



THE HOSPITAL FOR
SICK CHILDREN

Research Ethics Board

**Protocol Title: Personal Genome Project Canada
Eligibility Questionnaire (“Mini”) Consent Form**

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Purpose of the Research:

The Personal Genome Project Canada (also the “PGP” or the “study”) is an independent public genomics research project and a joint venture between the Hospital for Sick Children and the University of Toronto McLaughlin Centre for Molecular Medicine. The main scientific goal of this study is to explore ways to connect human genetic information with human trait information (i.e., human DNA sequence, medical information, tissue samples and physical traits) in a public fashion so that such data may be used for hypothesis-generating research and other scientific, clinical and commercial development efforts worldwide. Additional goals include (i) developing a fully consented and public dataset to aid in the development of computational tools and user interfaces for scientists, clinicians and individuals; and (ii) the education of participants and the general public about the potential benefits, risks, and uncertainties posed by the widespread availability of genetic and related information. More detail about the PGP will be described in the subsequent “full” consent document as this consent form is for the eligibility screening only.

This eligibility screening form for the Personal Genome Project Canada (this “Eligibility Screening”) is intended to help determine whether you are a candidate for registration in the PGP, a public and open-ended research study. In order to participate you must be 18 years or older, and willing to publicly share your personal genome sequence and trait information. Due to the novelty of this project, the consent process has been divided into different stages; this “mini” consent form represents the first stage. If you successfully complete this Eligibility Screening and meet all eligibility criteria (described below) you will be notified that you are registered. Additional consents will be required for registered individuals to fully participate in this project. Individuals who do not meet the eligibility criteria will be informed and given the reason why they are ineligible.

Upon successful registration in the PGP and completion of additional consents, including the “full” consent form, your genetic and trait information will be made available on a publicly accessible website and database. In order to complete this Eligibility Screening and to be considered for registration in the PGP, you are first required to complete certain eligibility screening procedures online, including the eligibility questionnaire and entrance exam described below, and review the “full” PGP consent form. This Eligibility Screening is intended to help determine whether you are a candidate for registration in the PGP.

Description of the Research:

Eligibility Screening Procedures

1) Eligibility Questionnaire:

(a) You will be asked to respond to 6 questions online (see Appendix 1) and provide the following personal information: name, year of birth, postal code, and email address.

(b) Upon completion of the eligibility questionnaire, you will be notified by the PGP that you are either: (1) eligible to continue or (2) ineligible.

2) Review of the “full” PGP consent form

PGP-Canada Mini Consent Form January 16, 2013

(a) You will be asked to review the “full” consent form for registration in the PGP. The “full” consent form outlines all the policies, procedures, risks and discomforts of participation in the PGP. You are being asked to become familiar with the fill consent form so you can decide whether to continue with the Eligibility screening process. You will be asked to sign the “full” consent form at a later time if you meet all eligibility criteria.

(b) A copy of the current PGP consent form is available on the PGP-Canada website.

3) Entrance Exam:

(a) You will be asked to respond to 27 questions online. The entrance exam is meant to evaluate knowledge in the four following categories: (1) risks associated with participation, (2) human subjects research guidelines, (3) PGP protocols, including content from the “full” consent document, and (4) basic genetics. Knowledge in these four areas are required before participants can make an informed decision about whether to participate.

(b) Correct responses to all exam questions are required to successfully complete this Eligibility Screening and to be considered for registration in the PGP.

(c) The entrance exam may be taken as many times as necessary to achieve correct responses to all questions.

4) Completion and Submission of the Eligibility Screening:

(a) After you have completed the eligibility questionnaire, the entrance exam and any other required eligibility screening procedures, and reviewed the PGP consent form, you will be given the option to submit the results of your Eligibility Screening to the PGP for review.

(b) If you choose not to submit the results of your Eligibility Screening no determination will be made by the PGP about your eligibility status and your participation in this Eligibility Screening will be terminated; any information you entered will be deleted. You may choose to participate in this Eligibility Screening again at a later date.

