**Executive Summary**

IRB XXX-XX

**Title of this Research Study**

**Description**

You are being asked to be in this research because you are having knee replacement surgery. Being in this research study is voluntary. You don’t have to participate.

**Purpose**

There are two main purposes of this study:

1. To see if using a medicine, tranexamic acid, is as good as using a tourniquet, to prevent bleeding during knee surgery. Doctors at UNMC usually use a tourniquet during knee surgery. Tranexamic acid is an approved medicine that helps decrease bleeding.

2. To see if using a tourniquet during surgery affects how well you walk 6 weeks after surgery. Using a tourniquet can injure nerves and muscles and can effect walking.

**Methods**

Before surgery you will have a walking test which involves walking on a mat. You will then be randomly assigned (like the flip of a coin) to either have your surgery with a tourniquet used or surgery with tranexamic acid but no tourniquet used.

Six weeks after your surgery you will come back to see your surgeon for regular follow-up. We will repeat the walking test then.

**Risks and Side Effects**

For both groups there is the risk that others who do not need to will see your information.

If you are in the tranexamic acid group (no tourniquet) there may be more bleeding or the surgery may take longer. Common side effects of tranexamic acid are headache, muscle pain, cramps, belly pain, nausea and vomiting. Serious but rare side effects are allergic reactions (which can be severe), seizures and blood clots (which can be serious or fatal).

If you are in the tourniquet group the risks are the same as if you weren’t in the research at all.

**Potential Benefits**

If you are in the tranexamic acid group (no tourniquet) you may avoid the side effects of using a tourniquet (like muscle damage, pain after surgery, swelling and leg weakness). Your walking may be better after the operation, but we do not know this.

If you are in the tourniquet group you will not have any benefit from this research study

This study may help researchers know whether not using a tourniquet will mean better function after the operation.

**Alternatives**

Instead of being in this research study, you can choose not to participate. You will still have your surgery and your surgeon will use a tourniquet.

Talk to your investigator [or your doctor] about your choices before you choose if you will be in this study.

**Additional Information**

Your investigator will review the main consent with you. The main consent has a complete description of this study.

Note: Flesch-Kincaid Reading level 8.7; Flesch Reading Ease 60.8 (excluding study title)