



Claims of Health Benefits and Chiropractic Care Deliberative Dialogue Information Sheet and Consent Form – Patients

In order to decide whether or not you want to be a part of this research study, you should understand what is involved and what the potential risks and benefits might be. This form gives detailed information about the study, which will be discussed with you. If you would like more information on the project you may contact the Study Lead, Dr. Mark Dobrow, at 647-267-1145 or mark.dobrow@utoronto.ca.

WHY IS THIS RESEARCH BEING DONE?

The Accessing Centre for Expertise (ACE) at the Institute of Health Policy, Management and Evaluation, University of Toronto, has been contracted by the College of Chiropractors of Ontario (CCO) to conduct an evaluation of policy-relevant evidence on regulatory standards of practice regarding claims of health benefit from chiropractic care. In the context of the COVID-19 pandemic, CCO has observed an increase in the number of complaints regarding chiropractors making health benefits claims due to chiropractic, specifically claims related to immunity benefits that are deemed to lack both a scientific evidence base and expert consensus. CCO would like to develop a policy for how to address what is permissible and what is not permissible in relation to chiropractors making health benefits claims regarding immunity and, in particular, what constitutes a sufficient evidence base for such claims. To consider these challenges, this study will proceed in three phases, (i) scoping review and targeted scan of policy documents, (ii) key informant interviews, and (iii) deliberative dialogues with stakeholders.

WHAT IS THE PURPOSE OF THIS STUDY?

The current phase of this research aims to elicit a diverse range of stakeholder perspectives on standards of practice regarding claims of health benefits from chiropractic care. Specifically, we aim to (i) draw on your lived experience with respect to health care generally and/or chiropractic care specifically to assess your level of trust in the claims made by the chiropractic profession and (iii) discuss your expectations for the types of information, data or evidence that should be provided to support chiropractic claims of health or immunity benefits.

WHAT WILL BE MY RESPONSIBILITIES IF I TAKE PART IN THE STUDY?

We would like to invite you to participate in a deliberative dialogue. Each deliberative dialogue will be led by a dedicated facilitator and note-taker (ACE team members) and conducted under Chatham House Rule whereby participants are asked to keep the nature of the discussion confidential and not to associate specific comments with any individual participant, thus allowing participants to engage in discussion more freely. The deliberative dialogue will be conducted remotely via Zoom and last for three hours.

Deliberative dialogue sessions will be audio recorded. This recording will be transcribed, word-for-word, by a professional transcriptionist. We use the word-for-word transcript of the discussion for analysis.



This consent form provides specific options for you to consider with respect to this invitation, including whether you: (i) agree to participate (Y/N), (ii) agree to be quoted anonymously in published reports, (iii) wish to receive a copy of the final report from this study, and (iv) agree to be re-contacted, if necessary.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

You are not at risk of physical harm if you participate in this study. The risks of this research are primarily social, related to your professional role. Although we will make every effort to ensure your privacy and confidentiality, the risk remains that very well-informed observers might guess that you have participated, or guess that an anonymized quotation in a public report comes from you. As well, if you are employed by an organization with an interest in the subject matter under review, you need to understand that we are not seeking the consent of your organization for these interviews. This could create additional social risks if results were to cast a negative light on the policies or practices of your organizations, and especially if your participation were guessed at by colleagues or superiors at your organization.

We will make every effort to minimize these risks, including by stripping all personally identifiable markers from the recording or transcript of your interview, and ensuring that any direct quotes used in publications or presentations do not inadvertently identify you.

HOW MANY PEOPLE WILL BE IN THIS STUDY?

We hope to engage approximately 60 stakeholders from across Canada and internationally during this phase of the study.

WHAT ARE THE POSSIBLE BENEFITS FOR ME AND/OR FOR SOCIETY?

If you agree to take part in the study, there will not be any direct benefit to you. We hope that the results will be of interest to you and will be relevant to the refinement of regulatory standards of practice regarding claims of health benefit from chiropractic care.

WHAT IF I DO NOT WANT TO TAKE PART IN THE STUDY?

You are free to choose not to participate in this study. If you decide not to participate in the study, there is no need to sign this form.

WHAT INFORMATION WILL BE KEPT PRIVATE?

We respect your privacy. No information about who you are will be given to anyone or be published without your permission, unless required by law.

The deliberative dialogue session will be recorded so that it may be transcribed, word-for-word by a professional transcriptionist. Your name and all other identifying information such as your email address or phone number will be removed from the transcript, and replaced by a unique study identification ID number. A list linking the study ID number with your name will be kept in a password-protected file separate from your data. The audio recording will be securely stored on a password-protected computer accessible only to core members of the research team. The data will be stored by study lead at the University of Toronto for analysis.



The data produced from this study will be stored in a secure, locked location. Only members of the core research team will have access to the data. Following completion of the research study the data will be kept as long as required (typically 7 years) then destroyed as required by University of Toronto policy. Published study results will not reveal your identity, or that of your organization.

The research study you are participating in may be reviewed for quality assurance to make sure that the required laws and guidelines are followed. If chosen, (a) representative(s) of the Human Research Ethics Program (HREP) may access study-related data and/or consent materials as part of the review. All information accessed by the HREP will be upheld to the same level of confidentiality that has been stated by the research team.

SPONSORSHIP

This study is funded by the College of Chiropractors of Ontario.

CONFLICT OF INTEREST

Dr. Mark Dobrow has no conflict of interest to declare.

CAN PARTICIPATION IN THE STUDY END EARLY?

Your participation in this research study is entirely your choice. You may withdraw at any time. If you withdraw before or during the deliberative dialogue, your data will be destroyed. If you decide to withdraw after the deliberative dialogue, but before data analysis is finalized or the study is published, you may contact the investigators and ask that your data be destroyed. We can withdraw your data until such time as the data analysis is finalized or the study is in press or published.

WILL I BE PAID TO PARTICIPATE IN THIS STUDY?

You will receive a \$100 gift card as thanks for your time and input.

WILL THERE BE ANY COSTS?

The only cost to you is the time you take to complete the deliberative dialogue session.

IF I HAVE ANY QUESTIONS OR PROBLEMS, WHOM CAN I CALL?

If you have any questions about the research now or later, please contact the study lead:

Mark Dobrow, Ph.D.
Associate Professor
Institute of Health Policy, Management and Evaluation
Dalla Lana School of Public Health
University of Toronto
Tel: 647-267-1145
Email: mark.dobrow@utoronto.ca



If you have questions about your rights as a subject in a study or injuries during a study, please contact Daniel Gyewu, Health Sciences Research Ethics Manager, Office of Research Ethics, University of Toronto, at telephone 416-946-5806 or by email: d.gyewu@utoronto.ca

CONSENT STATEMENT

Consent and Privacy Options	YES	NO
1. I understand and agree to participate in the research, I am willing to participate in a telephone interview to be scheduled/ conducted at my convenience.		
2. I am willing to allow the research to quote information offered in my interview (quoted anonymously, not ascribed directly to me).		
3. I would like to receive a copy of the final report when it is published.		
4. I would agree to be re-contacted, if necessary.		

Signature of Research Participant/ Legally-Authorized Representative:

I have read the above information thoroughly. I have had the opportunity to ask questions, and all of my questions have been answered to my satisfaction. I agree to participate in this study, in accordance with the terms specified above.

I understand that I will receive a signed copy of this form.

 Name of Participant

 Signature

 Date

Consent form administered and explained over the telephone by:

 Name and title

 Signature

 Date