**CONSENT TO PARTICIPATE IN RESEARCH**

# Registry of Recurrent Venous Thromboembolism in Patients with Cancer

We are asking you for consent to enter data on your disease and treatment to an international registry.

## PURPOSE AND BACKGROUND

In patients with cancer there is an increased risk of thrombosis (blood clots) in the veins or in the lungs. The treatment against thrombosis or to prevent new events is less effective in patients with cancer. There is uncertainty about the best treatment for patients with cancer who develop a new thrombosis in spite of receiving treatment for it. There are no studies on addressing this problem and no guidelines.

In this international registry we will collect information on the treatment for new thrombotic events that occurred in spite of treatment. This will include data on risk factors for new events, description of these events, what treatment was given after that and how safe and effective that treatment were.

The database will be maintained by Dr. Sam Schulman at the Thrombosis Service, HHS-General Hospital, McMaster University, Hamilton, Canada for the SSC subcommittee on Control of Anticoagulation along with Dr. Anna Falanga, Bergamo, Italy, Chair of the SSC Subcommittee on Hemostasis and Malignancy and the other co-chairs of this committee.

You to participate in this registry because you have had a new event of thrombosis during treatment against a previous event, and the diagnosis of cancer has been made.

## PROCEDURES

If you agree to be part of this registry, the following things will happen. You will be assigned a unique code that will only be known to the database staff/personnel. All information collected will be recorded under this unique code. Personal information such as your age, and sex will be collected. Information regarding the type of cancer, the thrombotic events, bleeding complications you developed, what treatment was given, how long the treatment was given, and if it was successful will be recorded. Information about the medication against thrombosis and results of the blood tests to measure the effect of this treatment will be collected. We will send this type of information to the registry on two occasions – now when you developed the new thrombosis event in spite of treatment and after 3 months.

## RISKS AND DISCOMFORTS

This is an information collection study, there is no anticipated physical risks or discomforts associated with your participation.

## BENEFITS

You may receive no medical benefit from your participation in this study. However, it is hoped that the information gained in this study will help doctors have a better understanding of how to treat thrombosis in patients with cancer.

**ALTERNATIVES**
If you do not want to take part in the study, you will continue to take the treatment against thrombosis that your physician considers the best alternative for you, but no data will be sent to the registry. Treatment with blood thinners has risks and benefits, which you can discuss with your physician.

**CONFIDENTIALITY**
Your name, address, date of birth (except year of birth) or other information that may reveal your identity will not be sent to the registry. Representatives from University Human Research Review Committee that oversees human subject research will be permitted access to your records. Also, your participation in the study and information in your study records may be disclosed to your doctors and nurses, and may be disclosed as otherwise provided by law. Your name will not be used in any published reports about this study.

**COSTS OF STUDY**
You will not be billed for participating in this study.

**EMERGENCY TREATMENT AND COMPENSATION FOR INJURY**
Since this is an information gathering study, we expect that you will not be physically injured in any way by being part of this study. If you have any questions about these issues, or believe you have been treated carelessly, in the study, please contact the Human Research Review Committee at the University/Institution for more information.

**NEW FINDINGS**
You will be informed of any significant new findings that become available during the course of the study, such as changes in the risk or benefits from the treatment against thrombosis or new alternatives to participation that might change your mind about participating.

**WITHDRAWAL**
Your participation in this study is strictly voluntary. You have the right to withdraw your participation at any point in this study without prejudice to your future health, care or other services to which you are otherwise entitled.

**QUESTIONS**
You or your legally authorized representative may ask questions and request information about this research project at any time.

**CONSENT**

You will be given a copy of this consent form to keep. By signing this consent form, you are not waiving any of your legal rights, claims, or remedies.

I have read (or someone has read to me) the information in this consent form. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. By signing this consent form, I acknowledge the risks of participation and willingly agree to have the data on my disease and treatment sent to the registry.

Name of Subject (type or print)

_____ _____

Signature of Subject or legal guardian(s) Date

_____

Name of Witness (type or print)

_____ _____

Signature of Witness Date

_____ _____

Physician Date