# **Appendix A: Screening Consent Form**

**TEMPLATE (Insert Institution header here)**

**Study Title:** Heart Outcomes Prevention and Evaluation 4 (HOPE-4): Cluster randomized trial of a model cardiovascular risk assessment, detection, treatment and control program

**Funding:** Canadian Institutes of Health Research and Grand Challenges Canada

**Sponsor:** Hamilton Health Sciences, Hamilton, ON, Canada

**International Coordinating Centre:** Population Health Research Institute (PHRI), Hamilton, ON, Canada

**National Coordinating Centre:** (insert name and location of national coordinating centre)

**HOPE-4 SCREENING INFORMATION SHEET**

INTRODUCTION: You are invited to be screened to join the HOPE-4 heart disease and high blood pressure reduction program. This document informs you about the screening questions and tests. Once you understand the screening process and if you agree to participate, you will be asked to sign the end of this form. Taking part is voluntary, and it will not affect any health care you normally receive. This research project has been reviewed and approved by the research ethics board (insert the name of the research ethics board).

PURPOSE: The purpose of the HOPE-4 program is to test if a community screening and treatment program for high blood pressure and heart disease can reduce blood pressure and the chance of having a major problem like a heart attack, stroke, or death.

SCREENING: Adults at least 50 years old can be screened. Screening will involve taking your blood pressure, and asking you questions about your current health and medical history. It may take 1 or 2 visits of up to 30 minutes each to finish the screening.

RISKS/BENEFITS and COMPENSATION: There are no known risks of this screening and there are no benefits of screening guaranteed to you. You may ask to know your blood pressure results. No compensation will be provided for your participation in this screening.

CONFIDENTIALITY AND RELEASE OF PERSONAL INFORMATION: Your personal information collected will be maintained in confidence, within the provisions of the law in (insert name of country). In order to keep an accurate record of who has been screened for this program, your name will be recorded by the health workers and stored at the National Project Office in (insert name of country). Your information collected in HOPE-4 will be available to authorized representatives of the program doctors and researchers, of the Population Health Research Institute, Hamilton Health Sciences (the sponsor), ethics committees, and domestic or international regulatory authorities, so that they can check that the project is being conducted correctly. Any reports or presentations made about the HOPE-4 program will not identify you by name, and no one will know that you participated. You may cancel this consent for screening at any time and without any reason.

WHOM TO CONTACT: For questions or issues relating to this research study, you may contact **(insert the relevant contact person)** at **(insert the relevant contact number). HOPE-4 STUDY PARTICIPANT SCREENING INFORMED CONSENT FORM**

Investigators: Name(s) of Primary and co-investigators specific to country

Site of Investigation: (Name of Institution, Complete address and phone number)

I have read, or have had read to me, the information sheet for this HOPE-4 screening process. I have received an explanation of the nature, purpose, duration, and foreseeable effects and risks of the screening process and what I will be expected to do. I have been given enough time to ask questions about the screening process and to decide whether or not to participate. My questions have been answered satisfactorily. I understand that the results will be kept confidential, in accordance with laws in my country.

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| --- | --- | --- | --- | --- | --- |
| By signing and dating this form, I agree to take part in screening for the HOPE-4 project and to follow the screening procedures as detailed above. I understand that I will receive a signed and dated copy of this informed consent. | | | | | |
| Participant’s name (printed) |  | | Signature of Participant (or Legally Acceptable Representative) |  | Date (YYYY-MM-DD) |
|  | | | | | |
| I, the undersigned, acknowledge having provided all the necessary information for understanding the HOPE-4 screening process to the individual mentioned above. I certify that to the best of my knowledge, the person signing this consent form understands the nature, demands, benefits and risks of participating and that his/her signature is valid and freely given. | | | | | |
| Name of person authorized to obtain consent (printed) | | |  | Signature |  | Date: (YYYY-MM-DD) |
|  | | | | | | |
| **Witness signature required only if participant or their legally acceptable representative is unable to read the screening consent form :**  I observed the process of consent. The prospective participant or their legal representative had this form read to them and the information contained in it explained accurately, was given the chance to ask questions, appeared to accept the answers, and freely gave consent to participate in this study screening. | | | | | |
| Witness’s name (printed) |  | | Signature |  | Date (YYYY-MM-DD) |
|  | | | | | |

**Note: Two signed copies of this form will be obtained. One must be stored in the study file at the national coordinating centre office and one must be given to the screening participant.**

