

## PARTICIPANT INFORMATION SHEET

**Title of the Study:** Evaluating the impact of personalized health recommendations on lifestyle behaviours and cardio-metabolic risk: The DNA-based life style enhancement (DNAble)Trial.

**Locally Responsible Investigator & Principal Investigator:** Dr. Guillaume Paré, Department of Pathology, McMaster University, Hamilton Health Sciences (HHS) - Hamilton General Hospital Site.

**Co-Investigators:** Michael Chong, Department of Biochemistry, McMaster University, HHS

**Study Coordinator:** Richard Carrozzella

**Sponsor/Funding Source:** GeneBlueprint, GoodLife Fitness, HHS, Southlake Regional Care Centre

You are being invited to participate in a research study to investigate to what extent, if any, individual genetic information along with personalized health recommendations help motivate people to adopt healthier lifestyle behaviours including higher levels of physical activity and healthier diets.

In order to decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study. Once you understand the study, you will be asked to sign this form if you wish to participate. Please take your time to make your decision. Feel free to discuss it with your friends and family, or your family physician.

HHS and the Principal Investigator, Dr. Guillaume Paré, are under contract with sponsors of this study and are receiving compensation through the Southlake Federal Development program to cover the costs of conducting the study. Dr. Guillaume Paré, and other co-investigators hold management positions at GeneBlueprint Corp. As such, procedures have been put in place to maintain scientific integrity and to ensure that participants' rights are upheld in light of this conflict of interest. All investigators will be blinded to study participant's intervention status through the course of the trial, and all statistical analyses will be conducted by an impartial third party.

### WHY IS THIS RESEARCH BEING DONE?

There is tremendous public interest in genetics and some evidence that providing genetic information can help improve health habits. However, no study to date has examined the effect of comprehensive genetic testing using cutting-edge polygenic score prediction and an interactive health portal on health behaviours and cardio-metabolic risk factors (cholesterol, insulin sensitivity, inflammation, and biological age). What is a polygenic score? Contrary to popular belief, most human traits like how tall we are or how much we weigh are not due to just one or two genetic variants but up to tens of thousands of genetic variants. All such genetic variants can be combined together to create a more powerful prediction, known as a "polygenic score", to estimate your height and weight, among other traits. Polygenic scores for approximately twenty traits related to health, fitness and nutrition will be provided to each study participant (e.g. adiposity, muscle strength, caffeine sensitivity). None of the polygenic

scores provide diagnostic information for risk of disease. To be clear, this means that your genetic results will NOT tell you about your risk for medical conditions or diseases including but not limited to: cancer, heart attack, stroke, celiac disease, hemophilia, and rare genetic disorders.

## **WHO IS ELIGIBLE TO PARTICIPATE?**

We are looking to enroll Hamilton Health Sciences Employees who are in overall good health and are capable and willing to adhere to exercise and dietary plans for 3 months.

Individuals will be excluded from participating in the trial if they:

- Plan to take vacation for more than 2 weeks from May 1, 2018 to July 31, 2018
- Are currently pregnant, breastfeeding or planning to be pregnant from May 1, 2018 to July 31, 2018
- Have a history of cardiovascular disease (stroke, heart attack, coronary artery bypass graft [CABG] surgery, peripheral artery disease, or coronary angioplasty).
- Have had a bone marrow transplant
- Have dietary restrictions for any reason
- Are unable to or unwilling to comply to registered dietician-approved meal plans
- Are unable to or unwilling to comply to trainer-approved training plans
- Are unwilling to provide blood samples for genetic testing
- Are unwilling to provide buccal (cheek) samples for genetic testing

## **WHAT IS INVOLVED IN THIS STUDY?**

Taking part in this research study is optional and entirely up to you. If you volunteer to participate, we will ask you to do the following things:

