London Heart Rhythm Program

London Health Sciences Centre, University Hospital, 339 Windermere Road, London, ON N6A 5A5
Tel: (519) 663-3746 Web Site: www.londoncardiac.ca Fax: (519) 663-3782

Informed Consent Form for Participation in a Research Study

Study Title: RASTA-Cohort: Reversal of Atrial Substrate to Prevent Atrial Fibrillation Cohort Study.

Principal Investigator: **Dr. Allan Skanes**
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339 Windermere Road
London, Ontario, Canada N6A 5A5

Sponsor/Funder(s): Nova Scotia Health Research Fund

INTRODUCTION

You are being invited to participate in a research study. You are invited to participate in this study because you have decided not to take part in the RASTA-AF randomized control trial (RCT), or you were eligible to participate but not offered the opportunity prior to your ablation. RASTA-AF is a study recruiting patients who are about to undergo a procedure called catheter ablation for symptoms relating to atrial fibrillation (AF). Catheter ablation is a minimally invasive procedure in which the doctor advances a flexible thin tube (catheter) through the blood vessels to your heart to ablate (stop) abnormal electrical pathways (signals) in the heart tissue.

This consent form provides you with information to help you make an informed choice. It may be provided in person, remotely through the mail, in an e-mail or via web-link from REDcap to which you may provide e-consent. REDcap is an electronic research database housed within our institution. Note that communication via e-mail is not secure in terms or exchanging personal health information. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. You may find it helpful to discuss it with your friends and family.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive outside the study.

IS THERE A CONFLICT OF INTEREST?

If you would like additional information about the funding for this study, or about the role of the doctor in charge of this study, please speak to the study staff or the Patient Relations Office at LHSC at (519) 685-8500 ext. 52036

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WHY IS THIS STUDY BEING DONE?

The purpose of this study is to help the RASTA-AF RCT investigators better understand how effective risk factor modification might be for people like yourself who have AF and have chosen to undergo catheter ablation but do not want to take part in the RASTA-AF trial or have already had an AF ablation (within the past 2 years). Randomized control trials are the best way to determine if an intervention is effective, however, it is well known that patients decline participation in clinical trials for many reasons, and that there are often differences between the people who agree to participate in a trial and those who do not. It is critical to understand the outcomes for patients who are eligible for a clinical trial but decide not to participate or who are eligible but have already had their ablation. This information can help doctors understand how effective the intervention might be to all people with a disease/condition.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about 200 people will take part in this study from research sites located within health centres across Canada. We anticipate up to 50 participants will be enrolled from our centre.

This study should take three *(*3) years to complete, and the results should be known in about four (4) years.

WHAT WILL HAPPEN DURING THIS STUDY?

You have decided not to take part in the RASTA-AF trial, which randomizes patients to aggressive risk factor management or standard of care. Due to the design of the RASTA trial, once you enroll in this cohort study you will no longer be eligible for the RCT. As well, due to the specific interventions/devices being provided in the RASTA trial (e.g., cardiac rehabilitation program, implanted cardiac monitoring device and pedometer) only patients who are randomized to the intervention arm of the RCT will be eligible to receive the aggressive risk factor modification intervention. If you are interested in more information about managing your risk factors for AF, you are encouraged to speak to your Cardiologist or family doctor.

During this cohort study there will be no study interventions, and we will only be collecting data from you and your health care records at three time-points: baseline, 12-months and 24-months.

At the in-person baseline visit, the following will be done:

- Medical history review,
- Physical exam (height, weight, waist circumference, blood pressure),
- Genesis-Praxy gender questionnaire

The gender questionnaire will take about 5 minutes to complete and will help us to understand

how an individual's gender may impact AF risk factors. The information you provide is for research purposes only. Some of the questions are personal and you can choose not to answer questions if you wish.

After asking about your medical history and having you complete the questionnaire, the researchers will collect additional information about you from your medical chart and enter this information into an electronic database. The data will be securely stored and maintained by the research team at Nova Scotia Health. The database can only be accessed by people who are involved in the research study.

Follow-up visits will be done by phone with your research coordinator at 12 and 24 months post baseline visit. During the call, your coordinator will ask you about:

- Blood Pressure (measured with an at-home cuff or at the pharmacy)
- Weight and waist circumference (measured at home)
- Emergency department visits and hospitalizations since your last visit
- Recurrence of AF since your last visits

After the phone call your coordinator will review your health records to collect information available from any cardiovascular-related hospital visits you have had as well as any standard of care tests you've had, such as ECGs and cardiac implantable device interrogations.

