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Informed Consent Form (ICF) for Prospective Research with Human Participants-GREB

**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 must use the term “participant”, not “subject”.
* You must use simple (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 Shading icon., select **No Colour**.
3. With the Heading still selected, select **Font Colour** Font colour icon., 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 (ICF) for Prospective Research with Human Participants-GREB

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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 (ICF) for Prospective Research with Human Participants-GREB**

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

**Short title:** Insert a simplified title (if applicable)

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

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

**Sponsor:** Insert name

**Funder:** Insert name (if different from sponsor)

# 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.

You are invited to participate in a research study because you add study specific information. 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 providers before choosing. All your questions should be answered before you decide whether to participate in this research 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 without penalty/any impact on your academic standing /any impact on your employment. You can also change your mind at any time. Whatever choice you make you will not lose access to your medical care or give up any legal rights or benefits.

# 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.

# Background

You need to describe the background information and the reason why this study is being done.

[Remove this instruction box]

# Purpose of study

The purpose of this research study is describe the purpose in simple language.

# Study procedures

This research study will take place at include name of study site.

Your participation in this research project will include add number visits. The overall time commitment for this study will be specify time. Each visit’s time commitment will be specified below.

During this study, a member of the research team, or yourself will perform the following tests or procedures:

You must describe all study procedures and specify which are experimental. Include the number of visits and duration of each visit. For easy reference and understanding by participants you should use a bullet point list (only use a numbered list if the procedures listed are meant to be completed in a specific order). If your study has multiple visits, you can list procedures by visit. You must list the procedures in simple language and the time commitment for each. These can be listed by visit, in point form. [Remove this instruction box]

## Procedure definitions

**Focus groups**

You will be asked to attend specify number focus group(s) at specify time point. A focus group is a small group of people who are asked to speak about their opinions on specify topic of focus group. The focus group will take place at specify location or virtual platform and be specify time long. The focus group will be recorded (specify audio, visual or both) and then later transcribed by include if this is done by a member of the study team, a transcriber that has signed a confidentiality agreement or the name of an online platform. For information about the security and privacy of this software refer to the confidentiality section of this form. When the focus group is transcribed, the participants’ information will be de-identified by replacing names with a unique participant IDs in the transcript. Please note, while the researchers can assure their own confidentiality of information, we cannot guarantee that privacy will be maintained by the other participants. In addition, withdrawal of your data may not be possible if your responses compromise information provided by other participants in the group.

**Questionnaires**

You will be asked to respond to specify number of questionnaires at specify time point (i.e., Visit 1, 2, etc.) as part of this study. These questionnaires will be completed specify the platform being used or if they will be completed on paper and will take about indicate time to complete. Some of the questions may be personal. If any questions, make you uncomfortable you may choose not to answer. Your responses will not be reviewed by your health care team.

**Participant diaries**

You will be asked to keep/fill out a diary specify how often they should complete. Please record specify what they need to do.

You will fill out this diary using specify how these are being completed (i.e., on paper or using a device online or mobile application). For information about the security and privacy of this software refer to: [insert web link here] OR if this is a Queen’s IT-approved platform, state: This platform meets Queen’s ITS standards.

You will be asked to return this diary specify when and where if applicable.

**Optional study procedures**

This study also has an optional component.

You need to briefly describe the optional study procedures. For easy reference and understanding by participants you should use a bullet point list (only use a numbered list if the information listed is meant to be understood in a specific order). [Remove this instruction box]

For this study, completion of:

* begin list here.

Detailed information regarding the optional study is explained at the end of this consent form.

If you wish to participate in the optional study procedures, please indicate your consent below. Whether you decide to participate in the optional part of the study will not impact your participation in the rest of the study.

# Risks

There are no known risks to this study.

Or

You may experience some risk(s) during your participation in this study. The known risks are listed below, however there may be other unexpected risks that are not known. You will be informed during the study of any new risk that may impact your willingness to participate.

