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ATTACHMENT A: CONSENT FORM
JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

INFORMED CONSENT DOCUMENT

Patient Consent Form

Study Title: PREVENTion of Clot in Orthopaedic Trauma (PREVENT CLOT): A Randomized Pragmatic Trial Comparing the Complications and Safety of Blood Clot Prevention Medicines Used in Orthopaedic Trauma Patients

Principal Investigator: Robert O'Toole, MD (Clinical PI) and Renan Castillo, PhD (Research PI)
IRB No.:
PI Version Date: Version 5; 9/25/2020

You are being asked to volunteer to be a part of a research study. Please read this form carefully before you sign it. This consent form explains the research study and your part in the study. It is up to you whether or not you want to be in this study. If you decide not to join the study, there will be no impact on your medical care. If you decide to join the study, you may quit at any time. Please ask the study doctor or staff to explain any words or procedures that are not clear. Please ask as many questions as you like. All of your questions should be answered to your satisfaction before you sign this form.

1. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

People who have surgery or trauma are at risk for blood clots. The purpose of this research study is to help figure out the best way to prevent blood clots after trauma. Blood clots can be very serious and can lead to death. Right now, doctors use two different medicines to prevent blood clots, but they don't know which one is better. One of these medicines to prevent blood clots is called low molecular weight heparin, or Lovenox. The other medicine doctors sometimes use is aspirin. This study is being done to find out whether low molecular weight heparin (Lovenox/Enoxaparin) or aspirin is better in preventing life threatening blot clots in trauma patients. Patients who join this study will get either the low molecular weight heparin (Lovenox/Enoxaparin) or aspirin to prevent blood clots. The low molecular weight heparin (Lovenox/Enoxaparin) is given by injection (shot). The aspirin is a pill taken by mouth or given through a feeding tube. Patients in this study will start their medicine in the hospital and then take the same medicine once they go home. We will then compare the medicines to see which one was better at preventing blood clots.

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The PREVENT CLOT Study is funded by the Patient-Centered Outcomes Research Institute (PCORI). The study is being done in more than 20 major trauma centers across the United States and Canada, including military centers that are taking care of service members who were injured in the line of duty.

2. WHY AM I BEING ASKED TO PARTICIPATE?

You are being asked to join this study because you are at least 18 years old and have had a traumatic orthopaedic injury(ies) which puts you at increased risk of blood clots. Your doctor believes you need to take blood clot prevention medicine. People around the country who need to start blood clot prevention medicine after trauma are being asked to take part in this study. You are one of over 12,000 patients expected to join the PREVENT CLOT study.

3. HOW LONG WILL THE STUDY LAST?

If you agree to take part in this study, we will follow up with you for up to three months after admission to the hospital for your traumatic injury. If the research team is unable to get in contact with you or someone you know, a member of the research team will review your medical record in order to record any information that is usually collected during the follow up visit.

4. HOW DOES THE STUDY WORK?

If you agree to join the PREVENT CLOT Study you will be assigned randomly, or by chance, (like flipping a coin) to one of the two treatments being studied:

- Treatment A: Low molecular weight heparin (Lovenox/Enoxaparin) medicine given two times a day as a shot or injection.
- Treatment B: Aspirin medicine given two times a day in pill form by mouth or feeding tube.

You will get *one* of these medicines as part of your normal treatment for your injuries. If you were not in the study, your doctor would make the choice about which of these medicines you would receive. In ths study,you have an equal chance of getting either one of the treatments and the treatment you receive will be decided by chance and not by your treating physican. Deciding randomly who gets the low molecular weight heparin (Lovenox/Enoxaparin) and who gets the aspirin is the best way to find out which medicine is better at preventing blood clots. Right now, we don't know which medicine is better at preventing clots for people with traumatic injuries.

If you join the study, you will begin receiving medicine as soon as your doctors wants you to start taking medicine to prevent blood clots. Usually this is immediately after you are enrolled. When you are discharged from the hospital you will continue taking the same medicine you were assigned for however long your doctor wants. Being in the study does not affect how long you take your medicin; your doctor makes that decision based on the types of injuries you have and

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any other medical conditions you may have. For example, for some types of injuries doctors may give the medicine for several weeks after patients leave the hospital. For other types of injuries people may need to take the medicine for several months.

Following discharge we would like to contact you every week. At the end of this form you will able to let us know if you prefer to be contacted weekly by telephone call, text message or email, or not at all. These calls will come from a computerized system at the study coordinating center at Johns Hopkins. We will ask you how many times you took your medication that week and the interview will last for about 3 minutes. You will be able to let us know the best way to contact you at the end of this form. If you do not reply to these messages, a member of the study team may call you to see how things are going and if you no longer want to receive weekly contact you will be able to let the study team know at the end of the call, text or email. If you prefer you may complete a post card with a calendar telling us what days you took your medicine.