At the end of this study, the RASTA-Cohort investigators will look at the characteristics of patients who chose not to participate in the RCT and use the findings to provide insight into the generalizability of the results of the RASTA-AF trial. The results of the RASTA-AF trial and any insights gathered from the RASTA-Cohort study will be shared with the scientific community at meetings and in journals.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this study, you will be expected to:

- Follow the directions of the research team,
- Report all medications being taken or that you plan on taking,
- Report any changes in your health to the research team,
- Report any problems that you experience that you think might be related to participating in the study.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

Your participation in this study will last for about 24 months.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the research team. After your withdrawal, no further information will be collected from you or your health record. In order to protect the integrity of the study, and ensure the researchers have enough data to answer the research questions after two years of follow-up, the information that was recorded before you withdrew will be used by the researchers for the purposes of the study.

CAN PARTICIPATION IN THIS STUDY END EARLY?

Your participation in the study may be stopped early, and without your consent, for reasons such as:

- New information shows that the research is no longer in your best interest
- The research team decides to stop the study
- The research ethics board withdraws permission for this study to continue

If you are removed from this study, the research team will discuss the reasons with you.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

While this research does not involve any interventional treatment, you may experience discomfort as a result of taking part.

Questionnaire
You may find the interviews and questionnaire you receive during the study upsetting or distressing. You may not like all the questions that you will be asked. You do not have to answer any questions that you find distressing.

Breach of confidentiality:
As with all research, there is a chance that confidentiality could be compromised; however, we are taking precautions to minimize this risk.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You may not receive direct benefit from participating in this study. We hope the information learned from this study will help other people with AF in the future.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the research team will only collect the information they

need for this study.

Records identifying you at this centre will be kept confidential. To the extent permitted by the applicable laws, your records will not be disclosed or made publicly available, except as described in this consent document. Any study data about you that is sent outside of this centre will have a code and will not contain your name, address, or any information that directly identifies you.

De-identified study data will be transferred to the sponsor as well as the research team at The Ottawa Heart Institute who will complete the study analysis for the RASTA-AF RTC and RASTA-Cohort.

Authorized representatives of the following organizations may look at your original (identifiable) medical records at the site where these records are held in order to check that the information collected for the study is correct and follows proper laws and guidelines.

- Dr. Ratika Parkash, the Sponsor of this study
- The RASTA-AF coordinating centre at Nova Scotia health who are managing the study database
- The research ethics board who oversees the ethical conduct of this study in Ontario
- This institution and affiliated sites, to oversee the conduct of research at this location
- The Quality Assurance and Education Officers from the hospital's Office of Research may audit this research study for quality assurance purposes.

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your study ID, sex, month, and year of birth.

The following organizations may also receive study data:

- Statisticians at Ottawa Heart institute who are conducting the statistical analysis for the RASTA-AF trial

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/ presented to the scientific community at meetings and in journals.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

A copy of the consent form that you sign to enter the study may be included in your health record/hospital chart.

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WHAT IS THE COST TO PARTICIPANTS?

Participation in this study will not involve any additional costs to your private health care insurance.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

You will not be paid to participate in this sub-study. Your costs related to parking for study visits will be paid or reimbursed.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please contact the research team.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form, you do not give up any of your legal rights against the sponsor or involved institutions for compensation, nor does this form relieve the sponsor or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT A RESEARCH PARTICIPANT?

During the study, the researchers may learn something about you that they didn't expect. In such a case, these results will be shared with you and your health care providers (e.g., family doctor and/or cardiologist).

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to the research team or the person who is in charge of the study at this institution.

That person is:
Dr. Allan Skanes, Principal Investigator, London Health Sciences Centre, 519-663-3746.
If you have any questions about your rights as a research participant or the conduct of this study, you may contact the Patient Relations Office at LHSC at (519) 685-8500 ext. 52036

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SIGNATURES

- All of my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to medical records and transfer of related personal health information as explained in this consent form,
- I do not give up any of my legal rights by signing this consent form,
- I agree to take part in this study.

Signature of Participant	PRINTED NAME	Date

Signature of Person Conducting the Consent Discussion	PRINTED NAME & ROLE	Date

The following attestation must be provided if the participant is unable to read or requires an oral translation:

If the participant is assisted during the consent process, please check the relevant box and complete the signature space below:

☐ The person signing below acted as an interpreter, and attests that the study as set out in the consent form was accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and additional discussion arising from this process.

PRINT NAME of Interpreter	Signature	Date

Language

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☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to the participant, and any questions have been answered.

_____	_____	_____
PRINT NAME of witness	Signature	Date

_____
Relationship to Participant