

**UNIVERSITY OF CALGARY**

**CONSENT TO PARTICIPATE IN RESEARCH**

**TITLE: Blinded Randomized trial of Anticoagulation to prevent Ischemic stroke and Neurocognitive Impairment in Atrial Fibrillation- Pharmacogenomic substudy**

**SPONSOR:**  Montreal Heart Institute

**FUNDING:** Government of Quebec **« Fonds d’accélération des collaborations en santé ».**

**INVESTIGATOR:** Local Principal Investigator: Stephen Wilton, M.D. (403-210-7102)

**BACKGROUND/INTRODUCTION:**

We invite you to participate in this substudy because you have already agreed to participate in the BRAIN-AF main study. We will be studying *pharmacogenomics* (how your genes/DNA affect your response to medicines)

Participation in this substudy is optional. You can choose not to participate and still be in the main study.

## Before you sign this informed consent form, please take as much time as you need to read (or have read to you) and understand the information written below. We invite you to ask any questions you may find useful regarding this substudy or this form.

This consent form describes the study procedures. If you agree to participate, you will be given a copy of the signed consent form to take home with you.

This substudy involves the collection of a saliva sample. The saliva collection kit will be sent to your home if you don’t want to come to the hospital or the clinic for a BRAIN-AF visit.

**WHY IS THIS STUDY BEING DONE?**

The purpose of this substudy is to analyze DNA (genetic material found in all cells of the body) in relation to how a person responds to drugs or an illness.

This type of analysis is part of a new kind of medical approach called “precision medicine” in which doctors can target treatments based on a patient’s specific genetic profile.

This substudy specifically hopes to identify genetic factors which could provide:

1. a better response to antithrombotic drug (rivaroxaban) in people with atrial fibrillation (AF) and at low risk of stroke;
2. the link between AF, the risk of stroke and of neurocognitive impairment;
3. the development of AF.

# HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

We are hoping to recruit about 1500 participants in this sub-study, all from sites participating in the main BRAIN-AF study. University of Calgary hopes to enrol 50 subjects.

# WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

If you agree to participate in this optional substudy, a saliva kit and instructions will be sent to your home by a courier service. You will fill the container with 2 mL (less than ½ teaspoon) of your saliva, which will be used for genetic analyses.

Once you have collected your saliva sample, you will notify a member of the research team who will arrange a courier to pick up your sample.

If you are scheduled for a BRAIN-AF visit at the hospital/clinic, it is possible for you to collect the saliva sample during this visit.

DNA will be extracted from your saliva sample at the Pharmacogenomics Centre of the Montreal Heart Institute for analysis and will not be used for any other purpose.

If the amount of DNA extracted from your saliva sample is not sufficient, an additional sample will be requested.

**WHAT ARE THE RISKS?**

There is no risk associated with collecting saliva.

# There is a risk related to a possible breach of confidentiality in terms of your personal information

# and your medical records and this could affect your privacy. However, this risk is minimal. Every

# effort will be made to protect your privacy and ensure your confidentiality, as described in the

# further in this document.

COVID 19 Related Risks:

If you choose to do this visit in clinic, there is an added risk of you being exposed to COVID 19 from other people within the facility or by use of public transit to attend your appointment. We have several measures in place to reduce this risk as much as possible including screening each patient who attends our facility, use of PPE for all staff and patients, restrictions on the number of people allowed within the space, enhanced general cleaning procedures and sanitization of any space a patient occupies immediately following their visit.

**WILL I BENEFIT IF I TAKE PART?**

There are no direct benefits to you as a result of your participation in this substudy, but it may provide important information and will contribute to the advancement of scientific knowledge in the field of AF and related events, including neurocognitive impairment.

**CAN I STOP BEING IN THE STUDY/WITHDRAW MY DATA?**

Your participation in this sub study is voluntary. Therefore, you may refuse to participate and withdraw at any time, without giving any reason, by informing the research team. If you change your mind and no longer want your samples to be used, the team will ensure that they are destroyed. However, it will not be possible to remove them if your samples have already been analyzed because withdrawal of data in clinical trials could bias the results.

