Patient Consent to Take Part in Research
(Intervention)

TITLE: Implementing and testing a cardiovascular assessment screening program (CASP) to promote healthy aging.

INVESTIGATOR(S): Jill Bruneau
SUPERVISOR: Dr. Donna Moralejo
CO-INVESTIGATORS: Dr. Catherine Donovan and Dr. Karen Parsons

You have been invited to take part in a research study. Taking part in this study is voluntary. It is up to you to decide whether to be in the study or not. You can decide not to take part in the study. If you decide to take part, you are free to leave at any time. This will not affect your health care.

Before you decide, you need to understand what the study is for, what risks you might take and what benefits you might receive. This consent form explains the study.

Please read this carefully. Take as much time as you like. If you like, take it home to think about for a while. Mark anything you do not understand, or want explained better. After you have read it, please ask questions about anything that is not clear.

The researchers will:

- discuss the study with you
- answer your questions
- keep confidential any information which could identify you personally
- be available during the study to deal with problems and answer questions

1. **Introduction/Background:**
   Heart disease and stroke is the leading cause of death in Canada and is the second leading cause of death in the province of Newfoundland and Labrador (NL). Having heart disease or a stroke may also result in long hospital stays as well as costly drugs and tests. Screening for heart disease earlier can lead to healthier lives for people as they age. A recent study explored different perspectives of health providers and patients to develop a heart health screening program for NL to promote healthy aging.

2. **Purpose of study:**
   To evaluate the effectiveness of a new heart health screening program called the Cardiovascular Assessment Screening Program (CASP).

3. Description of the study procedures:

There are two different groups of participants in this study, the intervention group and the control group. You will be asked to participate in one of these groups. Patients in the intervention group may be asked to do the following:

1. Fill out a questionnaire about your family history of heart disease, risk factors, medical conditions, and medications that you are taking
2. Answer questions about your heart health with a nurse practitioner (NP).
3. Have a physical exam to check your heart and blood vessels.
4. Give a blood sample of about 12ml (3 tubes) and a urine sample of about 30 ml at your nearest agency or hospital.
5. Have another appointment with the nurse practitioner to get the results of blood tests/procedures.
6. Provide feedback about your experience in this study by completing a questionnaire that will be given to you by the nurse practitioner to be mailed back to the researchers.
7. Allow us to review your health record

4. Length of time:

You may be expected to come to the clinic for another appointment with the nurse practitioner over the next month. The first appointment may take about 30 minutes. The second appointment may take up to 40 minutes to complete. You will decide with the NP whether other visits are required.

5. Possible risks and discomforts:

Possible risks of being in the study are physical in terms of having a blood test done since you may bleed or have a bruise. You may also become upset from learning about a new health issue that requires further tests or treatment. If you become upset, the NP will talk with you, or we will arrange time to speak with a counsellor.

6. Benefits:

It is not known whether this study will benefit you.

7. Liability statement:

Signing this form gives us your consent to be in this study. It tells us that you understand the information about the research study. When you sign this form, you do not give up your legal rights. Researchers or agencies involved in this research study still have their legal and professional responsibilities.

8. **What about my privacy and confidentiality?**

Protecting your privacy is an important part of this study. Every effort to protect your privacy will be made. However it cannot be guaranteed. For example we may be required by

law to allow access to research records. A copy of this consent will be put in your health record.

When you sign this consent form you give us permission to

- Collect information from you
- Collect information from your health record
- Share information with the people conducting the study
- Share information with the people responsible for protecting your safety

Access to records

The members of the research team will see health and study records that identify you by name. Other people may need to look at your health records and the study records that identify you by name. This might include the research ethics board. You may ask to see the list of these people. They can look at your records only when supervised by a member of the research team.

Use of your study information

The research team will collect and use only the information they need for this research study.

This information will include your

- age
- sex
- family history
- medical conditions
- medications
- the results of tests and procedures during the study
- information from questionnaires

Your health information will be kept secure by the research team in Newfoundland and Labrador. It will not be shared with others without your permission. Your name will not appear in any report or article published as a result of this study.

Information collected for this study will be kept for five years.

If you decide to withdraw from the study, the information collected up to that time will continue to be used by the research team. Blood and urine samples will be discarded once the tests are completed. It may not be removed. This information will only be used for the purposes of this study.

After your part in this study ends, we may continue to review your health records to check that the information we collected is correct. We may need to review your record at a later date in the future if further information if needed. You can contact the principal investigator (PI) to obtain a copy of the study summary and recommendations. We would like to follow your progress after this study and may need to contact you at a later date if you agree to

participate. The PI plans to do a follow-up study related to this topic in the future that would be approved by the research ethics board.

Information collected and used by the research team will be stored in a locked file at the Memorial University School of Nursing, Education Building, Room 5004, St. John's, NL. Jill Bruneau is the person responsible for keeping it secure.

Your access to records
You may ask the researcher to see the information that has been collected about you.

9. **Questions or problems:**

If you have any questions about taking part in this study, you can meet with the investigator who is in charge of the study. That person is:

Jill Bruneau 709-777-7258
Or you can speak to my supervisor(s): Dr. Donna Moralejo 709-864-3603

Or you can talk to someone who is not involved with the study at all, but can advise you on your rights as a participant in a research study. This person can be reached through:

Ethics Office at 709-777-6974
Email at info@hrea.ca

This study has been reviewed and given ethics approval by the Newfoundland and Labrador Health Research Ethics Board.

After signing this consent you will be given a copy

Signature Page

Study title: Implementing and testing a cardiovascular assessment screening program (CASP) to promote healthy aging.

Name of principal investigator: Jill Bruneau

To be filled out and signed by the participant:

Please check as appropriate:

I have read the consent and information sheet. Yes ☐ No ☐
I have had the opportunity to ask questions/to discuss this study. Yes ☐ No ☐
I have received satisfactory answers to all of my questions. Yes ☐ No ☐
I have received enough information about the study. Yes ☐ No ☐
I have spoken to the NP and he/she has answered my questions. Yes ☐ No ☐
I understand that I am free to withdraw from the study: Yes ☐ No ☐

- at any time
- without having to give a reason
- without affecting my future care

I understand that it is my choice to be in the study and that I may not benefit. Yes ☐ No ☐
I agree that a regulatory agency may read parts of my health record relevant to the study. Yes ☐ No ☐
I understand how my privacy is protected and my records kept confidential. Yes ☐ No ☐
I agree that my family doctor can be notified of my participation in this study Yes ☐ No ☐ NA ☐
I agree to take part in this study. Yes ☐ No ☐
I agree to be contacted for future studies on this topic. Yes ☐ No ☐

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Signature of participant Name printed Year Month Day

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Signature of person conducting the consent discussion Name printed Year Month Day

<u>To be signed by the investigator:</u>

I have explained this study to the best of my ability. I invited questions and gave answers. I believe that the participant fully understands what is involved in being in the study, any potential risks of the study and that he or she has freely chosen to be in the study.

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Signature of investigator Name Printed Year Month Day