List all known risks and their mitigation strategy if applicable. Only study related risks should be included in the consent form. [Remove this instruction box]

# Benefits

You must include information about potential benefits to participants (if none, state this) as well as in general, for the entire population. [Remove this instruction box]

There are no direct benefits to you for taking part in this study/You may or may not benefit from taking part in this study/The expected benefit(s) from participating in this study is/are (specify).

We hope that the results of this study may benefit specify in the future.

# What are your responsibilities?

If you decide to participate in this study, you should:

You need to list all the requirements for participants in this study, including any activities that is not permitted during the course of the study and all the study procedures participants are required to do (i.e., diary completion, etc.). [Remove this instruction box]

* begin list here.

1. **Withdrawal from this study**

You can choose to withdraw from this study at any time without providing a reason. To withdraw your participation from this study please contact: specify who they should contact and how.

You may also withdraw the data that was collected about you from this study by specify who they should contact and how. Please note that this will also mean (when you withdraw your data) that you are also withdrawing from the study.

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 research study 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.

The following information will be collected for this study specify all identifiable and demographic data being collected.

To protect your privacy, you will only be identified in the study documents by a participant ID. The master log linking your name/other identifier to your participant ID will be stored separately from other study data and will only be accessed by specify who has access. This master log will not leave the local site.

The study data will be stored:

* Specify storage for both paper and electronic study data.

If the study involves the use of non-Queen’s ITS-approved platforms you must add the following statement and edit it as appropriate (i.e., translation, transcription platforms, etc.).

[Remove this instruction box]

* Your participation in this study will involve sending your data list data here, facial images, audio recordings, video recordings, etc. to a third-party platform, insert name of platform here for the following specific purposes: list all purposes here. Visit the platform’s website insert third party’s privacy link here for information about the protection and use of the data. Once your data has been processed for the specific purposes mentioned above, it will be deleted from the third-party’s platform or state if the platform will retain the data and for what period of time, who has access to the data etc.

The following study data will not leave the local site:

* Specify what study data will be stored on-site or specify that above that no data will leave the local site.

The following study data will be sent to:

* Specify what study data will be sent and where. Include information about any platform used to store data.
* Include information about data sharing and the potential for the generation of identifiable information if databases will be linked.

The study data will be stored for specify time period.

Upon study completion, all insert the format of data (i.e., de-identified, anonymized) data used to develop the study results for publication will continue to be kept in a secure and encrypted location accessible only to the PI(s)/study team for specify data retention duration (must be at least 5 years as per Queen’s data retention policy. All other data will be deleted or destroyed. Once the data is no longer required for publication or research purposes, it will be deleted by the PI(s)/specify.

For studies with data that can be de-identified, use: [Remove this instruction box]

For publication, the data used to generate the study results may need to be deposited in a research data repository. If this is required, only de-identified data will be deposited, and the study data stored elsewhere will be deleted. Study data deposited in a research data repository may be accessible to other researchers for future, similar studies. If you do not want your de-identified data to be available to other researchers for future, similar studies, please indicate that in your consent options.

For studies with data that CANNOT be de-identified, use: [Remove this instruction box]

For publication, the data used to generate the study results may need to be reviewed by other researchers as part of the peer-review process. If this is required, only peer-reviewers identified by publications (e.g., academic journals) will be provided with a copy of the data for review purposes only. Once the review is completed, they will no longer have access to the data.

The minimum retention period is 5 years per Queen’s policy. There is no requirement to destroy data. It is suggested that the researchers consider using a data repository. [Remove this instruction box]

If indefinite data storage is required, that is not in a data repository, you need to specify arrangements for data custodianship. This might involve departmental oversight as a data custodian in the event of the current data custodian leaving Queen’s employment or following their death. [Remove this instruction box]

The data custodian(s) of the study data for the duration of this study data is/are specify.

