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Consent to Participate in a Clinical Research Study:

Cardiovascular Screening for Family Members of People with Acute Coronary Disease: A Patient-Initiated and Family-Oriented Strategy

Invitation to participate in a research study

You are invited to participate in a research study about heart health in people who live with or are related to people with heart disease. You are being asked to take part because you are an adult attending the Jewish General Hospital as a patient or are a family member (such as a spouse or a partner) of a patient.

Purpose of the study

Family members of people with heart disease are at higher risk of having heart disease themselves. We would like to know if people in the hospital for heart disease are willing to refer family members for a heart health evaluation with a heart specialist. We are also interested in identifying conditions such as high blood pressure, diabetes, and high cholesterol in family members and then treating these conditions. An important goal of the study is how much can the heart disease risk in family members be improved over a 6-month period.

Description of subject involvement

If you are a patient in the hospital who agrees to participate, a researcher will review your medical chart and will give you a letter to give to family members who may want to participate in the study. You may be contacted after you leave the hospital by a researcher to contact family members and to ask you a few questions about your experiences. You are encouraged but not required to attend healthcare appointments with your family member

If you are a family member who agrees to participate, you will have tests for blood sugar and cholesterol before the first visit with the heart specialist. At the first visit, the doctor will take a history and will examine you. Other tests and treatment to detect and prevent heart disease may be needed as determined by the doctor. The doctor will talk with you about ways that you can improve your heart health. 6-months later you will have another visit to the doctor. Other visits may be arranged as needed by your health condition. You will also fill out questionnaires about changes in your life (such as nutrition and physical activity) and about your experience in the study. You are encouraged but not required to all attend healthcare appointments with other family members. 1 year after the follow-up visit, you will receive a call from a researcher to ask about the changes in your life. The survey should take less than 10 minutes.

Risks and Discomforts

There are minimal risks with participating in this study. Blood tests and treatments will follow expert recommendations by the Canadian Cardiovascular Society. Drawing blood from a vein may cause local pain, bruising, occasional lightheadedness, fainting, and very rarely, infection at the site of the blood draw.

Benefits

As a patient, you may directly benefit from being in this study because you may receive advice on improving life habits (such as nutrition and physical activity) and from the emotional support of family members or people living with you.

As a family member, you may directly benefit from being in this study because you will receive a heart health evaluation, advice on how to improve heart health, and treatment for medical conditions if needed. At the end of the study, you will receive a personalized report of your heart disease risk and how much your risk has changed during the course of the study. If needed, you will receive information on how to find a general practitioner.

Alternatives

If you do not wish to participate in this study, you are entitled to receive the same care from your usual doctor without any penalties or restrictions.

Compensation

There is no compensation offered for your participation in this study.

Should you suffer any harm

Should you suffer harm of any kind following the administration of the study drug, or following any procedure related to the research study, you will receive the appropriate care and services as required by your state of health.

By agreeing to participate in this research study, you do not give up any of your legal rights nor discharging the doctor in charge of this research study, the sponsor of the institution, of their civil and professional responsibilities.

Voluntary participation/withdrawal

Your participation in this research project is voluntary. Therefore, you may refuse to participate. You may also withdraw from the project at any time, without giving any reason, by informing the doctor in charge of this research study or a member of the research team.

Your decision not to participate in the study, or to withdraw from it, will have no impact on the quality of care and services to which you are otherwise entitled, or on your relationship with the doctor in charge of this research study or the clinical team.

The doctor in charge of this research study or the WCMH MBM Research Ethics Committee may put an end to your participation without your consent. This may happen if new findings or information indicate that participation is no longer in your interest, if you do not follow study instructions, or if there are administrative reasons to terminate the project.

However, before you withdraw from the study we suggest that you return to the clinic for a final evaluation for safety reasons.

If you withdraw or are withdrawn from the study, the information collected during the study will nonetheless be stored, analyzed or used to protect the scientific integrity of the research project.

Any new findings that could influence your decision to stay in the research project will be shared with you as soon as possible. We may also learn information about you that was not known before, if this happens we will notify you and ensure that you receive appropriate medical care.

You will be given a copy of this consent form when you give your consent to participate in this study and you may request additional copies thereafter.

Funding

The study is funded by the division of cardiology of the Jewish General Hospital.

Confidentiality

All of the information (including your name and any other identifying information) will be coded and kept strictly confidential and will not be revealed to other parties except the investigators and delegates. The Research Ethics Committee and legal authorities such as Health Canada will have access to the collected data without compromising your confidentiality.

All information obtained will be anonymized, coded, and saved on encrypted workstations. You will not be identified in any publication of this study. All study documents will be kept in secured files by the investigators until the study is concluded. If you withdraw from this study, all information collected up to the point of withdrawal may still be used in order to preserve the scientific integrity of the study.

Contact Numbers

For questions concerning this research project, you may contact Dr. Michael Goldfarb at (514) 340-8222 ext. 25801.

For questions concerning your rights as a participant in this study, you may contact the Hospital Ombudsman, Mrs. Rosemary Steinberg, at (514) 340-8222 extension 25833.

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STATEMENT OF CONSENT

I have reviewed the information and consent form. Both the research study and the information and consent form were explained to me. My questions were answered, and I was given sufficient time to make a decision. After reflection, I consent to participate in this research study in accordance with the conditions stated above.
I authorize the research study team to have access to my medical record for the purposes of this study.
I do not give up any of my legal rights by signing this consent form.

I agree to take part in this study.

_____	_____	_____
Printed name of participant	Signature of participant	Date

Signature of person obtaining consent
I have explained the research project and the terms of this information and consent form to the research participant, and I answered all his/her questions.

_____	_____	_____
Name of person obtaining consent	Signature	Date

Signature of Principal Investigator
I certify that this information and consent form were explained to the research participant, and that the questions the participant had were answered.
I undertake, together with the research team, to respect what was agreed upon in the information and consent form, and to give a signed and dated copy of this form to the research participant.

_____	_____	_____
Name of the principal investigator	Signature	Date