

Informed Consent Form

Official Title: Extended Prophylactic Anticoagulation Following Spinal Surgery for Metastatic Disease

ClinicalTrials.gov ID (NCT number): Pending

Document Date: 7/13/2026



University of Pittsburgh

School of Medicine

Department of Neurological Surgery

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Extended prophylactic anticoagulation following spinal surgery for metastatic disease

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SOURCE OF SUPPORT: Beckwith Institute Frontline Innovation Program

PURPOSE OF STUDY:

Why is this study being done?

You are being asked to take part in this study because **you had surgery on your spine to treat cancer** that has spread (metastatic disease). People who have this type of surgery have a higher-than-normal chance of developing blood clots in their legs or lungs. These blood clots are called deep vein thrombosis (DVT, a clot in the leg) or pulmonary embolism (PE, a clot in the lung). Blood clots can cause pain, swelling, trouble breathing, and can sometimes be life-threatening.

In a recent review of patients at UPMC who had the same type of surgery you had, **about 15 out of 100 patients developed a blood clot within 90 days after leaving the hospital**. Right now, most patients receive blood-thinning medicine only while they are in the hospital. Once patients go home, they usually stop receiving this medicine. There is no standard guideline telling doctors whether blood-thinning medicine should continue after patients go home from spine surgery for cancer.

For other types of major cancer surgery (such as surgery on the abdomen), studies have shown that continuing blood-thinning medicine for about 4 weeks after surgery can help prevent blood clots. However, this has not been studied specifically in patients who have spine surgery for metastatic cancer.

The purpose of this study is to find out **if taking a blood-thinning medicine called apixaban (brand name Eliquis) by mouth for 30 days after you leave the hospital can help prevent blood clots**. Apixaban is already approved by the U.S. Food and Drug Administration (FDA) to prevent blood clots after hip and knee replacement surgery, but it is not specifically approved for use after spine surgery. The dose you will take in this study (2.5 mg twice a day) is the same dose approved by the FDA for preventing blood clots after joint replacement surgery.

About 50 people at UPMC will take part in this study. Your results will be compared to information from 68 patients who had the same type of surgery in the past but did not take apixaban after leaving the hospital.

STUDY PROCEDURES:

What will happen if I take part in this study?

Screening (before you enroll) Before you are asked to join the study, Dr. Bayley will look at your medical records to see if you may be eligible. This is a standard part of clinical research. You do not need to give separate permission for this review.

Enrollment (on the day you are discharged from the hospital) If you are eligible and agree to take part, you will be enrolled on the day you are ready to leave the hospital after your spine surgery. A member of the study team (either Dr. Bayley or a trained senior resident on the neurosurgery team) will explain the study to you, answer your questions, and ask you to sign this consent form. You will have as much time as you need to make your decision. You may also take this and discuss it with family or friends before deciding.

Before you enroll, the study team will confirm that you are alert, comfortable, and able to understand the study information. If you are still feeling effects from anesthesia or pain medicine that might make it hard to understand, the study team will wait until you feel ready.

Study medication If you agree to join the study, the study will provide apixaban (Eliquis) 2.5 mg tablets to you at no cost when you are discharged from the hospital. The study medicine will be prepared by the research pharmacy and given to you by a member of the study team on the day you leave the hospital. You will take **one tablet by mouth twice a day (morning and evening) for 30 days**, starting the day after you leave the hospital. Please take the medication as instructed on the label and call the research team if you have any questions.

Follow-up phone calls A member of the study team will call you by phone three times during the study. You do not need to come to the clinic for any extra visits as part of this study. The calls are:

Phone call 1 — about 2 days after you leave the hospital. This call will take about 5-10 minutes. We will ask how you are feeling, whether you have started taking the study medicine, and whether you have noticed any bleeding, bruising, or other side effects.

Phone call 2 — about 31 days after you leave the hospital (after you finish taking the study medicine). This call will take about 5-10 minutes. We will ask about any bleeding or blood clot symptoms, whether you had any problems taking the medicine, how many pills you have left (to check whether you were able to take the medicine as directed), and whether you have been to the emergency room or hospital since your last call.