# **Appendix B: Full Enrollment Consent for All cRCT Participants**

**TEMPLATE (Insert Institution header here)**

**Study Title:** Heart Outcomes Prevention and Evaluation 4 (HOPE-4): Cluster randomized trial of a model cardiovascular risk assessment, detection, treatment and control program

**Funding:** Canadian Institutes of Health Research and Grand Challenges Canada

**Sponsor:** Hamilton Health Sciences, Hamilton, ON, Canada

**International Coordinating Centre:** Population Health Research Institute (PHRI), Hamilton, ON, Canada

**National Coordinating Centre:** (insert name and location of national coordinating centre)

Investigators: Name(s) of Primary and co-investigators at national coordinating centre(s)

Site of Investigation: (Name of Institution, Complete address and phone number for national project office)

**INFORMATION SHEET – HOPE-4 PROGRAM ENROLLMENT**

The purpose of the HOPE-4 research program is to test if a community treatment program for high blood pressure and heart disease can reduce blood pressure and the chance of having a major problem like a heart attack, stroke, heart failure, death or hospitalization for heart disease, compared to normal care available in the community. This program will take place in Colombia and Malaysia and may expand to other countries. Up to 9,500 people are expected to participate. HOPE-4 has been reviewed and approved by the research ethics board **(insert the name of the research ethics board).**

PARTICIPATION – ALL COMMUNITIES

To take part in HOPE-4 you must be aged 50 years or older and have high blood pressure or a history of previous problems with blood pressure, heart disease, or diabetes. The HOPE-4 program will last at least one year (and possibly up to 6 years), and will require up to 4-5 hours of your time during the first year. The program may be extended, which will be reviewed with you at your 1 year visit. If you decide to take part in HOPE-4, you will be asked to sign this form to show that you agree to participate.

If you decide to participate, you will be given information about blood pressure, heart disease and healthy living created by health professionals for your country. You will also be asked to have a blood sample taken (less than 1 teaspoon) to test your cholesterol levels, blood sugar (glucose) levels, and tests to check that your kidney and liver are working properly. Cholesterol is a fat made by your liver that is important for normal body function, but high levels of some cholesterol types can increase the risk of heart disease. High glucose levels can be a sign of diabetes, and diabetes is a risk factor for heart disease. The health workers will also tell you about health care facilities in your community that you can visit if you have very high blood pressure.

At 6 months and 1 year after starting in the program, you will have a visit in person at your home or local clinic. The health workers will check your blood pressure, and ask you about any health problems you had since starting the program, including visits to a doctor, clinic, or hospital, and any heart problems. At 1 year, the health workers will also have you repeat the same blood testing done at the beginning of the study, and will ask you about tobacco use, diabetes, physical activity, and dietary habits.

HOPE-4 TREATMENT

After screening of all participants is complete in your community, your community will be randomly assigned by an automated system to either the blood pressure monitoring program or to the community treatment program described below. Your community will have an equal chance of being placed in either group (like the flip of a coin). Everyone in your community who joins the HOPE-4 study will receive the same program. The health workers in your community will contact you to tell you what treatment program is available in your community.

BLOOD PRESSURE MONITORING PROGRAM

If your community is participating in the community treatment program, you will be given information about blood pressure, heart disease and healthy living created by health professionals for your country. The health workers will also tell you about health care facilities in your community that you can visit if you have any health problems. At 6 months and 1 year after starting in the program, you will have the visit at your home or local clinic by the HOPE-4 health workers to check your blood pressure and ask you about health problems you may have.

COMMUNITY TREATMENT PROGRAM

If your community is participating in the community treatment program, you will be asked if you would like to choose a family member or friend to become your treatment supporter during the program. This individual will listen to the health and medical information provided to you during the study, and provide you with support and encouragement to take your medication (if any) and make recommended healthy lifestyle changes.

After reviewing your health information, the health workers will develop a plan for you that will include recommendations for lifestyle changes and medication, as appropriate. You and your treatment supporter (if applicable) will be provided with information about heart disease, proper use of medication, and recommendations for diet, physical activity, and tobacco and alcohol use.

If medication is recommended, the health workers will direct you to attend a local clinic (or make other similar arrangements) in order to gain your consent to receive HOPE-4 program medication. If you agree to start study medication and if the health workers and HOPE-4 doctors think it is needed, you will be provided with study medication at no cost to you. The health workers may also ask you to a see a doctor in person to review your medication and health needs, and follow-up visits with the health workers or doctors will be scheduled.

At 6 months and 1 year after starting in the program, you will have the visit at your home or local clinic by the HOPE-4 health workers to check your blood pressure and ask you about health problems you may have.