- 1) Fill in questionnaires querying exercise habits, diet habits, cardiovascular health, well-being, and attitudes towards genetics at baseline and 3-months follow-up.
- 2) Provide blood samples (two teaspoons worth) at baseline and 3-months follow-up to be used for laboratory testing (genetics and biomarker). Biomarkers that will be measured include biological markers that have been associated with cardio-metabolic disease, such as fasting glucose, cholesterol / triglycerides, C-reactive protein. Many of these biomarkers are analyzed during routine check-ups with your family physician.
- 3) Provide a mouth swab sample at baseline only. While blood samples are the gold standard starting material used for genetic testing, genetic material can also be obtained from the cells that line inside of your cheek, also called buccal cells.
- 4) Undergo two fitness assessments involving measurement of fitness-related attributes (e.g. height, weight, blood pressure, heart rate, calf circumference, etc.) but no actual physical exertion.
- 5) Attend GoodLife Fitness centre for baseline and follow-up assessments. During your first visit you will:
  - a. Receive a badge that grants you in-and-out privileges to multiple GoodLife Fitness locations. As per standard GoodLife protocol, this badge must be scanned every time you enter the gym. The frequency of badge scans will be recorded for the purposes of evaluating exercise frequency.
  - b. Have an orientation to familiarize yourself with the facilities and the rules.
  - c. Conduct your first fitness assessment.

- 6) Access your personalized health recommendations (meal plans, exercise plans, genetic results) through a secured web portal if you are assigned to the intervention arm.

Study participants will be assigned at random, that is, by a method of chance (like a flip of a coin), to one of two groups. You will have a 50% chance of being in the intervention group that receives personalized health recommendations and a 50% chance of being in the control group that does not receive personalized health recommendations for the duration of the study period. You will know which group you have been assigned to but the investigators of this study will not. At the end of the trial, all participants assigned to the control group will receive personalized health recommendations in the spirit of fairness. For more details, please see the “Study Participant Journey” in the Appendix.

## **WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**

**Blood Draw:** Peripheral venipuncture is a low risk procedure that is commonly performed for standard lab work. There is a small pinch at the time of blood draw and a small risk of infection at the site.

**Fitness Assessment:** The fitness assessment does not involve any physical exertion and thus no potential risk of injury. However, there is a risk for incidentally discovering undiagnosed malignant hypertension (SBP > 180/120 mmhg) or tachycardia (resting heart rate > 100 bpm). Malignant hypertension is a medical emergency and anyone identified with this condition will be referred to the hospital immediately. Study participants identified with tachycardia will be referred to an appropriate health professional.

**Exercise Plans:** Exercise plans have been developed by Nicholas Jones, UK Olympic strength coach. Special precautions have been undertaken to mitigate risk of injury by carefully designing the plans such that no prior knowledge or experience is required. Instructional videos will be provided to demonstrate how to safely perform exercises. Additionally, it will be emphasized that (1) exercises should be performed under the supervision of a GoodLife Fitness staff member and (2) to never perform types of exercises or use excessive weight they may be uncomfortable with.

**Meal Plans:** Meal plans are approved by a registered dietitian and are consistent with the Canadian recommended dietary allowances. If new food allergies develop throughout the course of the trial, these will be taken into consideration and dietary recommendations will be adjusted immediately. Depending on the severity of the allergy, the study participant may be referred for allergy testing.

**Genetic Results:** We will not be performing any additional analyses into your genetic code aside from calculation of polygenic scores for traits related to fitness and nutrition. Risk for medical conditions will not be identified or calculated. We will not provide such information to you or anyone else. Genetic information will not be disseminated to employers or insurers. **The “Genetic Non-Discrimination Act” protects Canadians and prohibits employers and insurers from requiring someone to conducting genetic testing or disclose findings from existing genetic test results.**

**Biomarker Results:** Blood testing at baseline and 3-months follow-up could reveal medical diagnoses unbeknownst to you warranting disclosure. Such findings include but are not limited to diabetes (fasting glucose > 7 mmol/L), hypercholesterolemia (LDLc > 5 mmol/L), and hypertriglyceridemia (triglycerides > 10 mmol/L). Upon confirmation of an aberrant test result, you will be referred to an appropriate health professional.

## **HOW MANY PEOPLE WILL BE IN THIS STUDY?**

A total of 500 participants will be enrolled for this study with no specified limit for each local study site. Participants will be enrolled on a first-come first-serve basis.

## **WHAT ARE THE POSSIBLE BENEFITS FOR ME AND/OR FOR SOCIETY?**

As a study participant, you will receive a 3-month GoodLife Fitness gym membership, personalized exercise and diet plans, and individual genetic information which will be accessed via an interactive web portal free-of-charge. The provided personalized health recommendations and access to a fitness facility may (but is not guaranteed to) confer improvements to your cardiovascular health. It should be noted that the 3-month GoodLife Fitness gym membership will NOT include access to a personal trainer. Your participation may also benefit the broader welfare of society as study findings may be used to develop new health policies to improve adoption and sustainability of healthy lifestyle behaviours.