(c) If you choose to submit the results of your Eligibility Screening your information will be transmitted to the PGP. Your information will be reviewed by the PGP and you will subsequently be notified by the PGP that you are either: (1) eligible to continue, or (2) ineligible. If you are eligible to continue then you are considered registered and can continue with the enrolment procedure. If you are ineligible, you will be informed of the reason why.

(d) Participants should keep in mind that any personal genome data produced from this project may not be used for any medical or clinical purpose unless the DNA sequence or other data, including any interpretations or findings presented in your Preliminary Research Report (described in the PGP-Canada full consent form), are first confirmed by a licensed healthcare professional. Genome sequencing is not an all-encompassing genetic screen for every possible condition.

Potential Harms:

We know of no harm from taking part in this Eligibility Screening could cause you

Potential Discomforts or Inconvenience:

The online eligibility questionnaire will take approximately 5-15 minutes.

The online entrance exam will take approximately 30-90 minutes, but may take longer depending on your familiarity with genetics and other concepts relevant to participation in the PGP.

Reading and reviewing the PGP consent form will take approximately 30-60 minutes, but may take longer depending on your familiarity with genetics and other concepts relevant to participation in the PGP.

Potential Benefits:

There are no proven benefits to you from your participation in this Eligibility Screening.

Confidentiality:

If you choose to submit the results of your Eligibility Screening, as described above, your name or identity will be linked to your responses and shared with PGP staff. PGP staff include: the PI, Co-PI's, a research coordinator, a database manager and one computer programmer. The PGP will take all reasonable precautions to ensure that your name and your Eligibility Screening responses and results are kept confidential.

The data produced from this phase of the study will be stored in a secure, locked location on a password protected computer. Sick Kids Clinical Research Monitors, employees of the funder or sponsor, or the regulator of the study may see your research record to check on the study. By signing this consent form, you agree to let these people look at your record.

You will be able to print a copy of this completed form for your records.

Reimbursement:

Regardless of whether or not you choose to submit the results of your Eligibility Screening, and regardless of whether the PGP determines that you are eligible to continue, you will not be compensated, including for any time lost, for your participation in this Eligibility Screening.

Participation:

It is your choice to take part in this study. You can stop at any time. The care you or your family members get at any healthcare institution, including Sick Kids will not be affected in any way by whether you take part in this study. Your signing this consent form does not interfere with your legal rights in any way. The staff of the study is still responsible legally and professionally, for what they do.

New information that we get while we are doing this study may affect your decision to take part in this study. If this happens, we will tell you about this new information. And we will ask you again if you still want to be in the study.

During this study we may create new tests, new medicines, or other things that may be worth some money. Although we may make money from these findings, we cannot give you any of this money now or in the future because you took part in this study.”

Sponsorship:

The Sponsor of this research is Dr. Stephen Scherer and the Funder of this research is the University of Toronto McLaughlin Centre for Molecular Medicine.

Conflict of Interest:

Dr. Stephen Scherer and the other research team members have no conflict of interest to declare.

Consent :

By signing this form, I agree that:

- 1) You have explained this study to me. You have answered all my questions.
- 2) You have explained the possible harms and benefits (if any) of this study.
- 3) I know what I could do instead of taking part in this study. I understand that I have the right not to take part in the study and the right to stop at any time. My decision about taking part in the study will not affect my health care at Sick Kids.
- 4) I am free now, and in the future, to ask questions about the study.
- 5) I have been told that my medical records will be kept private except as described to me.
- 6) I understand that no information about who I am will be given to anyone or be published without first asking my permission.
- 7) I have read and understood pages one to five of this document. I agree, or consent, to take part in this study.

Printed Name of Subject & Age

Subject's signature & date

Printed Name of person who explained consent
date

Signature of Person who explained consent &

If you have questions about your rights as a subject in a study or injuries during a study, please call the Research Ethics Manager at 416-813-5718. If you have any concerns or questions about this study please contact Steve Scherer by phone at (416) 813-7613 or by email at stephen.scherer@sickkids.ca.

