**Research informed Consent form**

***Please replace or delete the instructional text in red font before submitting to the REB. Arrange to give or send a copy of the Consent Form to participants.***

**Text in blue is sample wording that is acceptable to the REB. However, make sure to alter the plan, or to include any additional needed information. For the reproductive risks section, this exact wording must be included for clinical trial studies that include drugs/devices or NHP’s that pose any reproductive risks.**

# Study Title: *Insert Study Title;*

**Version Date: *Month/Day/Year***

# Name and Contact Information of Researchers

 *Name, Hospital or University, Department/School/Faculty of \*\*\**

 Tel.: \*\*

 Email: \*\*

 Supervisor and Contact Information: *(if any)*

Study Sponsor and Funder (if any)

 *Study Sponsor*

# Bruyère Health Research Ethics Board Approval

Date of Approval: \*\*\*

Study # \*\*\*\*

# Invitation

You are invited to take part in a research study because you are …. The information in this form is intended to help you understand what we are asking of you so that you can decide whether you agree to participate in this study. Your participation is entirely voluntary, and a decision not to participate will not be used against you in any way. As you read this form, and decide whether to participate, please ask all the questions you might have, take whatever time you need, and consult with others as you wish.

# What is the purpose of the study?

*Briefly describe the background and purpose of the study*

# What will I be asked to do?

If you agree to take part in the study, we will ask you to:

*For example:*

* *What will the participant be asked to do (e.g. complete a survey, individual interview, focus group, exercise program, etc.)?*
* *If the study requirements are more involved or involve ongoing activities, describe these.*
* *What is the nature of the information to be collected?*
* *Where will this take place?*
* *How many study visits will be involved and long is/are the activity(ies) expected to last?*
* *Will the interview be audio or videotaped, and if so, can the participant choose not to recorded?*
* *During the audio or video recording, what confidential data will be collected?*

# Risks and Inconveniences

*Describe any foreseeable physical, emotional/psychological, social/legal/economic, or privacy risks entailed by participating in the study along with any special discomforts or inconveniences that may be experienced. Mention only reasonably foreseeable risks.*

Or

We do not anticipate any risks to participating in this study.

**Reproductive Risks** *(only include this section if there are risks related to being or becoming pregnant or getting someone pregnant)*

The effects that the study drug(s) may have on eggs (ova), sperm, or on an unborn baby (fetus) are unknown/detail the known risks. You should not become pregnant or get someone pregnant while taking the study drug(s).

Participants who are able to become pregnant or produce sperm must agree to both of the following while taking the study drug(s) and for length of time afterward: i) not to get pregnant or get someone pregnant and ii) to use an appropriate family planning method as discussed and decided upon in consultation with a study investigator.

If you become pregnant or get someone pregnant while taking the study drug(s) or for length of time afterward, you should immediately notify the study investigators, who will discuss next steps with you.

# Possible Benefits

*Describe possible benefits or:*

You may not receive any direct benefit from your participation in this study. However, your participation may allow researchers to better understand…

# Compensation/Incentives

*Describe any compensation or incentives to be paid or given to participants. Where participation involves multiple visits or activities, describe if and how compensation will be prorated among these visits.*

Or

You will not be paid or compensated for your participation in this study.

# No waiver of your rights

By signing this form, you are not waiving any rights or releasing the researchers from any liability.

# Withdrawing from the study

If you withdraw your consent during the course of the study, all information collected from you before your withdrawal [will be discarded or] will still be used, unless you request that it be removed from the study data.

After the study, you may request that your data be removed from the study and deleted by notice given to the Principal Investigator (named above) [within *\*\* days/months* after your completion] or [before (date)].

# Confidentiality

We will remove all identifying information from the study data as soon as possible, which will be after …

We will treat your personal information as confidential, although absolute privacy cannot be guaranteed. However, research records identifying you may be accessed by *(Insert any other reasonably foreseeable disclosure obligations)* … and by the Bruyère Health Research Ethics Board for the purpose of auditing the research*.*

The results of this study may be published or presented at an academic conference or meeting, but the data will be presented so that it will not be possible to identify any participants unless you give your express consent. De-identified data from this study may be shared with other researchers for verification, and to permit them to build upon our findings.

You will be assigned a code [or pseudonym] so that your identity will not be directly associated with the data you have provided. All data, including coded information, will be kept in a password-protected [or encrypted] file on a secure computer.

*When potentially identifiable data will be stored on any server:* Your data will be stored and protected by [Organization], in a server located in [Country], but may be disclosed via a court order or data breach.

We will encrypt [or password protect] any research data that we store or transfer.

# Data Retention

After the study is completed, your de-identified data will be retained for future research use, and

Or

Your de-identified data will be retained for a minimum period of 10 years.

*If photographs, videos or audio recordings are to be used, describe whether they will identify the participant and ask for consent – see below.*

# New information during the study

In the event that any changes could affect your decision to continue participating in this study, you will be promptly informed.

**Contact Tracing**

***The text below is to be included only when participants will, at any time during their participation, attend onsite at any Bruyère Health site.***

During pandemic and other public health outbreak situations, it may be necessary to share your contact information with Bruyère Health’s Contact Tracing Team or Ottawa Public Health in order to support contact tracing efforts. This sharing of information will only be done when deemed necessary for public health and safety, and will only include your contact information, such as name, telephone number, and email address. We will not share any information about your participation in the research study, nor will your study data be accessed by non-authorized persons at Bruyère Health or Ottawa Public Health at any time.

In consenting to participate in this study, you consent to this sharing of information when necessary. To provide additional context, the two situations where this could occur are (1) someone you came into contact with while participating in a research study was later found to be infectious with COVID-19 or another serious contagious illness that is tracked by Bruyère Health and Ottawa Public Health, and they want to inform you of this event, or (2) you notify us that you may have been infectious with COVID-19 or another serious contagious illness while in contact with a member of a research team or onsite at Bruyère Health, and Bruyère Health’s Contact Tracing Team will want to follow up with you to determine whether they need to notify anyone else of a possible exposure to the illness.

**Ethics Review and Contact Information**

This study has been reviewed and approved by the Bruyère Health Research Ethics Board as study #\*\*\*\*\*. If you have any ethical concerns about the study, or the way it is conducted, please contact the Bruyère Health REB: REB@bruyere.org

# Statement of consent – print and sign name

I \_\_\_[*name of study participant*]\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, have read the information given in this informed consent and all my questions have been answered to my satisfaction. I have had sufficient time to consider whether to participate in this study. I understand that my participation in this study is voluntary and that I may withdraw from the study at any time without penalty.

I voluntarily agree to participate in this study.

I would like you to send me a summary of results from this study when they are available.

\_\_\_Yes \_\_\_No Email:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I agree to be contacted for quality improvement and/or feedback purposes by the study team and the Bruyère Health Research Institute.

\_\_\_Yes \_\_\_No Email:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I agree to be contacted about future research studies at the Bruyère Health Research Institute.

\_\_\_Yes \_\_\_No Email:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I agree to be (audio/video recorded/photographed …) \_\_\_Yes \_\_\_No

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant Date

To the best of my knowledge, the information in this consent form, and the information that I, *(print name)* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ have provided in response to any questions, fairly represents the study. I am committed to conducting this study in compliance with all the ethical standards that apply to studies that involve human participants. I will ensure that the participant receives a copy of this consent form.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of person conducting the consent discussion Date

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Signature of person conducting the consent discussion Date