I hereby give my consent and authorize


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

to treat the following conditions:

**Closure of Atrial Septal Defect (ASD) or Patent Foramen Ovale (PFO)**

by performing the following procedure(s):

*A thin hollow tube (catheter) with an echocardiogram probe will be inserted into a vein, following local anesthesia with lidocaine, and directed to the heart under x-ray guidance. A second catheter, with the closure device attached, will be directed to the hole (ASD/PFO) under echocardiography and x-ray guidance. Once the catheter crosses through the opening, the device will be deployed (released).*

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 to do 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, infection, blood vessel damage, need for blood and/or blood components, blood clot formation, stroke, heart attack, abnormal heart rhythm, need for emergency surgery, kidney damage, puncture of the lung, radiation induced skin injury, death.*

3. I understand that during the treatment a condition may be discovered which was not known about 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. At the discretion of the doctor I consent to the presence of manufacturer’s representatives to aid in the service and correct calibration of the correct instrumentation. I understand that at no time will these representatives actively participate in my procedure.

(continued on back)
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.

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

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

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).

For those procedures that have the potential for significant blood loss, 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 no transfusion is 100% safe, however present testing methods make the risks of infection very small. Risks include infection from viruses, bacteria, or parasites, including but not limited to HIV (the AIDS virus) and hepatitis, as well as fever, chills, allergy, volume overload, or death. I have discussed possible alternatives with my care provider, including no transfusion, autologous transfusion (donation of my own blood), designated/directed donor transfusion (collection of blood from donors selected by me) or blood salvage during the procedure. 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.

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.

Signature of Care Provider

Date

Time

Printed name and title