Participant Information and Consent Form

Title of Project: Evaluation of Pre-Participation Screening and Cardiovascular Risk Assessment in Masters Athletes in British Columbia

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Invitation:
You are being invited to participate in this study because you are considered a Masters athlete older than or equal to 35 years of age that is physically active or participates in sports (competitively or recreationally) at least 3 times per week. We want to evaluate the cardiovascular risk and the best screening method in Canadian masters athletes in order to prevent sudden cardiac arrest (SCA) and/or sudden cardiac death (SCD).

Your Participation is Voluntary
Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving.

You should be aware that there is a difference for both you and your doctor between being a patient and being a research participant. As a patient all medical procedures and treatments are carried out for your benefit only according to standard accepted practice. As a research participant you and your doctor also must take into account the requirements for the research study. These may include procedures and treatments that are not part of standard practice or are not yet proven. This consent form describes the diagnostic and treatment procedures that are being carried out for research purposes. Please review the consent document carefully when deciding whether or not you wish to be part of the research and sign this consent only if you accept being a research participant.

If you wish to participate in this study, you will be asked to sign this form.

Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

This study is funded by Sports Cardiology B.C., a Vancouver Coastal Health program, funded by the University of British Columbia and Vancouver General Hospital foundation.

Background
Sudden cardiac death (SCD) or a sudden adverse cardiovascular event in sport is traumatizing and shocking. Athletes are considered healthy and fit, two factors considered cardio-protective. However, although there are certainly benefits to exercise, the risk of myocardial infarction, aortic dissection, arrhythmias, sudden cardiac arrest and/or sudden cardiac death (SCD) is increased during and briefly after exercise. The exercise paradox emerges from evidence that vigorous exercise simultaneously triggers and protects against SCD. Both regular trainers (i.e. competitive athletes) and non-habitual but vigorous exercisers (i.e. weekend warriors) have a two to three fold

increase risk of SCD versus non-athletes. Sudden cardiac death is often the first clinical expression of cardiovascular disease because many do not have symptoms (asymptomatic) and are unaware they have cardiovascular disease (CVD). Screening for cardiovascular disease has the potential to detect these disorders and those with cardiovascular risk factors in order to prevent such devastating events.

Though pre-participation screening has the capacity to detect cardiovascular disease, it lacks systematic evaluation. In particular, pre-participation screening has received considerable attention in the young competitive athlete, whereas limited data exists on Masters athletes despite the higher risks for coronary artery disease. Currently, there is no official mandate in Canada for pre-participation screening in the Masters athlete and the prevalence of risk factors in this population is unknown. Previous research, outside of Canada, found a new cardiovascular abnormality in approximately 3% of athlete and 4.1% had multiple cardiovascular risk factors, putting them at risk for developing CVD.

This study could have implications on future care of athletes in Canada. Pre-participation screening has the potential to decrease the risk of death by detecting CVD, as well as the capacity to detect disorders related to SCD. It creates an awareness of risk factors, which has the potential to decrease the risk of developing disease, and ultimately slowing the atherosclerotic process and subsequent cardiac events. Surprisingly, many athletes are unaware they have cardiovascular risk factors (i.e. high blood pressure, diabetes, or dyslipidemia). Therefore, use of pre-participation screening may provide the greatest reductions in cardiovascular risk by assessing and reviewing one's own health profile. Finally, the pre-participation evaluation can be used as a vehicle to educate Masters athletes on the nature and significance of warning signs for CVD.

Purpose

The purpose of this study is to determine the prevalence of cardiovascular risk factors and disease in masters athletes in B.C using a heart health questionnaire, physical examination, Framingham Risk Score, resting 12-lead electrocardiogram (ECG), and a maximal exercise treadmill test when indicated. The effectiveness of these screening methods will also be evaluated. Additionally, we will inquire about your physical activity level (past and current), lifestyle (i.e. diet, alcohol consumption and smoking) and stress, as it relates to cardiovascular risk.

You are eligible to participate in this study if:

1. Male and female Master (≥ 35 years) *high performance athletes* (participate in organized team or individual sport that requires systematic training and regular competition against others and places a high premium on athletic performance on athletic excellence and achievement, such as at the provincial, national,

international and/or Olympic level) who perform exercise sessions at least 6 times per week.

2. Male and female Master (≥ 35 years) *recreational competitive athletes* (participate in a variety of informal recreational sports within a range of exercise levels from modest to vigorous, which does not require systematic training or the pursuit of excellence) who perform exercise sessions at least 3 times per week.