Phone call 3 — about 91 days after you leave the hospital. This call will take about 5-10 minutes. We will ask about any blood clot symptoms, bleeding events, hospitalizations, and your overall health since your last call.

If we cannot reach you by phone, we will try again up to three times. You may also call the study team at any time if you have questions or concerns.

Medical Records As part of this study, we are requesting your authorization to review your medical records. This will allow us to determine whether you meet the conditions for participation in this study and during the study, we will also review your medical records to look for any blood clots, bleeding events, hospital visits, or other health changes. The information we collect includes:

Basic information about you (age, weight, type of cancer, prior treatments)

Details about your surgery (length of surgery, blood loss, hospital stay)

Any blood clot or bleeding events after surgery, along with any relevant test or images

Medications you are taking

Your responses during follow-up phone calls

All of this information will be entered into a secure, password-protected electronic database (REDCap) that is managed by the University of Pittsburgh. No research data will be placed into your medical record as a result of this study.

Length of your participation Your active participation in this study will last about **91 days** (approximately 3 months) from the day you leave the hospital. The study medicine is taken for the first 30 days only. After that, you will receive two follow-up phone calls to check on your health.

RISKS:

What are the risks of taking part in this study?

As with any research study, there are risks to taking part. The most important risks are described below. Please read this section carefully and ask the study team about anything you do not understand.

Risks from the study medication (apixaban/Eliquis)

Apixaban is a blood-thinning medicine. The main risk of any blood thinner is **bleeding**. Because this medicine reduces your blood's ability to clot, cuts, injuries, or surgical wounds may bleed more than usual or take longer to stop bleeding.

The bleeding risks described below are based on large studies of apixaban used at the same dose (2.5 mg twice daily) as in this study.

Common side effects (may affect up to 4 out of 100 people):

- Minor bleeding or bruising that does not require medical attention
- Nosebleeds
- Blood in urine (pinkish or reddish urine)
- Bruising more easily than normal
- Bleeding from gums
- Nausea

Occasional side effects (may affect up to 3 out of 100 people):

- **Clinically relevant non-major bleeding:** this means bleeding that is not life-threatening but may cause you to contact your doctor, temporarily stop the study medicine, or have difficulty with daily activities. Examples include prolonged nosebleeds, heavy menstrual bleeding, blood in your stool, or significant bruising.

Rare but serious side effects (may affect fewer than 1 out of 100 people):

- **Major bleeding:** this includes bleeding that causes a large drop in your blood count, requires a blood transfusion of 2 or more units, occurs in a critical part of the body (such as the brain, spinal canal, or behind the eye), or is life-threatening
- **Spinal epidural hematoma:** because you have had spine surgery, there is a specific risk that bleeding could occur around the spinal cord at your surgery site. This is a rare but serious complication that could cause numbness, weakness, or paralysis in the legs. This could also lead to you needing a re-operation at the surgery site to remove the epidural hematoma and your bleeding risk from that surgery would be elevated due to the increased bleeding from apixaban.
- **Fatal bleeding:** death from bleeding is extremely rare with apixaban at this dose.

Allergic reactions (rare):

- Some people may have an allergic reaction to apixaban. Symptoms may include skin rash, itching, swelling of the face or throat, or difficulty breathing.

Liver effects (rare):

- Apixaban may uncommonly cause changes in liver blood tests. Serious liver injury is very rare and usually goes away when the medicine is stopped.

Risks related to drug interactions:

Apixaban can interact with certain other medicines. Some medicines can increase the blood-thinning effect of apixaban (raising bleeding risk), and others can reduce its effect (reducing protection against blood clots). Before you enroll, the study team will review your medications to make sure none of them interact in a dangerous way with apixaban. You should tell the study team if you start any new medicines during the study, especially:

- Antifungal medicines (such as ketoconazole or itraconazole)
- HIV medicines (such as ritonavir)
- Seizure medicines (such as phenytoin or carbamazepine)
- The antibiotic rifampin
- Heart or blood pressure medicines called calcium channel blockers (such as diltiazem)
- Anti-inflammatory medicines like ibuprofen or naproxen (NSAIDs), which can increase bleeding risk when taken with apixaban
- Aspirin or other blood thinners

Risks from study procedures (phone calls and data collection):

The risks from the phone follow-up calls are minimal. There is a small chance that:

- You may feel uncomfortable answering some questions about your health.
- Although we will take steps to keep your information private, there is a small risk that your personal health information could be accidentally seen by someone not involved in the study. Phone conversations are not encrypted and could theoretically be overheard. We will not leave detailed health information on voicemail.
- You may experience some inconvenience from the time spent on phone calls.

