

Supplementary file 4

GP notification letter

The Health Outcomes, Utility, and Costs of Returning Incidental Genomic Findings

[Date]

Dr. [Name]

Address

Address

Dear Dr. [Name],

RE: Surname, First name**DOB: mmm, dd, yyyy**

This letter is to inform you of [Participant's name]'s participation in a research study called **"The Health Outcomes, Utility, and Costs of Returning Incidental Genomic Findings."** This study is being conducted by investigators at St. Michael's Hospital and [Cancer Clinic Name] at [Hospital Name] where the participant was recruited by [Co-PI]. [Participant's name] has chosen to enroll into this study where she/he will undergo a genetic test called Whole Exome Sequencing (WES) and she/he will receive results pertinent to his/her primary cancer indication [and additional results known as incidental findings]. **All consultation notes and results will be forwarded to your office.** If you have any questions about the study please feel free to contact the study genetic counsellor [insert name] directly at [Insert number] or [email].

As you may already know, [Participant name] had previously undergone clinical genetic testing for his/her [cancer(s)] in the past, and tested **negative or had inconclusive results** for [gene(s)]. This research study aims to use WES which is a genetic test that utilizes Next Generation Sequencing (NGS) technology to analyze over 95% of the coding regions of the genome, which includes over 20,000 genes. Eligible participants for this study are those with a high suspicion of a hereditary cancer due to their clinical presentation, family history, and/or other factors, who have previously had negative genetic testing in the clinical setting.

[Participant name] will receive results pertinent to his/her primary cancer indication, if found. [*If in control arm:* She/he has received genetic counselling to review the benefits, risks, and limitations surrounding the possible results before making a decision regarding whether or not to participate.] Further, [Participant's name] has chosen to receive additional results known as incidental findings. Incidental findings are unrelated to the reason for undergoing genetic testing and because WES analyzes nearly all coding regions of the genome, it is possible to find genetic changes that are unexpected but may have important health implications. [Participant's name] has received genetic counselling to review the benefits, risks, and limitations surrounding incidental findings before making a decision regarding whether or not to receive them.]

Results may reveal that [Participant's name] is at increased risk for various hereditary conditions, and may have implications for medical recommendations such as uptake of screening procedures, early intervention strategies, medication changes and uptake of risk reducing measures. If applicable, [Participant's name] will be referred to a [genetics clinic] for clinical evaluation and further assessment of his/her findings. We emphasized to [Participant's name] that no matter how well or carefully performed, early intervention or risk reducing measures do

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not guarantee that disease will be detected at a stage that is curable or amenable to minimal treatment.

A summary of [Participant's name]'s sequencing results, interpretation and medical management recommendations will be provided to you within three to four months. Notes and results from any further specialist consultations will be forwarded to your office as well.

If you would like to speak to the study genetic counselor at any time about your patient's exome sequencing results, implications for medical management or referrals, you may contact him/her here:

[Study Genetic Counsellor's Name] [phone number]

If you have any questions, concerns or would like to speak to the study team for any reason, please call:

[PI name], Principal Investigator, [number]

[Research Coordinator name], Research Coordinator [number]

(Add name of site PI for recruiting hospital).

Thank you for the opportunity to be involved in this patient's care.

Sincerely,

PI name [Designation]
Research Scientist,
Li Ka Shing Knowledge Institute
St. Michael's Hospital

Copy to: [Participant's name]