You will not be eligible to participate in this study if:

1. You have known cardiovascular disease (i.e. coronary artery disease, heart valve disease, previous stroke, cardiomyopathy (enlarged heart), congenital heart disease, pericarditis (swelling of the sac that surrounds your heart), aorta disease, Marfan's syndrome, or heart failure).
2. You have a known irregular heart rhythm that could cause SCD (i.e. Brugada syndrome, long QT, short QT, White-Parkinson White syndrome, catecholaminergic polymorphic ventricular tachycardia (rhythm disorder of the large chambers of the heart)).
3. You have already undergone a cardiovascular examination for screening purposes or because of symptoms, within the past year.

Study Procedures:

If you agree to take part in this study, the procedures and visits you can expect will include the following:

One of the researchers will schedule the initial screening session, which includes a questionnaire, a resting 12-lead ECG and a cardiovascular physical examination. Prior to the initial screen you will be required to complete a lipid blood profile. The screening will take place at either the University of British Columbia Hospital or your sporting facility (your preference). Additional testing (if the initial screen is positive) will be conducted at the University of British Columbia Hospital, or one of its satellite locations.

This study will require 15-20 minutes of your time and up to 90 minutes of additional time if the initial screen discovers anything that is potentially abnormal.

Each subsequent year you will be asked to complete a follow up questionnaire, similar to the initial heart health questionnaire, redo your blood lipid profile, and come to UBC hospital to have the resting ECG re-administered. The questionnaire will be used to observe changes in your cardiovascular risk profile as well as to document any adverse cardiovascular events. The resting ECG will observe the presence of new cardiovascular disorders. The ECG and questionnaire will take approximately 10-20 minutes of your time.

The consent form will be reviewed at the initial screening session and your written consent will be sought should you decide to participate.

#1 – Before you begin the study

If you have not completed a recent blood lipid profile (within one year of the screen), needed to complete the Framingham Risk Score, please consult with your physician to acquire a laboratory blood lipid requisition (i.e. total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, fasting blood glucose) and complete prior to your screening session. If this is not possible or not complete on the day of screening you may acquire a requisition from the research team. Please complete this as soon as possible and inform your research coordinator, Barb Morrison at 604-719-2825 once it is complete.

Laboratory Blood Analysis

A hospital chart review will be performed to acquire your recent blood work or you may bring a copy of your recent blood lipid profile (within the last year) with you on the day of screening.

#2 – Screening Visit

On the day of testing, you will be asked to refrain from exercise and smoking for 2 hours prior to testing, and caffeine/alcohol on the day of the test.

Questionnaire

Two weeks prior to the screening date, you will be sent a questionnaire and will be asked to bring it with you on your screening date. You will not have to answer any questions that you are not comfortable with on any of the questionnaires. This questionnaire should take about 10 minutes to complete.

The health history questionnaire asks about aspects of your family history and personal symptoms relevant to this study, your educational background, your approximate income and your ethnic background. It also includes information on your past and current physical activity, psychological stress, and lifestyle (i.e. smoking, alcohol consumption, diet).

Electrocardiogram

The study will involve a resting electrocardiogram (ECG), which records your heart rate and rhythm and will be performed by a trained professional. Areas on your arms, legs and chest, where the ten electrodes will be placed, will be cleaned with alcohol wipes and you may need to be shaved to provide a clean, smooth surface to attach the electrode discs. Participants will be asked to remove their top garment for this test so that the electrodes can be placed on the proper areas of the chest. This is required for a proper reading of the electrical conductivity of the heart. Some ECG leads need to be

place on the body near the breasts. When dealing with female participants a female research associate, will be available to place the leads on these individuals. We will have private areas available for testing. This is painless and non-invasive. These measures should take 5 minutes to complete.

Physical Examination
This will include measurements of heart rate and blood pressure. A physician will also listen to your heart and assess for other cardiovascular risk features. This is painless and non-invasive and should take 5 minutes to complete.

#3 - Additional testing (if the initial screen is positive):
Exercise Stress Test
If you are 65 years or older, and/or the initial screen is positive as deemed by a cardiologist, you will be contacted to complete an exercise stress test. This test assesses your exercise capacity and your heart rate and rhythm while exercising. This will be determined by walking and/or running on a treadmill. You will be instructed to initially walk at a speed and grade of 1.7 mph and 10% grade, respectively. Every 3 minutes the speed and incline increases. Stage 2 is 2.5 mph at a 14% grade, stage 3 is 3.4 mph and 14% grade, stage 4 is 4.2 mph and 16% grade, stage 5 is 5.0 mph and 18% grade and stage 6 is 5.5 mph and 20% grade. This is known as the Bruce Protocol. You will be encouraged to exercise until you are too tired to continue, unless you experience symptoms that would cause you or the research team to terminate the test early. Your heart rate and rhythm will be continuously recorded throughout the test and your blood pressure will be measured at 2.5 minutes into each stage. This test takes approximately 30 minutes.