POSSIBLE RISKS OR SIDE EFFECTS OF TAKING PART IN THIS PROGRAM

There are no known risks of participating in the blood pressure measurements, heart disease risk assessments, or health education/counselling carried out in HOPE-4. The very minor risks of taking a blood sample include mild discomfort and minor bruising at the site of the blood draw. In the very rare event that you should become physically injured as a result of HOPE-4 activity, the investigator will provide or refer you for any necessary medical treatment. Costs for care for injuries or illnesses that are not a direct result of HOPE-4 activities will not be covered. Risks or side effects of taking study medication will be discussed with you if you are asked to consent to take study medication.

BENEFITS AND COMPENSATION

There are no direct benefits of participation guaranteed to you in either study group. You can find out your blood pressure and you will be given heart disease and healthy lifestyle education materials. Participants in communities assigned to the community treatment program will receive counselling about healthy lifestyle changes and may or may not be recommended to receive medication by health workers and local doctors at no charge. Participation in either group will be at no cost to you. No compensation will be provided for your participation.

PARTICIPATION AND WITHDRAWAL FROM THE STUDY

Your participation in this study is purely voluntary. Deciding not to participate, or stopping participation at any time, will involve no penalty or loss of benefits or health care to which you are otherwise entitled.

CONFIDENTIALITY AND RELEASE OF PERSONAL INFORMATION

In order to keep track of who has been included in the program, your name and contact information will be recorded and stored by the HOPE-4 team in (insert country name here). Your information collected in the HOPE-4 program will be maintained in confidence, within the provisions of the law in (insert country name here). Your information will be available to HOPE-4 doctors and health workers, and authorized representatives of HOPE-4 researchers, the Population Health Research Institute, Hamilton Health Sciences (the sponsor), ethics committees, or domestic or international regulatory authorities, so that they can check that the program is being conducted correctly. The HOPE-4 doctors may check your medical records at local clinics, hospitals, or health care facilities to collect more information about any health problems or hospitalizations you experience during your participation in the program.

For the purposes of this study, the study doctor will replace your name with a special code that identifies you. Any reports or presentations made about the HOPE-4 program will not identify you by name, and no one will know that you participated. You have the right to review your information and request changes to your HOPE-4 program information if it is not correct. You may withdraw from the program at any time, however, the program doctors will continue to retain and use any information that has already been collected to ensure the scientific integrity of the program.

WHOM TO CONTACT

For questions relating to this research study, you may contact (insert the relevant contact person) at (insert the relevant contact number). Questions regarding your rights as a volunteer may be addressed to the committee that reviewed the ethical aspects of this study at (insert the relevant contact number).

**HOPE-4 INFORMED CONSENT FORM**

Investigators: Name(s) of Primary and co-investigators specific to institution

Site of Investigation: (Name of Institution, Complete address and phone number)

I have read, or have had read to me, the informed consent document for the HOPE-4 program. I have received an explanation of the nature, purpose, duration, and foreseeable effects and risks of the program and what I will be expected to do. I have been given enough time to ask questions about the program and to decide whether or not to participate. My questions have been answered satisfactorily. I understand that the results will be kept confidential, in accordance with laws in my country.

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| I, the undersigned, agree to participate in the HOPE-4 program as described and authorize disclosure of my personal information as outlined in this consent form. I understand that I will be given a copy of the signed information sheet and consent form. | | | | | |
| Participant’s name (printed) |  | | Signature of Participant (or Legally Acceptable Representative) |  | Date (YYYY-MM-DD) |
| I, the undersigned, acknowledge having provided all the necessary information for understanding the HOPE-4 program to the individual mentioned above. I certify that to the best of my knowledge, the person signing this consent form understands the nature, demands, benefits and risks of participating and that his/her signature is valid and freely given. | | | | | |
| Name of person authorized to obtain consent (printed) | | |  | Signature |  | Date: (YYYY-MM-DD) |
|  | | | | | | |
| **Witness signature required only if participant or their legally acceptable representative is unable to read the consent form :**  I observed the process of consent. The prospective participant or their legal representative had this form read to them and the information contained in it explained accurately, was given the chance to ask questions, appeared to accept the answers, and freely gave consent to participate in the program. | | | | | |
| Witness’s name (printed) |  | | Signature |  | Date (YYYY-MM-DD) |
|  | | | | | |

**Note: Two signed copies of this form will be obtained. One must be stored in the study file at the national coordinating centre office and one must be given to the participant.**