You will come back for your normal follow up clinic visit with your surgeon approximately 3 months after your hospitalization. When you come for the 3 month follow up, we will ask you to do a 15-30 minute interview for this study. You will be asked questions about how your recovery is going, your overall satisfaction with the medicine you took to prevent blood clots, and overall how much money you spent on the medicine you took to prevent blood clots. If you are not able to come back, we may contact you by telephone or email to do these interviews.

While you are in the study, a member of the research team at your medical center will also review your medical record to see if you had any blood clots or other visits related to your injury. Your medical record will also be reviewed to see if you were tested for COVID-19 and record the results of your test (positive or negative). Your COVID-19 results, along with all other information collected for the purposes of this study, will be kept confidential.

Option A: If you do not complete any study visits and the study team is unable to speak with you or someone else who knows how things are going with you, the study team will send information about you, which may include your name, data of birth, and social security number, to the study team at Johns Hopkins, where they will enter the information into a large administrative database called the Limited Access Death Master File, which maintains records of all deaths that have been recorded in the social security system. This may enable the team to determine why you cannot be contacted. Your data will not be recorded or maintained by the study team once the search is complete.

Opition B: If you do not complete any study visits and the study team is unable to speak with you or someone else who knows how things are going with you, the study team will enter information about you, which may include your name, data of birth, and social security number, into a large administrative database called the Limited Access Death Master File, which maintains records of all deaths that have been recorded in the social security system. This may enable the team to determine why you cannot be contacted. Your data will not be recorded or maintained by the study team once the search is complete.

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5. WHAT ARE THE POTENTIAL RISKS OR DISCOMFORTS?

This study is comparing two widely used medicines. Each of these medicines has benefits; each also has some risks.

The risks of taking either medication are as follows:

- **Risks of Treatment A (Low molecular weight heparin (Lovenox/enoxaparin)):** nausea; diarrhea, injection site irritation, bruising, pain or possible infection; allergic reaction ranging from hives and itching to difficulty breathing or throat swelling; Heparin Induced Thrombocytopenia which results in a reduced number of platelets and impaired ability to form clots; bleeding complications which could require transfusion or operation and kidney damage.
- **Risk of Treatment B (Aspirin):** Risk of inflammation or ulceration of the stomach, allergic reaction (ranging from hives and itching to difficulty breathing or throat swelling), ringing of the ears, and worsening asthma. Increased risk of bleeding and of kidney damage. Potential risk of Reyes syndrome in younger partitipants during influenza season. Symptoms of Reyes syndrome include: fever, lack of energy or interest in things, sleepiness, changes in personality, vomiting or diarrhea.

The following symptoms are uncommon but extremely serious risks that can be associated with these medication. If you experience any of the following risks you should immediately go to the nearest emergency room:

Signs of bleeding, includingvomiting blood or vomit that looks like coffee grounds; coughing up blood; blood in the urine, black, red or tarry stools, bleeding from the gums, abnormal vaginal bleeding; bruising without a reason or that get bigger; or any severe or persistent bleeding), Severe dizzinessFainting, Fall or head injury, Confusion, Severe headache, Burning or numbness feeling or loss of strength. Signs of significant allergic reaction, including (wheezing, chest tightness, fever, itching, tight cough; change in skin color; seizures or swelling of face, lips, tongue or throat.)

If any of those happens, we would appreciate your also letting the study team know as well, once you are stable and feel better.

6. WHAT ARE THE POTENTIAL BENEFITS?

Patients after trauma need a medicine to prevent blood clots. You will get a medicine that will prevent blood clots in this study. Beyond that, you will not benefit from being in this study, but your being in this study will help us learn, for patients in the future with trauma, which of the two medicines works best for preventing blood clots.

7. DO I GET ANY PAYMENT FOR BEING IN THE STUDY?

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You will receive $20 in recognition of your time and effort after completing the 3 month visit in person, over the phone or by email.

8. ARE THERE ANY COSTS INVOLVED IN BEING IN THE STUDY?

All charges associated with your treatment will be billed to you or your insurance. There are no increased costs for taking part in this research study. The costs of your usual medical care are not covered by the study but will be billed to your insurance or to you, just as usual.

9. WILL MY INFORMATION BE KEPT PRIVATE?

The information we collect from you will be kept private to the best of our ability. We will be collecting information about any treatment you received in the hospital and after you leave the hospital, and asking you questions about your recovery. Your name, birth date, medical record number and any other information that could identify you will not be recorded on these data collection forms. Instead, we will label your forms with a unique study number. The information we collect on a weekly basis through the phone calls, texts, or emails, will be stored in a separate database. We will link the information between these two databases using only the study number.The link between your name and your study number will be kept confidential to the greatest extent provided by law. The information collected for the study will be stored in a password protected, HIPAA compliant computer database that only authorized members of our research team can use. When we report the results of the study, we will combine the information about you with similar information about hundreds of other people, and without names. That way, your individual information will not be identifiable.