#4 - Diagnostic Testing (If the exercise stress test is positive or inconclusive)
If the exercise stress test is positive or inconclusive you will be contacted for additional diagnostic testing, to make a diagnosis, including but not limited to: an echocardiogram (ultrasound of the heart), cardiac computed tomography (test that uses x-rays and a contrast dye to create detailed pictures of the heart), calcium artery score (test that detects calcium deposits found in atherosclerotic plaque in your heart arteries), cardiac catheterization (procedure that uses a long, thin flexible tube inserted into a blood vessel in your arm or groin and is threaded to your heart to take x-ray pictures and is used to make diagnosis of heart conditions or provide treatment), cardiac magnetic resonance imaging (test that uses radio waves, magnets and a computer to take pictures of your heart), endomyocardial biopsy (biopsy of the heart muscle), 24 hour blood pressure monitoring and/or 24 hour Holter test (electrocardiogram monitor that is worn for 24 hours). These tests can take an additional hour.

#5 – Follow-up Questionnaire and Resting Electrocardiogram

Each subsequent year you will be asked to complete a follow up questionnaire, redo your blood lipid profile, and come to UBC hospital to have the resting ECG re-administered. The questionnaire will be similar to the initial heart health questionnaire and will also include questions on whether or not you have experienced a new cardiovascular event. Two weeks prior to the date of your ECG being re-administered, you will be sent the questionnaire and will be asked to bring it with you on your screening date. The questionnaire and resting ECG will take approximately 10-20 minutes.

What are my responsibilities?

1. Please see your doctor and acquire a blood lipid profile requisition (i.e. total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, fasting blood glucose) and have this complete (and bring a copy with you) prior to screening. If this is not feasible, you can obtain a requisition from us on the day of screening, and notify us as soon as it is complete.
2. Complete a yearly questionnaire, blood lipid profile and resting ECG for 5 years.

Risks

There is no potential harm to the participant in the initial screen; however, there is a chance of a false-positive test result, which could lead to further testing and could cause an inconvenience to the patient, or unnecessary alarm. Although there is a small chance of a false-positive test (4.2%), the potential benefits could be considered to outweigh the potential unnecessary concern because in the case of a correct diagnosis; appropriate treatment, safe exercise/sport guidance, and saved lives could result. The initial screen will be conducted by a physician and a qualified professional will administer the ECG in order to minimize the chance of false-positives.

There is a slight chance that the some of the questions included in the questionnaire (i.e. psychological assessment) my cause minimal distress in some individuals. However, recent research reported that pre-participation screening does not cause excessive anxiety and could create an ease of mind knowing their cardiac risk.

If a high psychological stress profile is revealed on your heart health questionnaire, we will inform you of this and offer you counseling resources, but we will not be responsible for providing counseling.

The exercise stress test (if required) could cause you to become tired and short of breath. There are no known permanent adverse side effects that have resulted from these exercise sessions. Data from individuals with or without heart disease indicates that the likelihood of having a heart attack or dying during an exercise stress test is 1 in 10,000 tests. All exercise testing will be performed under the supervision of a Certified

Stress Lab technician or a Certified Exercise Physiologist. These individuals have received the most advanced exercise training in Canada; have performed a minimum of 100 stress tests under direct supervision, and are certified in first aid, CPR and the use of an automated external defibrillator (AED). All stress testing sites will be under the supervision of a physician at all times. A crash cart with defibrillation, suction, blood pressure monitoring, oxygen, etc. is within 10 meters of the stress machine. Distance from the emergency room is less than 10 kilometers.
Since there is a variable response from individuals during exercise, unanticipated complications may occur that would require treatment. Few problems have been associated with exercise testing, and the shortness of breath and muscular soreness usually clear quickly with little or no treatment. Every effort will be made to conduct the test in such a way as to minimize discomfort and risk. However, there exists the small possibility of potential risks from maximal exercise such as vomiting (5%), abnormal blood pressure, such as low blood pressure or hypotension following exercise (less than 1%), disorders of heartbeat, or arrhythmia (0.1%), and very rare instances of heart attack (less than 0.001%). Having trained professionals implement the tests will further reduce the risks associated with exercise testing.

Each participant will be required to have a lipid blood analysis. The risks of taking blood include pain, a bruise at the point where the blood was taken, redness and swelling of the vein and infection, and a rare risk of fainting.