## **WILL THERE BE ANY COSTS?**

Participation in this study will not involve any additional costs to you or your healthcare insurer.

## **WHAT HAPPENS IF I HAVE A RESEARCH-RELATED INJURY?**

Exercise-related injuries will not be considered as research-related as no study participant is obliged to perform the recommended exercises and we have implemented several procedures to ensure that exercise plans can be executed safely. If you sign this consent form it does not mean that you waive any legal rights you may have under the law, nor does it mean that you are releasing the investigators and institutions from their legal and professional responsibilities.

## **HOW WILL MY PERSONAL INFORMATION BE PROTECTED?**

Various protocols have been put into place designed to make it very difficult for the results from genetic research to be linked to you and to prevent re-identification. Your blood sample will be labelled with a unique sample number or 'code' number. Samples will not be labelled with your name or other personal information. Your laboratory measurements (genetic and biomarker) will also be assigned separate codes (double de-identification).

At the beginning of the study, the Investigator will use a computer file, also known as the "key", to connect the main study data to the code numbers assigned to your genetic and biomarker data. At the end of the study, the Investigator will delete the key so that genetic analyses from your sample are no longer connected to any personal identifiers. The types of study data that will be collected include age, sex (gender), ethnic group, health conditions, and exercise and dietary habits. These data are associated with your genetic and biomarker data by way of unique code numbers. These types of study data are connected to the sample even after the key is deleted.

It should be noted that polygenic scores will be connected to personal identifiers (e.g. your e-mail) because part of the intervention is to empower you with genetic information in the form of polygenic scores, accessible through a secure web portal. As discussed below, Polygenic scores do not represent highly sensitive genetic information.

Genetic results can be broadly classified into two categories: primary genetic data and polygenic scores. Primary genetic data is highly sensitive personal information as it represents an individual's genetic code, whereas polygenic scores are complex derivations of the primary genetic data. Polygenic scores and primary genetic data will be assigned separate code numbers. Strict security measures will be employed to safeguard genetic data and mitigate confidentiality breach:

(1) The primary genetic data will be stored on a secured server managed by the Information & Communications Technology (ICT) Team at HHS. HHS servers are secured using industry best standards, including nightly backups, high-end firewall systems, regular monitoring to ensure that any vulnerabilities are quickly found and patched.

(2) The primary genetic data comprising nearly a million genetic data points are used as the building blocks for polygenic scores. Polygenic scores are generated using a sophisticated algorithm to consolidate information into a single numerical value. Having knowledge of the algorithm and the specific set of genetic variants that comprise the score is not sufficient to deduce a participant's primary genetic data. In other words, it is impossible to deduce an individual's primary genetic data using the polygenic score, and only the polygenic score will be transferred to the web portal server. Importantly, no identifying information (i.e. name, email address, address, etc.) will ever be stored on the same server as the primary genetic data. The key linking both numbers will be kept in a secure computer different from the genetic server, minimizing the risk of a catastrophic hack.

(3) The GeneBlueprint web portal provides a secure means for participants to access and learn about the genetic basis of their health and wellness. The web portal is password-protected and this password is only known to the study participant. Additionally, the website itself employs many security measures to prevent prohibited access or disclosure through various physical, technical, and administrative means. All connections to the GeneBlueprint website are encrypted using Secure Socket Layer (SSL) technology. Some personal information (e.g. name, e-mail address, etc.) will be stored on the GeneBlueprint server. Security and privacy of personal information maintained on the GeneBlueprint portal adhere to both Canadian (Personal Information Protection and Electronic Documents Act) and US (Health Information Portability and Accountability Act) legislation.

If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your specific consent to the disclosure.

## **WHAT WILL HAPPEN TO MY SAMPLE?**

Upon collection of your blood and cheek swab samples, they will be stored within the secure laboratory of Dr. Guillaume Paré. At completion of the study, your sample will be stored for up to 25 years.

## **CAN PARTICIPATION IN THE STUDY END EARLY?**

If you volunteer to be in this study, you may withdraw at any time. Also, you can request that your blood sample be destroyed as medical waste and/or to remove your data from the study (genetic, biomarker, questionnaire data, etc.). You may also refuse to answer any questions you don't want to answer and still remain in the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so.

