Informed Consent Form (Qualitative study)

Project title
Heavy Conversations: Doctors, Patients and Weight Loss

Study investigators
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Funding source
This study is funded by the Public Health Agency of Canada (PHAC) using internal funds.

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 your relationship with the researcher. 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. During the research study, we will tell you about any significant finding that could affect your willingness to continue to participate in this study.

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 understand more about the primary health care experiences and expectations of overweight patients and the doctors who treat them. By exploring the perspectives of both groups, we expect that this research will lead to improved communication between patients and their medical doctors 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 (1) visit at the Health Promotion and Chronic Disease Prevention Laboratory at PHAC. 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 your permission the focus group will be recorded and then transcribed to accurately record your views and opinions. If you 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. 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: There is no guarantee that you will benefit directly 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
In order to acknowledge the time that you have taken to be involved in this project and to defray your transportation costs, each participant will receive a $20 gift card. If you consent to participate, but change your mind before coming to the session, you will not receive this money. If you consent to participate but change your mind during the session, the compensation will be provided regardless of your decision to withdraw.

Privacy and confidentiality
All hard copies of documents and recordings will be identified only by code number and kept in a locked filing cabinet. You will not be identified by name in either the recording or the focus group transcript. 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. Participants will not be identified by name in any reports of the completed study.

The personal information collected in this research project is handled in accordance with the *Privacy Act*. We only collect the information we need to carry out the research as authorized under section 4 of the *Department of Health Act*. In addition to protecting your personal information, the *Privacy Act* gives you the right to request access to, and correction of, your personal information. For more information about these rights, or about our privacy practices, please contact the Health Canada and the Public Health Agency of Canada's Privacy Management Division at 613-954-9165 or hc.privacy-vie.privee.sc@canada.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

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, unless required by law. Instances where researchers are required, by law, to breach confidentiality include the following: child abuse or neglect that is ongoing and unknown to police, cases of imminent risk of physical harm to oneself or another, cases of sexual abuse, sexual assault, or sexual harassment by a health professional.

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 the Public Health Agency of Canada's internal use, a brief for health care providers, and plain language summaries. We will only report group results, therefore, you will not be identified in any way in our reports. Any quotes will be anonymized 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. Your decision to withdraw will not influence your relationship with the researcher in any way. 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 anonymized and we will not be able to remove your data.

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:

Dr. John Smith
613-555-1212
john.smith@canada.ca

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

Health Canada-PHAC Research Ethics Board Secretariat
70 Colombine Driveway, Room 941C, PL: 0909C
Brooke Claxton Building, Tunney's Pasture
Ottawa, ON K1A 0K9

Telephone: 613-941-5199
Facsimile: 613-941-9093
Email: hc.reb-cer.sc@canada.ca

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

Signature Page

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

Lead researcher: Dr. John Smith

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 kept confidential

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 identify me will be released or printed without asking me first
- 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 and anonymously ☐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

Canada