily consent to and authorize this (these) procedure(s): **Instillation of of Bacillus Calmette Guerin (BCG).**

**Procedure Description:** This procedure involves placing a medication directly into your bladder. This is done using a urinary catheter. A catheter is a long thin tube. The medication in this case is BCG (Bacillus Calmette Guerin).

Your provider will insert the catheter into your bladder. This will allow urine to drain from the bladder. Your provider will put the medication into your bladder through the catheter. Your provider will remove the catheter after treatment. You will be asked to hold the drug in your bladder for a period of time.

You may receive this treatment a number of times for several weeks or months. The total number of treatments varies. Your doctor will advise you during the treatment course.

**Proposed Benefit(s):** This procedure may delay the spread of cancer. It may prevent cancer from coming back. You may have fewer side effects compared to other therapies.

**Site or location of the operation/procedure:** See description of treatment/procedure.

**MATERIAL RISKS:** Just as there may be risks and hazards in continuing my present condition without treatment, there are also risks related to the performance of the surgical, medical and/or diagnostic procedure(s) planned for me, including:

- Cancer may not be cured. It may come back.
- Fever.
- Flu-like symptoms.
- Pain or discomfort.
- Risks to the unborn baby if you become pregnant during treatment.
- The procedure may need to be repeated.
- The procedure may not cure or relieve your condition of symptoms. They may back and even worsen.
- You may need additional tests or treatment
- Irritation or inflammation of the bladder and/or urethra.
- Reaction to local anesthesia or other medicines given during or after the procedure.
- Reaction to the medicine(s) given or used during or after the procedure.
- Sepsis, a dangerous infection of the blood or other tissues.
- Urinary tract infection.
- Bladder inflammation, leading to scarring, contraction, smaller bladder capacity, or pain.
- Burning or bleeding from the urethra during or after the procedure.
- Damage to the bladder or nearby structures. This may be discovered during the procedure or later. You may need a catheter or surgery.
- Inability to urinate. You may need a catheter to empty the bladder.
- Urinary tract after procedure. This can include difficulty holding urine, frequent urination, bleeding, and pain. These may be temporary or permanent.
- Damage to the urethra, bladder, or nearby organs. This may be discovered during the procedure, or later.

Additional material risks of surgical, medical and/or diagnostic procedure(s) include: death, cardiac arrest, brain damage, disfiguring scar, paralysis or partial paralysis, loss or loss of function a limb or organ, blood clots in veins or lungs, severe loss of blood, allergic reaction, and infection.

**ALTERNATIVES TO PROCEDURE:** The following practical alternatives to this procedure, including the risks and benefits of those alternatives, have been discussed with me:

- Watching and waiting with the doctor.
- Other drug treatments put into the bladder.
- Intravenous chemotherapy.
- High-dose vitamin therapy.
- Radiation therapy. Radiation therapy uses high-dose x-rays to kill cancer cells.

- Surgery of the bladder
- You may choose to not have this procedure.

**LIKELY OUTCOME IF NO TREATMENT:** I have been informed of the likely outcome if no treatment is provided, as follows: If you choose not to have this procedure, bladder cancer may come back. It may grow and spread. It may be difficult or impossible to treat at a later time. Cancer can lead to death.

**TREATMENT LIMITATIONS:** I impose no specific limitations or prohibitions regarding treatment other than those that follow:

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**DISPOSAL OF TISSUE:** I (we) authorize the disposal of any surgically removed tissue or parts resulting from the procedure according to accustomed practice.

**BLOOD PRODUCTS:** I (we) understand that if blood products are required, their use may improve my overall condition or save my life. I (we) understand that certain complications may result from the use of blood products. The more common risks include (but are not limited to) infection/irritation where the needle is placed, fever, chills, and skin rashes. Other rare but more serious complications may occur such as allergic reactions, shock, or death. I also know there is a very small risk of infection, including the risk of hepatitis {<1 in 200,000} and/or HIV/AIDS {<1 in 2 million}.

I (we), **consent** to the use/administration/transfusion of blood products as deemed necessary.

I (we), **do not consent** to the use/administration/transfusion of blood products as deemed necessary.

**CONSENT TO TREATMENT OF UNFORESEEN CONDITIONS:** I (we) understand that my physician may encounter or discover other or different conditions which require additional or different procedures than those planned. I (we) authorize my physician, and associated technical assistants, and other health care providers to perform such other procedures which are advisable in their professional judgment.

**OUTCOME:** I (we) understand that the practice of medicine is not an exact science, and that no warranty or guarantee has been made to me as to result or cure.

**CONSENT TO TRAINING PARTICIPATION:** My physician or this facility may have an educational role in the training of paramedical personnel.

Admittance of students and/or technical representatives

I (we) consent to the admittance of students and/or technical representatives for the purpose of advancing medical education and/or product usage.

I (we) do not consent to the admittance of students and/or technical representatives for the purpose of advancing medical education and/or product usage.

Admittance of students and/or technical representatives

I (we) consent to the participation of students and/or technical representatives for the purpose of advancing medical education and/or product usage.

I (we) do not consent to the participation of students and/or technical representatives for the purpose of advancing medical education and/or product usage.

**PHOTOGRAPHY:** I (we) agree that still or video photography, audio recordings, or medical data may be taken during these treatments/procedures. These may be placed in my permanent medical record. I (we) agree that these images, recordings, or data may be used for education, training, or performance improvement programs as long as no information that could identify me is used.

**MEDICAL DEVICES:** I (we) accept that during the treatments/procedures, the doctor or dentist may need to place a medical device in my body. If a medical device is implanted in my body, personal information (such as my name, social security number, and medical information) will be given to the maker of the device for quality control purposes.

**CONSENT:**

I (we) have been given sufficient opportunity to ask questions about my condition, alternative treatments, risks of treatment, the procedures to be used, and the risks and hazards involved. All of my questions have been answered to my satisfaction, and I (we) have sufficient information to give this informed consent. I hereby consent to the procedure described above.

I (we) certify that this form has been fully explained to me (us), and that I (we) have read it, or have had it read to me (us), that the blank spaces have been filled in and that I (we) understand its contents.

\_\_\_\_\_  
Signature of patient or person authorized  
to give consent

\_\_\_\_\_  
(Relationship to patient)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of patient or person authorized to give consent

\_\_\_\_\_  
Signature of Witness (Include Position I Title)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Witness

\_\_\_\_\_  
To Be Completed By Physician After Patient Consent Completed:

I certify that the procedure(s) described above, including the risks, possible complications, anticipated results, alternative treatment options, including non-treatment, have been explained by me to the patient or his or her legal representative before the patient or his/her legal representative consented.

\_\_\_\_\_  
Signature of Treating Physician

\_\_\_\_\_  
Date