DISCLOSURE AND CONSENT FOR THERAPEUTIC ANGIOGRAPHY - EMBOLIZATION AND SCLEROSIS

TO THE PATIENT: You have the right to be informed about 1) your condition, 2) the recommended medical care or surgical procedure, and 3) the risks related to this care/procedure. This disclosure is designed to provide you this information, so that you can decide whether to consent to receive this care/procedure. Please ask your physician/health care provider any remaining questions you have before signing this form.

Description of Medical Care and Surgical Procedure(s)
I voluntarily request my physician/health care provider _____and other health care providers, to treat my condition which is:

_____
(Diagnosis)

I understand that the following care/procedure(s) are planned for me (patient/other legally responsible person initial):

_____ Therapeutic Angiography with Occlusion Techniques (Embolization and Sclerosis)

Potential for Additional Necessary Care/Procedure(s)

I understand that during my care/procedure(s) my physician/health care provider may discover other conditions which require additional or different care/procedure(s) than originally planned.

I authorize my physicians/health care providers to use their professional judgment to perform the additional or different care/procedure(s) they believe are needed.

Use of Blood - Please initial "Yes" or "No":

_____ Yes ____ No I consent to the use of blood and blood products as necessary for my health during the care/procedure(s). The risks that may occur with the use of blood and blood products are:

1. Serious infection including but not limited to Hepatitis and HIV which can lead to organ damage and permanent impairment.
2. Transfusion related injury resulting in impairment of lungs, heart, liver, kidneys, and immune system.
3. Severe allergic reaction, potentially fatal.

Photographing or Videotaping - Please initial "Yes" or "No":

____ Yes ____ No I consent to the photographing or videotaping of the operations or procedures to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, providing my identity is not revealed by descriptive texts accompanying the pictures.

Manufacturer's Technical Representatives - Please initial "Yes" or "No":

____ Yes ____ No I consent to have one or more manufacturer's technical representatives, as requested by my physician in the room during the procedure. I understand that one or more representatives from the equipment and/or Supply Company for the products the physician will use during my procedure, may be present for the procedure but will not perform any portion of the procedure. I further understand that all manufacturer's technical representatives present have confidentiality agreements and that none of my personal health information will be disclosed to anyone other than my caregivers with the hospital.

____ Yes ____ No I consent to the disposal by hospital authorities of any tissue or parts which may be removed.

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Risks Related to this Care/Procedure(s)

Just as there may be risks and hazards to my health without treatment, there are also risks and hazards related to the care/procedure(s) planned for me.

I understand that all care/procedure(s) involve some risks, ranging from minor to severe. These risks include infection, blood clots in veins, lungs or other organs, hemorrhage (severe bleeding), allergic reactions, poor wound healing, and death.

The chances of these occurring may be different for each patient based on the care/procedure(s) and the patient's current health.

Risks of this care/procedure(s) include, but are not limited to **[include additional risks if any]:**

- Unintended injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention
- Hemorrhage (severe bleeding)
- Damage to parts of the body supplied by the artery with resulting loss or amputation (removal of body part)
- Contrast nephropathy (kidney damage due to contrast agent used during procedure)
- Paralysis (inability to move) and inflammation of nerves (for procedures involving blood vessels supplying the spine)
- Unintended thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere
- Worsening of the condition for which the procedure being done
- Loss or injury to body parts with potential need for surgery, including death of overlying skin for sclerotherapy/treatment of superficial lesions/vessels and nerve injury with associated pain, numbness or tingling or paralysis (inability to move)
- Infection in the form of abscess (infected fluid collection) or septicemia (infection of blood stream)
- Nontarget embolization (blocking of blood vessels other than those intended) which can result in injury to tissues supplied by those vessels
- For procedures involving the thoracic aorta and/or vessels supplying the brain, spinal cord, head, neck or arms these risks include stroke, seizure, paralysis (inability to move), inflammation or other injury of nerves
- For studies of the blood vessels of the brain: contrast related, temporary blindness or memory loss
- For female pelvic arterial embolizations including uterine fibroid embolization additional risks include premature menopause with resulting sterility, injury to or infection involving the uterus which might necessitate hysterectomy (removal of uterus) with resulting sterility, prolonged vaginal discharge after fibroid embolization, expulsion/delayed expulsion of fibroid tissue possibly requiring a procedure to deliver/remove the tissue after fibroid embolization.
- **For male pelvic arterial embolizations, impotence (difficulty with or inability to obtain penile erection)**
- For embolizations of pulmonary arteriovenous fistula/malformations, additional risk include new or worsening pulmonary hypertension (high blood pressure in the lung blood vessels), paradoxical embolization (passage of air or occluding device beyond the fistula/malformation and into the arterial circulation) causing blockage of blood flow to tissues supplied by the receiving artery and damage to tissues served (for example the blood vessels supplying the heart which could cause chest pain and/or heart attack) or brain (which could cause stroke, paralysis (inability to move) or other neurological injury).
- For varicocele embolization, additional risks include phlebitis/inflammation of veins draining the testicles leading to decreased size and possibly decreased function of affected testis and sterility (if both sides performed), nerve injury
- For cases utilizing ethanol (alcohol injection, additional risk include shock or severe lowering of blood pressure
- _____
- _____

PATIENT IDENTIFICATION

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Granting of Consent for this Care/Procedure(s)
In signing below, I consent to the care/procedure(s) described above. I acknowledge the following:

- I understand this care/procedure(s) does not guarantee a result or a cure to my condition.
  - I have been given an opportunity to ask questions I may have about:
    1. Alternative forms of treatment,
    2. Risks of non-treatment,
    3. Steps that will occur during my care/procedure(s), and
    4. Risks and hazards involved in the care/procedure(s).
  - I believe I have enough information to give this informed consent.
  - I certify this form has been fully explained to me and the blank spaces have been filled in.
  - I have read this form or had it read to me.
  - I understand the information on this form.

If any of those statements are not true for you, please talk to your physician/health care provider before continuing.

Patient/Other Legally Authorized Representative (signature required):

Print Name _____ Signature _____

If Legally Authorized Representative, list relationship to Patient: _____

Date: _____ Time: _____ AM/PM

Witness:

Print Name _____ Signature _____

Address (Street or P.O. Box) _____

City, State, Zip Code _____

Second Witness if Telephone Consent:

Print Name _____ **Signature** _____

Language Services Used ☐ **Yes** ☐ **No** **Language Provider Confirmation Number:** _____

Physician Attestation
I have explained the Risks, Hazards and Benefits involved in the medical care, technical and/or surgical procedure(s) outlined on this consent form to the patient or the person authorized to give informed consent prior to their consent. If written materials explaining the Risks/Hazards/Benefits are required to be provided to the patient by the provider performing the medical care and/or surgical procedure, those have been provided.

Physician Signature: _____ Date: _____ Time: _____ AM/PM _____

Consent and Disclosure Form Adopted from the Texas Administrative Code Figure: 25 TAC §601.4(a)(1).