All study records will be considered confidential, and your name will not be used in reports or publications.

10. WILL YOU SHARE MY INFORMATION WITH OTHERS?

Your name and the phone number and/or email you provide will be shared with investigators at the data coordinating center at the Johns Hopkins Bloomberg School of Public Health if you choose to participate in this part of the study. This information will be stored separately from all study data, and will be used only for reaching out to you to see how things are going with taking your medicine every week. After your participation is the study is complete, we will destroy this information.

We will use the information we collect from you only for the purposes of this study. Large groups of data from the study may be published. You will never be identified by name. People from each participating research institution may look at sections of your medical and research records related to the study. This includes people designated by The Johns Hopkins Bloomberg School of Public Health who are overseeing this study. Everyone using study information will

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work to keep your personal information confidential. Your personal information will not be given out unless required by law.

The Patient-Centered Outcomes Research Institute (PCORI) is the group funding this study. Our funder and the ethics committee (IRB) are also allowed to look at research records if they believe it will help protect the people in the study.

11. WHAT ARE MY ALTERNATIVES TO PARTICIPATION?

Your alternative is to not take part. If you choose not to take part, your healthcare will not be affected and you will still receive blood clot prevention medicine. Your doctor will make the choice of what medicine to give you.

You may also participate in the study and choose not to participate in the weekly calls. This will not affect any other part of your participation in the study.

12. WHAT HAPPENS IF I LEAVE THE STUDY EARLY?

Your participation in this study is completely voluntary. You have the right to withdraw from the research study at any time without penalty. Your decision will not affect the medical care you receive. If you decide to stop participating, you should notify the study doctor or the research coordinator at your center.

You may choose to stop participating in the weekly contact at any time, and it will not affect your participation in the overall study.

Your participation in this research study could be ended by the researchers, either because the study is ending early or for other reasons.

13. WHAT HAPPENS IF I AM INJURED OR BECOME ILL BECAUSE I TOOK PART IN THIS STUDY?

If you are injured or become ill because you were part of this study, you will receive emergency medical care if needed and you will receive assistance in getting other medical care as needed. You or your insurance carrier will be billed for the cost of care, just as you would be billed for any other medical care. If you have any costs that are not covered by insurance, they are your responsibility.

You do not give up any of your legal rights by signing this form. You can seek legal compensation for any injury that may occur to you during the study as a result of an error by a member of the research staff or others.

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14. WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

- <<insert name>>, the study coordinator at your hospital has discussed this information with you and offered to answer any questions you may have. If you have further questions or get sick or injured as a result of being in this study, you can contact << insert him/her>> at <<telephone number>>. You may also call the Director of the Study at your hospital, <<insert name>>, at <<telephone number>>.
- If you have further questions about your rights as a study participant you can call or contact the Johns Hopkins Bloomberg School of Public Health IRB Office. The Johns Hopkins Bloomberg School of Public Health is serving as the overall coordinating center for this study that is being conducted in hospitals around the country. Contact the Johns Hopkins IRB if you feel you have not been treated fairly or if you have other concerns. The IRB contact information is:

  Address: Johns Hopkins Bloomberg School of Public Health
  615 N. Wolfe Street, Suite E1100
  Baltimore, MD 21205
  Telephone: 410-955-3193
  Toll Free: 1-888-262-3242
  Fax: 410-502-0584
  E-mail: irboffice@jhsph.edu

Please let us know what way you would like to be contacted and which way your prefer.

Which methods may we use to contact you? (check all that apply):	**What is your preferred communication method?**
☐ **Phone call**	☐
☐ **Text message**	☐
☐ **Email**	☐
☐ **Mail**	☐
☐ **I do not want to be contacted weekly**	

What does your signature (or thumbprint/mark) on this consent form mean?

Your signature (or thumbprint/mark) on this form means:

- You have been informed about this study's purpose, procedures, possible benefits and risks.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this study.

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_____ _____ _____

Print name of Adult Participant Signature of Adult Participant Date

_____ _____ _____

Print name of Legally Authorized Representative (LAR) Signature of LAR Date

_____

Relationship of LAR to Participant

Ask the participant to mark a "left thumb impression" in this box if the participant (or participant's parent) is unable to provide a signature above.

_____ _____ _____

Print name of Person Obtaining Consent Signature of Person Obtaining Consent Date

Give one copy to the participant and keep one copy in study records