In the event that further diagnostic testing (individuals with a positive screen and exercise treadmill test) few risks are involved and are described as follows:

- Cardiac computed tomography (CCT): CCT is a non-invasive test, however, there is a small amount of radiation, similar to the amount that you are naturally exposed to over 1-5 years. New methods reduce the amount of radiation and the benefit of an accurate diagnosis outweighs the risk. CCT is painless, however, some people have side effects from the contrast dye that might be used during the scan. An itchy feeling or rash may appear after the contrast die is injected. These side effects don't normally last long.
- Coronary artery calcium score (CACS): CACS has very few risks. This is a non-invasive test, however a small amount of radiation is used, which is equivalent to the amount you are naturally exposed to in a single year. No dye is used.
- Cardiac catheterization: An invasive, common medical procedure that rarely causes serious problems but complications that can occur include: bleeding, infection, pain at the catheter insertion site, damage to blood vessels, an allergic reaction to the dye, abnormal heart rhythm, kidney damage caused by the dye, blood clots, low blood pressure, a buildup of blood or fluid in the sac that surrounds the heart.

- Endomyocaridal biopsy: An invasive procedure, and follows the same procedure as cardiac catheterization, with the same risk and complications (rare).
- Cardiac magnetic resonance imaging (CMR): This is a non-invasive test that uses magnetic fields and radio waves and does not have side effects. It does not carry the risk of causing cancer or birth defects. Serious reactions to the contrast agent are very rare, but are possible and include: headache, nausea, dizziness, changes in taste, and allergic reactions.

Benefits:
No one knows whether or not you will benefit from this study. There may or may not be direct benefits to you from taking part in this study.

Potential benefits from participating in this study include diagnosis of an underlying cardiovascular disease that can cause significant harm. Information collected from this study can be used in the future to benefit athletes with cardiovascular disease.

Athletes with general concerns about health and well-being while participating in competitive sports may gain comfort in the knowledge that they have undergone testing that indicates they have no indications of a cardiovascular disorder.

The participants will receive a cardiovascular risk profile of their results and recommendations for their positive risk factors.

By evaluating Masters athletes, we could potentially decrease the incidence of SCA/SCD, and improve the health profile of active individuals and subsequently lessen the burden on the health care system and save lives.

We hope that the information learned from this study can be used in the future to benefit other people with a similar disease.

Confidentiality
Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of Sports Cardiology BC and the clinical research ethics board for the purpose of monitoring the research. Your date of birth will also be provided if requested by the sponsor or responsible regulatory agency. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a subject in this study. This number will not include any personal information that could identify you (e.g. it will not include your

personal health number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected. You also have the legal right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

Participants with positive results for cardiovascular disease will be notified. Participants who wish to view their ECG results can do so upon by contacting the number seen above.

Disclosure of Race/Ethnicity
This study involves collecting information on race, ethnicity, sex and age as these characteristics may indicate a predisposition to certain cardiovascular disease and will be important to note for future research. Providing this information is voluntary.

Study withdrawal
You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, you have the right to request the withdrawal of your information collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn for example where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please let your study doctor know. If your participation in this study includes enrolling in any optional studies, or long term follow-up, you will be asked whether you wish to withdraw from these as well.

What will this study cost me?
All research-related medical care and treatment and any related tests that you will receive during your participation in this study will be provided at no cost to you.

Reimbursement
You will receive no financial reimbursement or remuneration for your participation in the study.

Legal Rights
By signing this form, you do not give up any of your legal rights against the investigators, or anyone else, and you do not release the study doctor or other participating institutions from their legal and professional duties. There will be no costs to you for participation in this study. You will not be charged for any research procedures. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan.

Contacts
I understand that if I have any questions or need any further information about this study, I should contact Dr. Saul Isserow at 604-822-1747 or Barb Morrison at 604-822-1751.

If you have any concerns or complaints about your rights as a research subject and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598)

Primary Care Physician(s)/Specialist(s) Notification
Your family physician will be notified of your participation in the study in the event that additional testing is necessary.
The name of the medical clinic I attend is:_____
Name of family doctor is: _____
Fax number is: _____
Participant Initials:_____

Evaluation of Pre-Participation Screening and Cardiovascular Risk Assessment in Masters Athletes in British Columbia
PARTICIPANT CONSENT TO PARTICIPATE
My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have had enough time to think about the information provided.
- I have been able to ask for advice if needed.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive
- I authorize access to my laboratory lipid blood profile as described in this consent form.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me.

I will receive a signed copy of this consent form for my own records.
I consent to participate in this study.
Subject Consent:

_____
(Participant Signature) (Printed Name) (Date)

Signature of Person Obtaining Consent:

_____
(Signature of person obtaining consent) (Printed Name/Study Role) (Date)