Note: For student projects, after a student graduates, the supervisor is responsible for managing the data and the disposal of data if it is not submitted to a repository. Research supervisors should be described as joint custodians of all research files and data while students are active in their degrees.

[Remove this instruction box]

There are organizations and their representatives that may look at or receive copies of some of the information in your study records for data analysis and quality assurance for monitoring, control, safety, and security. These may include:

* Members of the study team, as delegated by the principal investigator.
* Specify name, the funder of the study.
* Authorized Representatives of Queen’s University, its affiliated hospitals and/or Queen’s University General Research Ethics Board (GREB).
* Specify other organization(s) that may access study records/.

The results of this research study data may be published or shared during scientific meetings however you will/will not be identified during the dissemination of study results or publication. All efforts will be made to protect your privacy and the likelihood that someone may identify you is small, however it cannot be eliminated.

Quotes from some of the interviews/focus groups may be used when presenting study results, you can consent below whether or not you agree to the use of quotes (Note: If use of quotes is mandatory, remove this statement). These quotes will never include any real names with quotes and researchers will do their best to ensure quotes do not identify participants. During the interview(s)/focus group(s), please let us know if you say anything you don’t want quoted.

# Cost for participation

The cost of the device/intervention will be covered at no cost to you while you take part in this study. After the study, please specify if device/intervention will be available at a cost or not available and why.

If there are additional costs to participants, you must specify what they are and the plan to handle these costs (i.e., see section on reimbursement).

[Remove this instruction box]

# Reimbursement

You will not be paid for taking part in this study.

Or

If you decide to participate, you will receive:

You must specify the amount, type of payment (gift card, cash, cheque), and method of payment. If using gift cards, you need to specify where the gift card can be used. If there is a payment plan, specify the payment schedule (i.e., payment per visit/stage of the study). Clearly state how compensation will be addressed if a participant withdraws early.

For reimbursement, you must specify what is being reimbursed, the maximum dollar amount and what participants need to provide to get this reimbursement (e.g., itemized receipts). [Remove this instruction box]

# Incentives

You must specify the method of incentives for participation, the amount, type of payment (gift card, cash, cheque), and method of payment. If using gift cards, you need to specify where the gift card can be used. If you will be using a draw, please refer to the guidelines on the REO website (https://www.queensu.ca/vpr/ethics/guidelines-policies) for required information to ensure your draw is legally compliant. See below for mandatory language to be included for a draw.

After submitting your survey responses, you will be directed to a separate survey and can enter your contact information to be entered into a draw for a chance to win prize. Your odds of winning are based on the number of individuals who participate in the survey.

Your name and email will be stored securely and separately from your survey responses and permanently erased once the draw is complete. The survey will close on date. Entry into the draw will close on date/once all survey responses have been received.

The draw will take place x days/weeks/months after the survey closes and be conducted by impartial third party/random number generator.

Only one prize will be awarded per participant.

Winners will be contacted using the contact information provided upon entry into the draw. If a winner has not responded within timeframe, the winner will forfeit the prize, and another draw will be held to determine a winner. The prize must be accepted as awarded or forfeited and cannot be redeemed for cash.

Participation is not required for entry into the draw; to enter without participating in the study, insert information on how the participant can enter the draw without participating in the study. For example: “submit a 3x5 index card with your name and contact information, along with the study title, printed by hand to lab address. Entries must be received by the closing date above to be eligible. We are not responsible for lost, late, incomplete, illegible, damaged, destroyed, postage due, or misdirected entries. No bulk mailings will be accepted. All entries will become the property of the study team and will not be returned.”

# Research related injury

If you are injured as a result of participating in this study and need medical treatment, please talk with the study team immediately about your treatment options. Medical care will be provided in case of research injury or side effects, or you will be referred for appropriate medical care at no cost to you.

