Affix Patient Label	
Patient Name:	Date of Birth:

Informed Consent: Cerebral Angiography with Possible Percutaneous Transluminal Angioplasty and/or Stent Placement

This information is given to you so that you can make an informed decision about having a **Cerebral Angiography with Possible Percutaneous Transluminal Angioplasty and/or Stent Placement**. This procedure is most often done with moderate sedation or anesthesia.

Reason and Purpose of this Procedure:

In this procedure, a contrast (dye) is sent into your bloodstream. This helps the doctor watch blood flow to your brain. The doctor may see blocks or narrow arteries. The doctor may use a balloon inflated in the area of narrowing to open up the artery, place a stent (a tiny tube-like device) in the artery to keep it open, or may utilize another method to fix the problem.

Benefits of this Procedure:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Diagnose intracranial and/or carotid vascular disease. Help decide the best way to treat the disease.
- If you have intracranial and/or carotid blood vessel blockage, a balloon, stent, or other method may relieve the symptoms caused by the blockage.

General Risks of Procedures:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

- **Clots may form in the legs, with pain and swelling.** These are called DVTs or deep vein thrombosis. Rarely, part of the clot may break off and go to the lungs. This can be fatal.
- **A strain** on the heart or a stroke may occur.
- **Bleeding** may occur. If bleeding is excessive, you may need a transfusion.
- **Reaction to the anesthetic** may occur. The most common reactions are nausea and vomiting. In rare cases, death may occur. The anesthesiologist will discuss this with you.

Risks of this Procedure:

- **Abnormal heart rhythms.** Fluids, medicines or permanent pacing may be needed.
- **Allergic reaction to the contrast.** Fluids and /or medications may be needed.
- **Blood loss.** Fluids or a blood transfusion may be needed.
- **Brain hemorrhage (bleeding in the brain).** You may need hospitalization and treatment.
- **Bleeding and/or swelling at the puncture site.** Bleeding can occur at the catheter insertion site and cause a hematoma (blood under the skin with swelling). This may need surgery.
- **A puncture site closure device may be used to close the vessel**. Rarely, this can be dislodged.
- **Contrast induced renal failure or CIRF.** There is a risk of kidney failure caused by the contrast used during the procedure. This risk is higher for people with poor kidney function, kidney transplant, taking ACE (Angiotensin-converting-enzyme) inhibitors, NSAIDS (non-steroidal anti-inflammatory drugs) or metformin and people over the age of 70. You may need to stay in the hospital longer.
- **Infection.** Infection may occur in the wound. Antibiotics or other treatment may be needed.
- **Stroke.** There is a risk of stroke or worsening of a suspected stroke caused by the catheter. While being moved

through the arteries the catheter could break off a plaque. This could block a smaller blood vessel in the brain and lead to another stroke. Rehabilitation may be needed.

- **Vessel dissection.** Damage to an artery from the catheter. Rarely, this damage could lead to loss of function of the affected arm or leg.
- **Additional tests or treatment may be needed.** The procedure may not cure or relieve your condition. After treating a stenosis, it may recur in the future and need another procedure.
- **Emergency surgery.**
- **Death** may occur.

Risks Associated with Smoking:

Smoking is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks Associated with Obesity:

Obesity is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks Specific to You:

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Alternative Treatments:

Other choices:

- Observation.
- Medicine(s) to relieve symptoms.
- Do nothing. You can decide not to have the procedure.

If you Choose not to have this Treatment:

- Your symptoms may get worse.

Information on Moderate Sedation:

You will be given medicine in an IV to relax you. This medicine will also make you more comfortable. This is called “moderate sedation”. You will feel sleepy. You may even sleep through parts of your procedure. We will monitor your heart rate and your blood pressure. We will also monitor your oxygen level.

If your heart rate, blood pressure or oxygen levels fall outside the normal range, we may give medications to reverse the sedation. We may be unable to reverse the sedation. We may need to support your breathing.

Even if you have a NO CODE status:

- You may need intubation to support your breathing.
- You may need medications to support your blood pressure.

We will re-evaluate your medical treatment plan and your NO CODE status when sedation has cleared your body.

Benefits of Moderate Sedation:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Less pain during the procedure.
- Less anxiety or worry.
- Decreasing your memory of the procedure.

Risks of Moderate Sedation:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect. The list includes:

- Decreased breathing during the procedure and dropping oxygen levels. To help you breathe, a tube may be placed into the mouth or nose and into the trachea to help you breathe.
- Allergic reactions: nausea & vomiting, swelling, rash.
- Vomit material getting into the lungs.
- A drop in blood pressure. This needs fluids or medicine to increase blood pressure.
- Heart rhythm changes that may require medicines to treat.
- Not enough sedation or analgesia resulting in pain or discomfort.

Your physical and mental ability may not be back to normal right away. You should not drive, or make important decisions for at least 24 hours after the procedure.

General Information:

During this procedure, the doctor may need to perform more or different procedures than I agreed to.

During the procedure, the doctor may need to do more tests or treatment.

Tissues or organs taken from the body may be tested. They may be kept for research or teaching. I agree the hospital may discard these in a proper way.

Students, technical sales people and other staff may be present during the procedure. My doctor will supervise them.

Pictures and videos may be taken during the procedure. These may be added to my medical record. These may be published for teaching purposes. My identity will be protected.

Medical Implants/Explants:

I agree to release my social security number, my name and address, and my date of birth to the company that makes the medical device that is put in or removed during this procedure. Federal laws and rules require this. The company will use this information to locate me.

Affix Patient Label	
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By signing this form, I agree:

- I have read this form or had it explained to me in words I can understand.
- I understand its contents.
- I have had time to speak with the doctor. My questions have been answered.
- I want to have this procedure: **Cerebral Angiography with Possible Percutaneous Transluminal Angioplasty and/or Stent Placement** ☐ Right | ☐Left | ☐ Other ___________________ | ☐ ______________ (target vessel)
- I understand that my doctor may ask a partner to do the procedure.
- I understand that other doctors, including medical residents or other staff may help with the procedure. The tasks will be based on their skill level. My doctor will supervise them.

Provider: This patient may require a type and screen or type and cross prior to procedure. If so, please obtain consent for blood/products.

Patient Signature: ____ Date: __________ Time: __________

Relationship: ☐ **Patient** ☐ **Closest relative (relationship)** ___________ ☐ **Guardian/POA Healthcare**

Reason patient is unable to sign: ____ ☐ Telephone Consent Obtained

First Witness Signature: _____________ Second Witness Signature: ____________ Date: __________ Time: __________

(One witness signature MUST be from a registered nurse (RN) or provider)

Interpreter's Statement: I have interpreted the doctor's explanation of the consent form to the patient, a parent, closest relative or legal guardian.

Interpreter's Signature: _________________________________ ID #: __________ Date: __________ Time: __________

For Provider Use ONLY:

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Provider signature: ____ Date: ___________ Time: __________

Teach Back:

Patient shows understanding by stating in his or her own words:

_______ Reason(s) for the treatment/procedure: ____

_______ Area(s) of the body that will be affected: ____

_______ Benefit(s) of the procedure: ____

_______ Risk(s) of the procedure: ____

_______ Alternative(s) to the procedure: ____

OR

_______ Patient elects not to proceed: ______________________________ Date: ___________ Time: ___________

(Patient signature)

Validated/Witness: ____ Date: ___________ Time: ___________