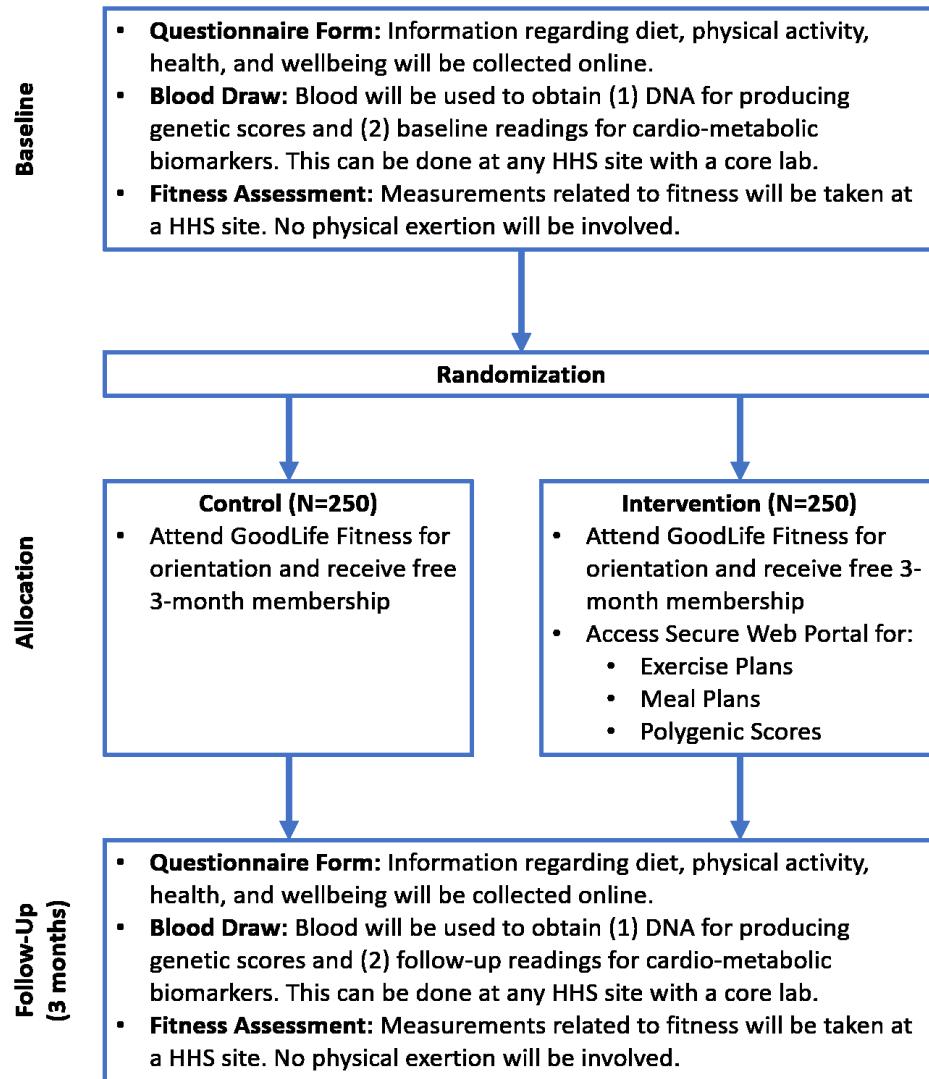
## **WHOM DO I CALL IF I HAVE ANY QUESTIONS?**

For general questions about the study, please contact [DNABLE@geneblueprint.com](mailto:DNABLE@geneblueprint.com).

If you have any questions regarding your rights as a research participant, you may contact the Office of the Chair of the Hamilton Integrated Research Ethics Board at 905-521-2100, ext. 42013.

## Appendix

### DNA<sub>ble</sub> Study Participant Journey



## CONSENT STATEMENT

### SIGNATURE OF RESEARCH PARTICIPANT

**I have read the preceding information thoroughly. I have had the opportunity to ask questions, and all of my questions have been answered to my satisfaction. I agree to participate in this study. I understand that I will receive a signed copy of this form. In signing this form and donating samples for genetic research, I do not give up any of my legal rights.**

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Name of Participant

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Signature of Participant

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Date

### Consent form administered and explained in person by:

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Name and title

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Signature

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Date

### SIGNATURE OF INVESTIGATOR:

**In my judgement, the participant is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.**

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Signature of Investigator

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Date