HIGHLAND HOSPITAL
STRONG MEMORIAL HOSPITAL
CONSENT FOR DEVICE IMPLANT
SH 419ICD MR

419

☐ Inpatient
☐ Outpatient
☐ ED

Patient Name: _____ DOB: _____

I hereby give my consent and authorize

_____

(The list of possible assistants, all of whom are privileged to provide surgical services at the hospital, is available)

to treat the following conditions:

Abnormal heart rhythm(s), congestive heart failure, syncope or fainting.

by performing the following procedure(s) (when appropriate, specify site and laterality; for serial procedures, indicate expected frequency and duration, not to exceed one year):

To implant or revise, replace or remove a pacemaker, defibrillator (ICD) or loop recorder. After anesthesia or intravenous sedation and sterile preparation, one or more incisions will be made and a pocket created or revised for the pacemaker, ICD or loop recorder under the skin. One or more pacemaker or ICD leads may be positioned or removed from the heart. X-ray (fluoroscopy), ultrasound, contrast dye, and cardioversion of abnormal heart rhythms may be used. The device battery will require replacement eventually.

1. The care provider has explained my condition to me, the benefits of having the above treatment procedure, and alternate ways of treating my condition. I understand that no guarantees have been made to me about the result of the treatment. The alternatives to this procedure include:

   Not performing the procedure.

2. The care provider has discussed with me the reasonably foreseeable risks of the treatment and that there may be undesirable results. The risks that are specifically related to this procedure include:

   Bleeding or bruising at implant sites; infection or erosion through the skin (possibly requiring removal of the device and leads); bleeding around the heart (cardiac tamponade); injury to blood vessels, heart valves or other organs; pneumothorax (collapsed lung); possible need for elective or emergent surgery or procedure to repair an injury; possible need for re-operation due to lead dislodgment or other abnormality of the device system; irregular heart rhythms which could require cardioversion shock, blood clot, allergic reactions; respiratory (breathing) depression which could require assisted breathing with a respirator (breathing machine) x-ray induced skin injury or other risks; possible need for blood transfusion; stroke; myocardial infarction; or death.

3. I understand that during the treatment a condition may be discovered which was not known before the treatment started. Therefore, I authorize the care provider to perform any additional or different treatment which is thought necessary and available.

4. I consent to the administration of local, regional or general anesthesia and/or sedation as deemed most appropriate for the procedure to be performed. (The list of possible anesthesia providers, all of whom are credentialed to provide anesthesia at this hospital, is available).

5. Any tissue, parts, or substances removed during the procedure may be retained or disposed of in accordance with customary scientific, educational and clinical practice.

6. If a vendor representative is expected to be present during my procedure, it has been explained to me that the vendor representative works for: _____ (manufacturer of the device to be used) and that his/her role includes: ☐ helping the OR staff prepare the device my doctor has chosen, ☐ providing information and support to hospital staff regarding the device, ☐ other, including any hands on assistance (describe): _____.

   I consent to the vendor representative's presence and involvement as described. If circumstances change and a decision is made during my procedure that a vendor representative's presence is needed, I will be notified of the above after my procedure is completed.

(continued on back)

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Patient Name: _____ DOB: _____

7. **Patient Consent for Medical or Surgical Procedure: I have carefully read and fully understand this informed consent form, and have had sufficient opportunity to discuss my condition and the above procedure(s) with the care provider and his/her associates, and all of my questions have been answered to my satisfaction.**

Patient Sign here →

_____ _____ _____
Signature of Patient Date Time

_____ _____
Signature of Parent or Legal Guardian (if Patient is unable to sign or is a minor) Relationship to the Patient

Complete this section for all OR procedures and all other invasive internal procedures performed in any setting.

8. **Consent for Receipt of Tissue(s):**
   - ☐ yes (please list), _____
   - ☐ not expected to be needed, but may be required and given in an emergency
   - ☐ refused
   - ☐ n/a

9. **Consent for Blood Transfusion:**
   - ☐ yes
   - ☐ not expected to be needed, but may be required and given in an emergency
   - ☐ refused. Refer to SMH Policy 9.18 (Refusal of Blood (or Blood Products) Transfusions or HH Policy 4.1 (Blood Transfusion-Refusal to Permit).
   - ☐ n/a

   For procedures that have the potential for significant blood loss and instances where blood products may be required in an emergency, I consent to the transfusion of blood or blood components that may be necessary before, during, or after the procedure. I have been informed that transfusion is not 100% safe. Risks include lung injury, fluid overload, rash, fever, chills, allergic reaction, weakened immune system, infection from bacteria, viruses, or parasites, including but not limited to HIV (the AIDS virus) and hepatitis, and death. I have discussed possible alternatives with my care provider, including no transfusion, autologous (my own blood) donation, cell salvage, drugs which cause my body to make more blood, and drugs which can decrease bleeding. I understand that these alternatives may not be available due to timing or health reasons and the above risks may still apply.

10. **Patient Consent for Blood/Tissue: I have had a chance to discuss the risks, benefits and alternatives regarding transfusion/receipt of tissue (as above) with my healthcare provider. My decision(s) regarding the transfusion of blood or blood components and/or the receipt of tissue are as above. I understand this covers my perioperative/periprocedural (before, during, and after the surgery/procedure) course of treatment.**

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_____ _____ _____
Signature of Patient Date Time

_____ _____
Signature of Parent or Legal Guardian (if Patient is unable to sign or is a minor) Relationship to the Patient

ATTESTATION

I have discussed the planned procedure, including the potential for any transfusion of blood products or receipt of tissue as necessary, expected benefits, the potential complications and risks and possible alternatives and their benefits and risks with the patient or the patient's surrogate. In my opinion, the patient or the patient's surrogate understands the proposed procedure, its risks, benefits, and alternatives.

Provider Sign here →

_____ _____ _____
Signature of Care Provider Date Time

_____
Printed name and title