Participant Information and Consent Form

Project title
Heavy Conversations: Doctors, Patients and Weight Loss

Study investigators
Principal Investigator: [insert name, title, organization]
Phone: [insert phone number]
Email: [insert email address]

Co-investigator(s): [insert name, title, organization]
Phone: [insert phone number]
Email: [insert email address]

Funding source
This study is funded by [organization/source of funding].

Invitation to participate
You are being invited to participate in a research study. Choosing whether or not to participate is entirely your choice. If you decide not to participate, there will be no negative impacts on the care you receive from your health care provider. The information provided in this form tells you about what is involved in the research, what you will be asked to do, and any potential risks or benefits. Please read this form carefully, take all the time you need, and ask any questions you may have.

Consent is an ongoing process that continues for as long as you are in the study. If something changes during the research study, or there is any new information that could affect your willingness to continue to participate, we will tell you and ask whether you still consent to participate in the study. Remember that you are free to withdraw your consent at any time for any reason, even if nothing in the study has changed.

Purpose of the research study
Managing body weight has become a highly charged issue in primary care settings in recent years. Doctors are under increased pressure to help their patients manage their weight, which results in additional pressure on their overweight patients. The goal of this research is to learn more about the primary health care experiences and expectations of overweight patients and the doctors who treat them. We expect that this research will lead to improved communication between patients and their health care providers about managing body weight.

What you will be asked to do
If you decide to participate in this research, you will be asked to attend one visit at [insert location]. This visit will take approximately 2 hours and will involve taking part in a focus group with up to 10 people. During this session, you will be asked about your history of weight gain/loss, your personal perspectives on weight management, your visits to your medical

doctor, and your interactions with your medical doctor. With the consent of all participants, the focus group will be audio recorded and then transcribed to accurately record your views and opinions. If you or another participant would prefer the focus group not to be recorded, only written notes will be taken.

Who can take part in the research study?
To be involved in this study, you must be considered overweight by your doctor and be at least 18 years old. We are looking to recruit 50 participants in total.

Possible risks and benefits

Risks: As the focus group will deal with the topic of body weight and your experiences in primary care settings, it is possible that it may raise issues or feelings that you would like support in dealing with. If this happens, the researcher can refer you to a free counselor, or to other resources in the community that can help you. You can leave the focus group at any time, and you do not have to answer any questions that make you feel uncomfortable. You can also withdraw your participation in the project at any time (within the limits described below). By agreeing to participate in this research you are not giving up or waiving any legal rights in the event that you are harmed during the research.

Benefits: You may not receive any direct benefit from participating in this study. However, the focus group will provide you with the opportunity to voice your opinion on your experiences and will hopefully raise awareness of how patients would like to interact with medical doctors in primary care settings around the topic of weight management.

Compensation/reimbursement
To acknowledge your time and to contribute to your transportation costs, each participant will receive a $20 gift card to [indicate type: name of store, online merchant, Visa/Mastercard, etc.]. If you consent to participate, but change your mind before coming to the session, you will not receive this gift card. If you consent to participate but change your mind during the session, the compensation will be provided regardless of your decision to withdraw.

Privacy protections and confidentiality
We will assign each participant an ID code which means your name will not appear on any documents or recordings. This ID code will be recorded on a password-protected encrypted electronic file. A master list, which provides the link between your identifying information and your ID code, will be stored securely and separately from your name and contact information, but only the researchers involved in the study will have access to this document. Your data will also be stored in an encrypted electronic file protected by a password.

Hard copies of the focus group notes and transcripts will be stored in a locked filing cabinet in the office of the Principal Investigator and electronic copies will be kept on the local hard drives of team members' computers – all of which are password protected. Audio recordings of the focus groups will be destroyed as soon as they have been transcribed, and any identifying

information will be removed from the transcripts. All other documents and files will be destroyed 10 years after the study is completed. Participants will not be identified by name in any reports of the completed study.

Limits to confidentiality: Please be aware that there are limits to confidentiality in a focus group setting. All members of the focus group will be asked to respect the privacy of other members and to keep what is said confidential. However, there is no guarantee that they will do so. Please keep this in mind when deciding what you feel comfortable sharing.

No personal information will be shared with anyone outside of the core research team, except in certain limited circumstances as outlined in the Privacy Notice. We are also required by law, under the Regulated Health Professions Act (RHPA), to report any instances where a health care provider may have acted inappropriately.

Reporting of results

Although the project outcomes will be determined by the research findings, possible research products will include: articles in scientific journals, a report for our organization's internal use, a brief for health care providers, and plain language summaries. We will only report group results, to reduce the risk to as low as possible that you are identified in our reports. If we include any quotes from participants, we will only do so with your permission. Quotes will not include information that could directly identify you, such as names or identifying numbers, and will not be attributed to a specific individual. If you wish to be informed of the results of the research, please indicate this on the signature page below.

Withdrawing from the study

Your participation is completely voluntary, and you are under no obligation to participate. If you decide to participate but change your mind later on, you are free to withdraw at any time without consequence. If you decide to withdraw during the focus group, it may not be possible to remove your data, although we will make our best effort to avoid referring to your responses. If you decide to withdraw after the session, your data will already be de-identified and we will not be able to remove your data. To withdraw from the study, please contact the Principal Investigator mentioned below.

Conflicts of interest

None of the researchers have any conflicts of interest in this study.

Questions and contact information

If you have any questions about the study or would like more information, please contact:

Principal Investigator: [insert name, title, organization]
Phone: [insert phone number]
Email: [insert email address]

If you have any questions about your rights as a research participant, you may contact:

Health Canada-PHAC Research Ethics Board Secretariat
Telephone: 613-941-5199
Email: reb-cer@hc-sc.gc.ca

This research study was reviewed by the Health Canada and Public Health Agency of Canada Research Ethics Board.

Signature Page

Project title: Heavy Conversations: Doctors, Patients and Weight Loss

Lead researcher: [insert name of Principal Investigator, title, organization]

Privacy Notice [only for projects led by Health Canada or PHAC researchers: Insert privacy notice as developed in consultation with the Health Canada-PHAC Privacy Management Division]

Statement of consent

By signing this form, I agree that:

- The study has been explained to me
- All my questions have been answered
- Possible harm and discomforts and possible benefits (if any) of this study have been explained to me
- I have been told that my personal information will be protected

In addition, I understand that:

- I have the right not to participate and the right to stop at any time
- I may refuse to participate without consequence
- I have a choice of not answering specific questions
- I am free now, and in the future, to ask any questions about the study
- No information that would directly identify me will be released or printed without my consent
- I will receive a signed copy of this consent form

You can still participate in the research if you select "no":

I agree that I may be quoted directly, but any quotes will not include information that could directly identify me ☐ Yes ☐ No

I agree that the focus group may be audio recorded ☐ Yes ☐ No

_____	_____	_____
Name	Signature	Date

Please provide an email address below if you would like to be sent a summary of the study results.

Email address: _____

Signature of the person obtaining consent

By signing this form, I attest that:

- I have explained the study to the prospective participant
- I answered all of their questions
- I provided a copy of this consent form to the participant
- The participant seemed to understand the consent form and agreed to participate

_____	_____	_____
Name	Signature	Date