# Consent to Participate in a Case Report

**PLEASE NOTE: A case report with three or fewer patients does not meet the definition of research on the basis that the information in the case report has not been obtained through a systematic investigation and was not collected with prior research intent. As per TCPS2, research is defined as “an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation.” The information presented in a case report is not considered to be generalizable. Therefore, case studies that involve three or fewer patients do not require REB review and approval.**

 **If anything was done in the course of care with a research intent, then the case report becomes research. If more than three patients are included in the project, it then becomes a case series, this is considered research and requires REB review and approval.**

**Case Report:** Insert TITLE

**Physician:** Insert Name, degrees held

 Insert Institution

 Insert Contact Phone Number, E-mail, Fax

You are being asked to consider allowing Dr. (insert name) to use information about your (insert condition/disease/experience) to write what is called a case report. Case reports are typically used to share new unique information experienced by one patient during his/her clinical care that may be useful for other physicians and members of a health care team. A case report may be published for others to read, and/or presented at a conference. This form explains the purpose of this case report. Please read this form carefully and take your time to make your decision and ask any questions that you may have.

The purpose of this case report is to inform other physicians that (insert specific reason i.e. patients presenting to the ER with X may be related to Y, however, was masked by a common over the counter medication Z).

Your information being used for this case report includes (insert specific personal health information here).

All persons involved in the study are committed to respecting your privacy. Dr. (insert name) will protect your privacy and not disclose your personal information (information about you and your health that identifies you as an individual e.g. name, date of birth, medical record number). When the case report is published or presented, your identity will not be disclosed.

The information that is collected for the case report will be kept in a locked and secure area by the study doctor for 7 years. Only the study will be allowed to look at your records.

The study personnel will make every effort to keep your personal health information private and confidential in accordance with all applicable privacy legislation, including the Personal Health Information Protection Act (PHIPA) of Ontario. Although your personal information collected or obtained will be kept confidential and protected to the fullest extent of the law, there continues to be the risk of an unintentional release of information. The chance that personal information or study data will be accidentally released or accessed without authorization is small.

You will not directly benefit from participating in this case report. The information that can be shared with other health care professionals, however, may improve the care that is received by others in the future.

Allowing your information to be used in this case report will not involve any additional costs to you. You will not receive any compensation.

Taking part in this case report is your choice (voluntary). You may choose not to take part or you may change your mind at any time. However, once the case report is written and published, it will not be possible for you to withdraw it. Your decision will not result in any penalty or loss of benefits to which you are entitled including the quality of care you receive.

You will be told about any new information relating to this case report that may affect you.

Your signature below means that you have read the above information about this Case Report and have had a chance to ask questions to help you understand how your information will be used and that you give permission to allow your information to be used in this case report.

If you have any questions or concerns about this case report, please call (insert contact information here)

## SUBJECT CONSENT TO PARTICIPATE

Case Report (insert title here):

### Participant/Substitute decision-maker

By signing this form, I confirm that:

* The case report has been fully explained to me and all of my questions have been answered to my satisfaction
* I have been informed of the risks and benefits, if any, of allowing my information to be used in this case report
* I have been informed that I do not have to participate in this case report
* I have read each page of this form
* I authorize access to my personal health information (medical record) as explained in this form
* I have agreed to participate in this case report

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Name of Participant/Substitute Signature Date

Decision-maker (print)

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Substitute Decision Maker relationship to participant