You will be informed of any new findings during the course of the study, which may influence your decision to continue.

If you have any problems or questions regarding this substudy, you should contact Dr. Wilton at 403-210-7102 or the study coordinator, Jennifer McKeage at 403-210-6047

**WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?**

No, you will not be paid to participate in this study. All courier costs will be paid.

**WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?**

During your participation in this substudy, Dr Wilton’s study team will only collect information necessary to meet the scientific objectives of this substudy.

The information collected in the BRAIN-AF main study will be used and may include information contained in your medical file regarding your past and present health status, your lifestyle and the results procedures or analyses.

All information collected is strictly confidential. Any transfer of this information will take place in compliance with regulations protecting the processing and transfer of personal data.

To protect your identity, your name will be replaced with a study code. The key linking your name to your research file will be stored by Dr Wilton’s study team for 25 years and then be destroyed.

Your saliva sample and collected data will be sent to the Montreal Heart Institute (MHI) and

be only identified by your assigned code and will not include your name, your address or any otherinformation that could identify you directly. Once you provide the specimens you will not have access to them. The specimens will be used for research and may result in discoveries that could become the basis for new products or therapeutic agents. In some instances, these discoveries may be of potential commercial value. You will not receive any money or other benefits derived from such products.

Your sample will be stored securely at the Beaulieu-Saucier Pharmacogenomics Centre of the Montreal Heart Institute under the responsibility of Dr. Marie-Pierre Dubé, Director of the Center, until 5 years after the end of the study, or, if you agree (at the end of this form) that your biological material and data be made completely anonymous (no link to this study) and then used for additional research projects.

When you donate your sample for genetic testing you are not only sharing genetic information about yourself, but also about blood relatives who share your DNA(genes)
There are laws in Canada that protect your genetic information, and privacy and confidentiality. Your sample will not leave Canada.

The results of this substudy will be published and presented, but no information which may identify

you will be disclosed.

For monitoring, control, safety and security purposes, it is possible that a delegate of regulatory

authorities, in Canada or in other countries, such as Health Canada, as well as by representatives

of the institution, the Research Ethics Board or the sponsor (Montreal Heart Institute) will view

your research data and your medical file. All these individuals and organizations adhere to strict

policies on confidentiality.

You have the right to consult your research record in order to verify the information collected, and correct it as long as the study doctor or institution holds this information. However, to preserve the scientific integrity of the project, you can not access some of this information once your participation ended.

# WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

**The Research Team:**

You may contact Dr. Stephen Wilton at (403) 210-7102 or 403-210-6047 with any questions or concerns about the research or your participation in this study.

**Conjoint Health Research Ethics Board (CHREB):**

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

**Public Information about this Study:**

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

 **CONSENT**

I have had an opportunity to ask all the questions about this research project and have received satisfactory answers. I understand that I remain free to withdraw from this project at any time without it affecting my future medical care in any way. I have read or have been read this information and consent form and I understand its content. After consideration, I accept to participate in this research project with the conditions indicated below:

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| --- | --- | --- |
| In the event that the results obtained in this substudy lead to the development of another research project, I agree to be re-contacted to be asked if I am interested to participate in this new project. | [ ] I agree | [ ] I refuse |

|  |  |  |
| --- | --- | --- |
| I agree that my sample and research data be anonymized (no re-identification possible) and used for other research projects. | [ ] I agree | [ ] I refuse |

**SIGNATURES**

**SIGNATURE OF STUDY PARTICIPANT**

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Name of Participant

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Signature of Participant Date

**SIGNATURE OF PERSON OBTAINING CONSENT/Investigator or Delegate**

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Name of Person Obtaining Consent Contact Number

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Signature of Person Obtaining Consent Date

**SIGNATURE OF WITNESS**

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Name of Witness

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Signature of Witness Date

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.