Participant Consent Form

Instructions: All titles in black and text in grey are standard text and descriptions that are typically required by your Research Ethics Board. More detailed information about this standard text should be obtained from your Research Ethics Board. Information regarding Secondary Analysis to Generate Evidence (SAGE) is in **teal**, and will help facilitate storage in our data repository as well as secondary use and linkage.

TITLE: Full title of the research project

INVESTIGATORS: State name of the local Principal Investigator, and any other co-investigators if desired

BACKGROUND
State the rationale of the study

WHAT IS REASON/PURPOSE OF THE STUDY?
Describe the purpose of the study, and what it hopes to answer

WHAT WOULD I HAVE TO DO?
Describe the study overall first, then what exactly has to be done in chronological order.
Bullet forms may increase clarity. Include the following:

- Estimated time required to participate, frequency, and type/number of test, interviews, visits or questionnaires.
- For clinical trials explain any randomization, treatment groups, etc.
- With your consent, allow re-contact for potential follow-up or future research.
- With your consent, allow storage and re-use of study data through a secure data repository to facilitate future research.
- With your consent, allow linkage of study data to other datasets to facilitate future research.

WHAT ARE THE RISKS?
Include information on any known risks or discomforts of the study.

WHAT ARE THE BENEFITS?
Include any direct or indirect benefits that can be anticipated from participation.

DO I HAVE TO PARTICIPATE?
Should take about the voluntary nature of the study and withdraw from study at any time without jeopardizing their health care.

WILL MY INFORMATION BE KEPT PRIVATE?
Explain who will have access to the information. Include how confidentiality will be protected, if they are not confidential; describe how they will be presented, etc.

After study completion, you have the option of allowing your study data will be stored in a secure data repository to facilitate re-use of data by approved researchers. Any of your personal information (i.e. your name, address, telephone number) that can identify you will be removed or changed prior to sharing with other researchers. Researchers that wish to use study data must 1) have their new study

approved by an ethics board; 2) sign an agreement ensuring your confidentiality and restricting data use to only the approved study.

In addition, your study data may be linked with other data to enable further research. In this case, identifying information will be provided to the secure data repository. This information will be stored on a secure isolated server, and use this information only to link your data to other datasets. Again, any of your personal information (i.e. your name, address, telephone number) that can identify you will be removed or changed prior to sharing with other researchers.

WHAT IF I HAVE QUESTIONS?

List contact information for the researchers involved in the study.

	Yes	No
Do you understand you have been asked to be in a research study?	☐	☐
Have you read and received a copy of the attached Information Sheet?	☐	☐
Do you understand the benefits and risks involved in taking part in this research study?	☐	☐
Have you had the opportunity to ask questions and discuss the study?	☐	☐
Do you understand you are free to leave the study at any time without having to a give a reason and without affecting your future care?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐
Do you understand who will have access to your study records, including personally identifiable health information?	☐	☐
Future Contact	**Yes**	**No**
I agree to be re-contacted for follow-up or to facilitate future research. I understand that my participation in follow-up or future research is voluntary	☐	☐
Use of the information I provide beyond this project	**Yes**	**No**
I agree for my study data to be securely stored in a secure data repository to facilitate future research. I understand that my study data may be made available to other researchers but my identity will be protected and my confidentiality will be preserved	☐	☐
I agree for my personal identifiers to be securely stored to facilitate future research and to permit linkage with other data	☐	☐
I understand that my study data may be linked to other information but my identity will be protected and my confidentiality will be preserved	☐	☐

SIGNATURES

Participant's Name	Signature and Date
Investigator/Delegate's Name	Signature and Date
Witness' Name	Signature and Date

Adapted from University of Calgary and University of Alberta consent templates