The Ottawa Hospital | L'Hôpital d'Ottawa
RESEARCH INSTITUTE | INSTITUT DE RECHERCHE
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Main Informed Consent Form for Participation in a Research Study – Online Survey

Study Title: Understanding the barriers and drivers to clinical trial participation across clinical areas: A theory-guided survey framework.

OHSN-REB Number*:* 20180250-01H

Local Site Principal Investigator (PI): Dr. Jamie Brehaut (613) 737-8899 ext. 73820

Funding Agency: Clinical Trials Ontario

INTRODUCTION

You are being invited to participate in an online questionnaire for a research study. You are invited to participate in this study because of your experience with breast cancer. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. Taking part in this study is voluntary. Deciding not to take part or deciding to leave the study later will not result in any penalty.

IS THERE A CONFLICT OF INTEREST?

There are no conflicts of interest to declare related to this study.

WHY IS THIS STUDY BEING DONE?

Participation in clinical trials and other clinical research has been declining for decades. Low participation increases the cost of research, lowers the quality of studies, slows innovation, and potentially lowers the quality of patient care by wasting resources that could be better used in other ways. Our goal is to develop and evaluate different strategies to address this issue by better understanding how people decide to participate, or not to participate, in trials.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that approximately 1,625 participants will take part in this study.

This study should take 2 years to complete from the time of the first interview until the submission of the final manuscript.

WHAT WILL HAPPEN DURING THIS STUDY?

You will be provided with a link to an online questionnaire. The purpose of the questionnaire is to explore your knowledge of clinical trials, as well as understand what you think are the most important barriers and drivers to participation in clinical trials. It is estimated that the questionnaire will take approximately 15-20 minutes to complete.

You may skip any questions that make you uncomfortable or that you do not wish to answer.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

Your participation in the study will last approximately 15-20 minutes for the questionnaire.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the research team.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the research team know. However, this would also mean that you withdraw from the study.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

You might find that some of the questions are sensitive in nature, and or personal. You can choose not to answer questions that make you feel uncomfortable.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You may not receive any direct benefit from your participation in this study. We hope that findings from this study will help us conduct clinical research more efficiently and effectively in the future.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the research team will only collect the information they need for this study. Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- The Ottawa Health Science Network Research Ethics Board who oversees the ethical conduct of this study
- Ottawa Hospital Research Institute, to oversee the conduct of research at this location

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Your name, address, or other information that may directly identify you will not be used. The records received by these organizations may contain your participant code.

This research study is collecting information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond. Providing information on your race or ethnic origin is voluntary.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/ presented to the scientific community at meetings and in journals.

Your de-identified data from this study may be used for other research purposes. If your study data is shared with other researchers, information that links your study data directly to you will not be shared.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

You will not be paid for taking part in this study

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please contact the research team.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form, you do not give up any of your legal rights against the researcher, or involved institutions for compensation, nor does this form relieve the researcher or their agents of their legal and professional responsibilities.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, please contact Dr. Jamie Brehaut at 613-737-8888 ext. 73820 or via email at jbrehaut@ohri.ca, or you may contact Kelly Carroll (Research Coordinator) at 613-737-8899 ext. 73824 or via email at kecarroll@ohri.ca

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. Please contact The Ottawa Health Science Network Research Ethics Board, Chairperson at 613-798-5555 extension 16719.

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