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

# Future studies

If asking permission to add name and contact information into a re-contact database for future studies, add the following (amend as applicable):

[Remove this instruction box]

In the consent section, you will be given the option to consent to your specify what data is being collected and entered into a re-contact database for future studies. Suppose you agree below to be part of the re-contact database. In that case, you may be contacted in the future about research studies in specify subject/area of research being conducted by this study team/department. Note: Consenting to future contact is not equivalent to consenting to participate in future studies. This recontact database is maintained by specify custodian and will be active for specify time period. You can withdraw from this database at any time if this is not the case, specify without reason by contacting add contact detail for this person.

If de-identified data may be used or shared for future research include the following:

[Remove this instruction box]

Your de-identified study data from this study may be used or shared with other researchers inside and outside of Canada for future studies.

Include the following if the data will be stored outside of Canada:

[Remove this instruction box]

Your data could be shared with researchers not subject to the same ethical guidelines as researchers from Canadian Institutions. De-identified means that identifiers such as name and date of birth will be removed and replaced by a unique participant/study ID. This may include storing the de-identified study data in controlled-access databases, for which access is limited to researcher(s) who submit a study plan and who sign an agreement to use the study data only for that research. The master log matching your study data with your name and other directly identifying study data will not be shared. The custodian of this database is (specify custodian), and it is expected that this database will be active specify time period. If you wish to withdraw from this database, please contact (add contact details). Once your data has been entered into the de-identified database, it will not be possible for you to withdraw it because (state reason). If you do not wish for your study data to be shared for future studies below, you can indicate this in the consent section below.

If you are depositing de-identified data in a publicly accessible repository:

[Remove this instruction box]

De-identified study data and/or the full coded data set may/will also be placed in an open access, publicly accessible repository add name of repository if known as may be required by scientific journals or funding partners.

partners.

# Contact information

If you have questions about this study or if you suffer a research-related injury, 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 General Research Ethics Board (GREB) at 1-844-535- 2988 (Toll free in North America) or email [chair.GREB@queensu.ca.](mailto:chair.GREB@queensu.ca)Use 1-613-533-2988 if outside North America. Please note that GREB communicates in English only.

# Optional study

This part of the consent form is about optional studies that you can choose to take part in. Optional studies will either be directly related to the main study or will be for future research not related to the main study.

The researchers leading this optional study/these optional studies hope the results will help other people with add details in the future.

Taking part in this optional study/these optional studies is your choice. You can still take part in the main study even if you say “no” to this study/any or all these studies. There will be no loss of benefits for saying “no.” If you consent but cannot complete this study/any of these studies for any reason, you can still take part in the main study.

## Optional study procedures

You must specify which procedures are experimental. Include the number of visits, duration of each visit and overall time commitment for these optional components. Use of subheadings or point form list is effective.

[Remove this instruction box]

## Optional study procedures

You must specify which procedures are experimental. Include the number of visits, duration of each visit and overall time commitment for these optional components. Use of subheadings or point form list is effective.

[Remove this instruction box]

# Consent and signatures

By signing this consent form, I agree that:

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

|  |  |
| --- | --- |
| I consent to participate in the main study | Yes  No |
| I consent to audio recording | Yes  No |
| I consent to video recording | Yes  No |
| I consent to the use of quotes | Yes  No |
| You can re-contact me to inform me about future research projects that I may consider participating in. | Yes  No |
| You have my consent to store my data for future unspecified research. | Yes  No |

Add consent checkboxes for any other optional aspects of the study. [Remove this instruction box]

|  |  |
| --- | --- |
| I consent to participate in the optional portion of this study | Yes  No |

For online checkbox consent or implied consent, remove all signature blocks as consent will be obtained by the participant completing the survey or by clicking the consent box.

For implied consent add the following:

Survey completion will represent consent. (include a link to the survey)

[Remove this instruction box]

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]

|  |  |  |
| --- | --- | --- |
|  |  |  |
| 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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You must download a new template, for each new application, to account for updates to this form. [Remove this box]