Risks from reviewing your medical records:

The risk from the research team looking at your medical records is a small chance that your private health information could be seen by someone outside the study team. We take steps to protect your information (described in the confidentiality section of this form).

Unknown or unforeseen risks:

There may be side effects or risks that researchers do not yet know about. Some of these unknown risks could be serious or long-lasting. If we learn about any important new risks during the study, we will tell you so you can decide whether you want to continue taking part.

Risks specific to your situation:

Because you have cancer that has spread to your spine, you may be at higher risk for both blood clots and bleeding than the general population. Your cancer, other treatments you may be receiving (such as chemotherapy), and your overall health condition may affect how apixaban works in your body. The study team will monitor you for these risks.

BENEFITS:

There is no established benefit to you from participating in this study. Based on existing data, we believe that participating in this study may reduce the risk of developing blood clots after surgery which will be beneficial, but this is the purpose of this study and has not been shown.

NEW INFORMATION:

If we learn of any new information about study risks that could cause you to change your mind about continuing to participate, we will notify you promptly.

COST AND PAYMENTS:

Neither you, nor your insurance provider will be charged for the cost of the procedures performed only for the purposes of this research study. The study will provide the study medication (apixaban) at no cost to you.

You and/or your insurer will be billed in the usual manner for your standard medical care (care you would receive even if you were not participating in this research study).

You will not be compensated for participating in this research study.

COMPENSATION FOR INJURY:

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not waive any rights by signing this form.

CONFIDENTIALITY:

Any information about you obtained from this research will be kept as confidential (private) as possible. Most information for this study will be stored electronically on our password-protected server using a coded ID rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. All paper records related to your involvement in this research study will be stored in a locked file cabinet. While we will protect your privacy and the confidentiality of your records, as described in this document, we cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University.

This research study will involve the recording of, past, current and/or future identifiable medical information from your hospital and/or other (e.g., physician office) records. The information that will be recorded will be limited to information concerning any changes to your health. This information will be used for the purpose of assessing potential changes related to study procedures.

Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for the purpose of ensuring the appropriate conduct of this research study. They may access your research records for the purpose of protecting human subjects and analyzing the study data. In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

Your information will be maintained by the investigators after your participation is completed. The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of seven years after final reporting or publication of a project. Per University policy, data will be maintained up to 7 years after completion of research study.

We may share your de-identified research information with other researchers interested in this topic at the University of Pittsburgh and researchers outside of the University.

We might use your research data in future studies. These future studies might be done by us or by other investigators. In most cases, before we use your data, we will remove any information that shows your

identity. There still may be a chance that someone could figure out that the information is about you.

RIGHT TO PARTICIPATE or WITHDRAW FROM PARTICIPATION:

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. You can do this by contacting Dr. Bayley by phone or in writing at the contact information listed on the first page and you will be withdrawn from the study immediately. Your decision to withdraw will have no effect on your current or future relationship with UPMC.

Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above. **If the investigators feel that you cannot complete the study requirements safely, they may withdraw you from the study. In the case of non-compliance with the study medication, the investigators may also withdraw you from the study.**

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider. Any of the data collected before you withdrew will be kept in a secure file cabinet with the rest of the identifiable data. The collection and storage of this data will follow the procedures that have been discussed previously in this document.

Your doctor may be involved as an investigator in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not obligated to be a part of any research study offered by your doctor.

VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that have occurred during my participation.

By signing this form, I consent to participate in this research study and provide my authorization to use and share my medical records. A copy of this consent form will be given to me.

Participant's Signature

Printed Name of Participant

Date

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date