Notice: Do not save for reuse

You must download a new case report consent template, for each new HSREB/GREB case report application, to account for updates to this form. [Remove this box]

Consent Form for Case Report

This consent form is a case report template that has been designed to meet current regulatory and ethical standards.

# Important things to remember when completing your consent form:

* You must add all relevant institutional logos into the header.
* You will add a version date in the footer. Only one version date should be listed. This document version date will be listed on the approval letter from the Research Ethics Office (REO).
* You will use the term “participant”, not “subject”.
* You should use plain (lay) language at a grade 6-8 reading level ([instructions for assessing reading level](https://support.microsoft.com/en-au/office/get-your-document-s-readability-and-level-statistics-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2#:~:text=In%20your%20Word%20document%2C%20select,reading%20level%20of%20your%20document.)).
* You must fully write out all acronyms and abbreviations when they are first used.
* You must make sure the size and font of the text are consistent (Open Sans, black, 10pt, as per [Queen’s Brand Central](https://www.queensu.ca/brand-central/visual-identity/typography)).
* You must check that page numbers in the footer are correct after you have completed the form and removed all unnecessary sections (including these instruction pages).

# Instructions for how to use/modify/alter this template:

* **Text in black**

You should not remove or alter headings and text that are in black. This text represents Queen’s University’s approved template wording, that should not be altered without justification.

* Text in a black box with a grey background

These areas indicate instructions specific to a heading/section/area of text. Once you have added your information to that heading/section/area, please remove the instruction box.

* Text in a dashed outline with a yellow background

Provides you with a prompt to adapt/alter that area of text to reflect your research study (i.e., add contact information, specify, or choose from several options). If the text is applicable to your study, you must change it to black text with no background colour. If the yellow highlighted area text is not applicable to your study, please remove it.

**How to change your text to black and remove background colour**

1. Select the paragraph/text you wish to change.
2. Under **Home>** **Styles>** right click **Normal**, left click **Modify.**
3. Ensure **Formatting** is set to Open Sans, 10, Automatic. Click OK
4. Left click on **Normal** to select Style.
* **Headings in blue text with a pale blue background**

Provides you with a Heading for sections that include suggested text. You should only use these if relevant to your study. If the heading is applicable to your study, you must change it to black text with no background colour. If the Heading is not applicable to your study, please remove it.

**How to change your Heading text to black and remove background**

1. Select the Heading you wish to change.
2. Select the **Shading** dropdown , select **No Colour**.
3. With the Heading still selected, select **Font Colour** , select **Automatic**.
* Text in blue with a pale blue background

Provides you with suggested text/example that you should use only if relevant to your study. If the text is applicable to your study, you must change it to black text with no background colour. If the text is not applicable to your study, please remove it.

**How to change your text to black and remove background colour**

1. Select the paragraph/text you wish to change.
2. Under **Home>** **Styles>** right click **Normal**, left click **Modify.**
3. Ensure **Formatting** is set to Open Sans, 10, Automatic. Click OK
4. Left click on **Normal** to select Style.

These pages provide you with directions for navigating/altering this document/form.

You must remove these pages when you have completed the form. [Remove this instruction box]

Informed Consent Form for Case Report

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This Content list is to help you navigate this form.

You must remove the Content list when you have completed the form below. [Remove this instruction box]

Informed Consent Form for Case Report

**Study title:** Insert title as written on the protocol

**Principal Investigator:** Insert name, department, and telephone number

**Co-Investigator(s)/Supervisor:** Insert name(s)

# Introduction

As a Substitute Decision Maker, you are being asked to provide informed consent on behalf of a person who cannot provide consent for themselves. If the participant gains the capacity to consent for themselves, your consent for them will end. Throughout this form, “you” means the person you are representing.

For medical case report forms being submitted to HSREB use the first paragraph, for case reports being submitted to GREB use the second paragraph below. [Remove this instruction box]

You are invited to participate in this case report because we were involved with your medical care at Kingston Health Sciences Centre/Provicial Care for list condition or treatment and /or during specify procedure as applicable, add study specific information and we wish to write and publish a case report on your medical case. This consent form provides information to help you make an informed choice. Please read this document carefully and ask any questions you may have. You can discuss your participation with friends, family, Elders or other healthcare providers before choosing. All your questions should be answered before you decide whether to participate in this case report study. This study has received ethical approval by the Queen’s University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB).

