Consent for Coronary Angiography ("Heart Dye-Study") and/or an Intervention Procedure ("Opening blood vessels in the heart")

We are asking you to sign this form because it is very important that you be part of the decisions about your care. It is important to understand the procedure, its risks, benefits and alternatives. Your doctor will talk with you about these. Be sure you get your questions answered before you sign this Consent Form. Please initial and date here to show that you understand.

__________________________  _________________________
Patient’s initials or authorized individual  Date

I hereby authorize Dr. Biran Williams and any associates/assistants to perform the following procedure: **Coronary angiogram with possible percutaneous coronary intervention.**

Cardiac catheterization is a medical procedure used to diagnose and treat certain heart conditions. A long, thin, flexible tube called a catheter is put into a blood vessel in the arm, upper thigh (groin), or neck and threaded up into the heart. Through the catheter, doctors can perform diagnostic tests and treatments on the heart.

During the procedure, a special dye is put into the catheter to make the inside of the heart and blood vessels show up on x-rays; this is known as **coronary angiography** (Figure 1). Angiography can help your doctors determine if the blood vessels that supply your heart have any blockages that may be giving you symptoms or may put you at increased risk for a heart attack.

Figure 1

If a vessel is blocked, your doctor may decide to treat the blockage with an angioplasty and/or a stent implant. (If your doctor decides that surgery is needed instead of a procedure, a coronary artery bypass graft (CABG) may be done at a later time.)

**Angioplasty:** In this procedure an expandable balloon on a catheter is used to help unblock arteries. The balloon expands and presses the plaque blockage against the artery wall (Figure 2). The procedure opens the artery and allows better blood flow.
**Stent Implant:** A catheter is used to deliver a small metal mesh tube (stent) to a blockage in an artery (Figure 3). A stent, which helps keep the artery open, is often implanted after angioplasty.

The doctor has explained the benefits of the procedure(s) to me. I understand there is no guarantee that I will achieve those benefits. I understand that unknown things may happen during this procedure. Because of that, a different procedure may be needed. Therefore, I authorize the doctor, associates, or assistants to perform any procedure(s) needed to best take care of me. I authorize sedation and/or anesthesia to be given to me for my comfort, well-being, and safety. This would be done by: WESTPORT ANESTHESIA or CARDIOTHORACIC ANESTHESIA ASSOCIATES

The doctor has explained to me that there are risks with this procedure. It is possible that unexpected things may happen. These might include, but are not limited to:

**Risk of In-Hospital Complication**
Ranges of outcome(s) for patients with similar clinical profiles

<table>
<thead>
<tr>
<th></th>
<th>Percent (%) chance</th>
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<tbody>
<tr>
<td>Death</td>
<td>0.6</td>
</tr>
<tr>
<td>Bleeding</td>
<td>5.49</td>
</tr>
</tbody>
</table>

where Death denotes the risk of death and Bleeding denotes the risk of major bleeding. It is important to understand that your risk of dying in the hospital after the procedure is mostly related to how sick or healthy you are prior to the procedure. Death as a direct result of the procedure is a very rare event.

I understand that my procedure must be performed with x-ray. X-ray exposure may lead to radiation injury that can include but is not limited to skin burns and/or skin breakdown that may show up months or years after the procedure.

My doctor or a designated health care professional will inform me if I am exposed to an x-ray dose that might result in radiation injury and I will receive specific skin care instructions.
Sometimes after opening a blocked artery the artery closes again. This procedure may need to be done again. There are 2 types of stents that can be used to keep arteries open, bare metal stents or drug eluting stents. After either type of stent, patients must take aspirin plus a blood thinner, like Plavix. Patients with drug eluting stents need to take this medicine for longer than patients with a bare metal stent. Patients with a drug eluting stent may need to take the medicine for at least 1 year. This extra medicine can be costly, depending on your insurance. It is important to take the medicine until your doctor tells you to stop. The graphs show your chance for another procedure in the next year if you are treated with a bare metal or a drug eluting stent:

![Graph showing Restenosis Risk (%)](image)

**Restenosis Risk (%)**
Ranges of outcome(s) for patients with similar clinical profiles

<table>
<thead>
<tr>
<th></th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bare Metal</td>
<td></td>
<td>16.04</td>
<td></td>
</tr>
<tr>
<td>Drug Eluting</td>
<td></td>
<td>9.85</td>
<td></td>
</tr>
</tbody>
</table>

Percent (%) chance of needing a repeat procedure within a year.

where **Bare Metal** is the risk of the vessel closing within the next year when a bare metal stent is used, and **Drug Eluting** is the risk of the vessel closing within the next year when a drug eluting stent is used.

**NOTE:** These graphs use data from many previously treated patients. It is important to know that your results may differ from these prior patients, even though they had similar medical conditions to you. It is impossible to predict for certain what will happen in your case. This information is not a guarantee of your results.

I understand that I may need a blood transfusion during the procedure. I know that there are risks with a transfusion. This might be fever, a kidney reaction, hepatitis, Acquired Immune Deficiency Syndrome (A.I.D.S.) or other infections.

Possible alternatives to the procedure have been explained to me. This includes not having this procedure at all. Other alternatives might include, but are not limited to:

If I get a medical device, my Social Security number can be released to the maker of the device. This is because of the Federal Food and Cosmetic Act section 519(e).
Because this facility is an academic hospital, my medical record may be used for scientific purposes. I understand I may be contacted in the future about my recovery from this procedure.

I consent to any photographing or videotaping of the procedure(s). The pictures or the words describing the pictures will not reveal my identity. I also consent to students or equipment representatives being in the procedure room. This is for medical education or to get important product information.

In the event that a health care worker is exposed to my blood, I consent to the drawing of my blood for testing for HIV or hepatitis infection.

________________________  ________________
Date                         Time

Patient / Other Legally Responsible Signature

________________________
Date

Certification of Witness

I hereby certify that I have witnessed or confirmed the patient /authorized individual's signature and have verified the following:

☐ The patient / authorized individual has read this form or had it read to him/her.
☐ The patient / authorized individual states that he/she understands this information.
☐ The patient / authorized individual has no further questions.

________________________  ________________
Date                         Time

Signature of Witness

________________________  ________________
Date                         Time

Signature of Witness

Certification of Physician

I hereby certify that I have discussed and explained the nature, purpose, benefits, and risks associated with this and any alternative procedure(s) described in this consent form with the individual granting consent. I have further discussed possible consequences of the procedure, the principle risks involved, and possible complications.

________________________  ________________
Date                         Time

Signature of Physician