



INFORMED CONSENT FORM

Research Study Title: [Click here to enter text](#)

Protocol number: [Click here to enter text](#)

Researcher responsible for the research study: [Name, Department, Institution \(MUHC\)](#)

Co-Investigator(s)/sites: [Name, Department, Institution](#)

Sponsor: [Click here to enter text](#)

INTRODUCTION

We are inviting you to take part in this research study because you [Click here to enter text](#).

However, before you accept to take part in this study and sign this Informed consent form, please take the time to read, understand and carefully examine the following information. You may also want to discuss this study with your family doctor, a family member or a close friend.

This form may contain words that you do not understand. We invite you to speak to the researcher responsible for this study (the “study doctor”) or to other members of the research team, and ask them to explain to you any word or information that is unclear to you before you sign this form.

BACKGROUND

[Click here to enter text](#)

PURPOSE OF THE RESEARCH STUDY

The purpose of this study is [click here to enter text](#) .

For this research study, we will recruit participants, men and women, aged between .

DESCRIPTION OF THE RESEARCH PROCEDURES

This research study will take place at [enter name of study site](#) .

1. Duration and number of visits

Your participation in this research project will last months and will include visits. Each visit will last minutes.

2. Study drug

When participating in this research project, you will be assigned to one of the following groups:

Group 1: [Click here to enter text](#)

Group 2: [Click here to enter text](#)

The placebo used in this research study looks exactly like the study drug but it does not contain any active medication. We are using a placebo to compare with the study drug and to ensure that the changes you report in your health, good or bad, are not only due to chance. In this Informed consent form, the use of “study drug” refers either to the drug being studied or to the placebo.

Furthermore, this study is randomized which means that you will be assigned to one of the groups. You may not choose the group to which you will be assigned; this process is done randomly like flipping a coin. One person out of (%) will receive the study drug whereas one person out of (%) will receive the placebo.

This is a double blind study, which means that neither you, the study doctor, nor the research team will know which study drug you will receive during this project. However, in case of emergency, the study doctor will have access to this information.

3. Tests and procedures

During your participation in this research study, the study doctor or a member of the research team will conduct the following tests and procedures [to collect the data needed for the research project](#):

DESCRIPTION OF STUDY PROCEDURES	
Procedure	Description

The schedule of procedures for each visit is listed below:

SCHEDULE OF STUDY PROCEDURES									
Procedure	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9
Blood draw	X			X		X		X	
X-Ray					X				
Questionnaire(s)	X						X		X

PARTICIPANT’S RESPONSIBILITIES

- Click here to enter text
- Click here to enter text

BENEFITS ASSOCIATED WITH THE RESEARCH STUDY

There is no direct benefit to you for participating in this research. However, we hope that the study results will contribute to the advancement of scientific knowledge in this field and help us find better treatments for patients.

OR

You may or may not personally benefit from your participation in this research project. However, we hope that the study results will contribute to the advancement of scientific knowledge in this field and help us find better treatments for patients.

RISKS ASSOCIATED WITH THE RESEARCH STUDY

The study drug is experimental and therefore we may not know all the discomforts, side effects and other possible risks associated with it.

Therefore, if you have noticed side effects, whatever they may be, during this research study, you must tell the study doctor immediately, regardless of whether you think these effects are related to the study drug. Even once your participation in the study is over, do not hesitate to contact the study doctor if you experience a side effect that may be linked to the study drug.

The study doctor and members of his or her team will answer any questions that you may have regarding the risks, discomforts and side effect associated with this study. Also, at each visit, the study doctor and members of his or her team will ask you questions about any side effects you may have experienced.

You will find below a list of the side effects and the frequency with which these side effects were experienced by participants between the ages of and when they received the study drug.