**or**

You are invited to participate in this case report because specify the reason this case report is being written and we wish to write and publish a case report on your case. This consent form provides information to help you make an informed choice. Please read this document carefully and ask any questions you may have. You can discuss your participation with friends, family, and elders before choosing. All your questions should be answered before you decide whether to participate in this case report study. This study has received ethical approval by the Queen’s University General Research Ethics Board (GREB).

Participation is voluntary, and you can decline to participate in any aspect of the research penalty without impact on your medical care/academic standing/employment.

# Conflict of interest

You must include information about the presence of any real, potential or perceived conflicts of interest/personal benefits to the researchers and the possibility of commercialization of research findings. If there is a conflict of interest, mitigation strategies must be clearly outlined.

[Remove this instruction box]

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

Or

Insert name has a conflict of interest to declare related to this study. Details are as follows: insert details.

# Purpose of study

The purpose of this case report is to communicate why this case was unusual because it was identified that include information as to why this case needs to be published.

# What are your responsibilities?

You do not need to do anything other than provide informed consent. There will be no additional medical visits or tests.

# Risks and benefits

There are no risks and no direct benefits to your participation, but we hope that the information learned from this case report can be used in the future to help other people with a similar disease and/or health condition/situation or specify as needed.

# Withdrawal from this study

You can change your mind about participation at any time prior to publication of the case report. You do not need to give a reason and withdrawing will not have penalty/any effect on your current or future medical care/academic standing/employment.

You may also withdraw the data that was collected about you from this study by specify who they should contact and how.

You must include any limitations to this withdrawal of the data (i.e., can’t withdraw after submission of an anonymous survey/following publication). [Remove this instruction box]

# Confidentiality

All the information collected during the case report will remain strictly confidential to the extent permitted by the applicable laws. If you decide to participate in this study, the research team will only collect the information needed. This case report will be limited to the collection of information from your medical record and/or add any other data sources. The following information will be collected specify all identifiable and demographic data being collected. All information collected about you will be de-identified, which means any information gathered will be kept confidential and not shared with anyone else except with members of the case report team. Data will be stored securely on hospital servers/specify where data is being stored separate from hospital records for specify data retention duration (must be at least 5 years as per Queen’s data retention policy after which they will be destroyed (if storage plan are different amend as applicable) but you will not be identified.

Queen’s University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB) may require access to study-related records to monitor the ethical conduct of the research. HSREB is bound by confidentiality agreements concerning any personal information/ The Queen's General Research Ethics Board (GREB) may request access to study data and/or all other study materials used in this research to ensure that we (the research team) have or are meeting our ethical obligations in conducting this research. GREB is bound by confidentiality agreements and will not release any personal information.”.

# Contact information

If you have questions about this case report you can contact:

Specify name and contact details (include email address and/or phone number).

Students must include the name and contact information of their research supervisor(s).

[Remove this instruction box]

For ethics concerns, please contact The Queen’s University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB) at 1-844-535-2988 (Toll free in North America) or email HSREB@queensu.ca./ the General Research Ethics Board (GREB) at 1-844-535- 2988 (Toll free in North America) or email chair.GREB@queensu.ca. For research conducted outside of North America use: 1-613-533-2988. If non-English speaking participants wish to contact the Chair for ethics concerns, translation assistance may be necessary, as the REB Chairs communicate in English only.

# Consent and signatures

By signing this consent form, I agree that:

* I have read the Letter of Information/Consent Form.
* I have had all my questions answered.
* I have been provided a copy or directed to keep a copy of the LOI/CF for my records.
* A signed copy of the LOI/CF will be kept by the research team.
* By consenting, I have not waived any legal right in the event of research-related harm.

When collecting verbal consent (i.e., no signed consent forms), remove the signature portion of the participant/Substitute Decision-Maker below and complete the verbal consent log as documentation of consent. Retain the Signature of the Person Conducting the Consent Discussion. [Remove this instruction box]

|  |  |
| --- | --- |
| I consent to Participating in this case report | Yes [ ]  No [ ]  |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of Participant | Printed Name | Date |
|  |  |  |
| Signature of Participant/Guardian/Substitute Decision-Maker (if applicable) | Printed Name | Date |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of Person Conducting the Consent Discussion | Printed Name | Date |

The person signing below acted as an interpreter and attests that the study as set out in the consent form was accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and additional discussion arising from this process.

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| Signature of Translator | Printed Name | Date | Language |

☐ The consent form was read to the participant. The person signing below attests this study was accurately explained to the participant, and any questions have been answered.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of Witness | Printed Name | Date |

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