Official title of the study: Feasibility and Implementation of a Healthy Lifestyles Program: A Pilot Study

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McMaster University

Appendix 8. Interview letter of information/consent – Family focus group

Title of study: Evaluating a healthy lifestyles program

Principal investigator: Elizabeth Alvarez, MD, MPH, PhD, CMCBT

Co-investigator(s): Lawrence Mbuagbaw, MD, MPH, PhD; Majdi Qutob, MD, MSc, MBA; Cynthia Lokker, PhD; Marjan Walli-Attaei, PhD candidate; John N. Lavis, MD, PhD; Zena Samaan, MD, MSc, MRCPsych, PhD

You are being invited to participate in a research study. The purpose of the study is to evaluate a healthy lifestyles program and to better understand the role of the family in making healthy life changes. Specifically, you are being invited to participate in a focus group with other family members of those who are enrolled in a healthy lifestyles program. Your involvement would mean participating in a 2-3 hour (roughly) group meeting to be scheduled by the research coordinator. During the meeting, a research assistant/student investigator will ask you questions about your thoughts on the healthy lifestyles program, about whether or not you think there have been any changes in your family member who is part of the program, what you think your role or the role of other family members is in making lifestyle changes, and whether you have been involved in making changes to your own lifestyle.

Your participation in this research study is voluntary. You may refuse to participate in the research study and you may choose to withdraw from the focus group at any time. We cannot promise any personal benefits to you from your participation in this study. However, a possible benefit includes helping improve the healthy lifestyles program and related programs, research or policy, especially around the role of families in supporting healthy lifestyle changes.

Your information will be treated in a confidential way. The research assistant/student investigator will take notes during the focus group and audio-record in case the research team needs to review the tapes for completeness of information. Personal identifiers will be assigned to the notes, the audio-recorded digital file and the transcript. We will ensure that any documents are kept in a locked cabinet, the digital files containing the audio-recordings and transcripts are stored on a security protected computer, and the digital files, transcript and confidential documents are destroyed 10 years after the last publication of our findings. We will make the summary of our findings publicly available for use by others interested in improving programs, research or policy around healthy lifestyles.

Your anonymity as a research study participant will be safeguarded. We will ensure that the list of study participants and their participant numbers will be stored in a different locked cabinet or security protected computer from those where the digital files, transcripts and confidential documents are stored. There is minimal risk expected from participating in this study. There is a

slight chance that someone may be recognizable by his/her comments. However, every effort will be made to report information in a way which will not identify individual respondents. It is also expected that participants treat this meeting in a confidential way, that is, information from this session should not be shared with others.

Please check yes or no to the questions below to indicate whether you consent to participate in our study. We would be pleased to provide you with additional information about our study and your potential participation. Please see contact information below if you have any questions about entering the study or while you are enrolled in the study. For the purposes of ensuring the proper monitoring of the research study, it is possible that a member of the Hamilton Integrated Research Ethics Board may consult your research data. However, no records which identify you – be it name or initials will be allowed to leave the university. By signing this consent form, you authorize such access.

Request for consent	Yes	No
1. I am willing to participate in a 2-3 hour (roughly) focus group with about 6-10 people and I understand that this will be audio-recorded		
2. Please contact me. I would like additional information about the study and/or my participation.		

I will receive a signed copy of this form.

Participant Date: _____

Print name: _____ Signature:_____

Person obtaining consent Date: _____

Print name: _____ Signature:_____

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HIREB). The HIREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call The Office of the Chair, HIREB at 1-905-521-2100 x 42013.

Sincerely

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