1. Risks associated with the study drug

- There is a risk that insert name of study drug , like any other medication, could provoke an allergic reaction in people who receive it. This allergic reaction could range from mild to life-threatening. Symptoms of a life-threatening allergic reaction (called anaphylaxis) may include difficulty breathing, rapid heartbeat, tongue swelling, nausea, fainting, hives, fever, and dizziness. If you suspect that you are having an allergic reaction, call 911 or go to the closest emergency room.
- Click here to enter text
- Click here to enter text

2. Risks associated with other medications used during this research study

- Click here to enter text
- Click here to enter text

3. Risks associated with research procedures

- Click here to enter text
- Click here to enter text

RISKS ASSOCIATED WITH PREGNANCY

Participation in this study may include risks, known or unknown, for a pregnant ~~women~~person, unborn children or to children of a breastfeeding ~~women~~person. Consequently, a pregnant or breastfeeding ~~women~~person cannot take part in this project.

If you are a ~~woman~~ person of childbearing potential, you must undergo a pregnancy test before you start participating in the study. This test will take place again at visit . In addition, if you are sexually active, and could become pregnant you must use a medically accepted contraceptive method throughout your participation in the study and weeks after the end of your participation in this research.

The medically accepted contraceptive methods are oral contraception, hormonal implants, hormonal patches, IDU, diaphragm and spermicide, cervical cape with spermicide, and condom with spermicide.

The study doctor or the research team will discuss your contraceptive method with you to ensure that it is medically accepted.

If you suspect that you have become pregnant during your participation in the research study, you must inform the study doctor immediately in order to discuss different options with him or her.

OTHER POSSIBLE TREATMENTS

You do not have to take part in this study to receive medical care for your condition. Other options exist such as [Click here to enter text](#). We encourage you to discuss with the study doctor all available options.

VOLUNTARY PARTICIPATION AND THE RIGHT TO WITHDRAW

Your participation in this research study is voluntary. Therefore, you may refuse to participate. You may also withdraw at any time, without giving any reasons, by informing the doctor in charge of this research or a member of the research team.

Your doctor is one of the investigators in this study. As such, your doctor's interest lies primarily in your well-being and also in the successful pursuit of this study. Therefore, before you sign up for the study or at any time thereafter, you may wish to consult with another doctor who is not part of this study. You are by no means obligated to participate in whatever study is offered to you.

Your decision not to participate in the study, or to withdraw from it, will have no impact on the quality of care and services to which you are otherwise entitled, or on your relationship with the teams providing them.

The doctor in charge of this research study, the Research Ethics Board, (REB), the funding agency, or the sponsor may put an end to your participation without your consent. This may happen if new findings or information indicate that participation in this research study is no longer in your best interests, if you do not follow study instructions, or if there are administrative reasons to terminate the study.

However, before you withdraw from the study, we suggest that you take part in a final evaluation, for safety reasons.

You have the right to modulate your withdrawal from the study at any time, by

- Stopping the study drug,
- Stopping the follow-up visits on site,
- Stopping telephone follow-up,
- Allowing only medical chart information to be transmitted to the sponsor, or
- Withdrawing from the study completely.

If you withdraw or are withdrawn from the study, no further data or samples will be collected. However, the information and biological material, blood and tissue samples, audio and video recordings, images and MRI already collected for the study will be stored, analyzed and used to ensure the integrity of the study, as described in this document.

Any new findings acquired during the course of the study that could influence your decision to continue your participation will be shared with you quickly.

CONFIDENTIALITY

During your participation in this study, the doctor in charge of the study and the research team will collect in a study file all of the information and samples about you needed to meet the scientific objectives of the study.

The study file may include:

- health information from your medical charts including your choose: identity, such as your name, gender, date of birth, ethnicity , past and present health status, lifestyle, and ~~the results of all tests, exams, and procedures that will be performed.~~

the results of all tests, exams, and procedures that will be performed.

~~In addition, participation in this study involves the use of a Choose: connected device / application and insert the name of the connected device or app provided by insert the name of the company. The use of name of connected device/application is mandatory to participate in the study. The use of the name of connected device/application involves the sharing of information about you. Part of the collection, processing, storage, and destruction of anonymized data is carried out by the company that provides the name of connected device/application. This data will likely be saved in a cloud solution located outside of Canada (e.g., United States of America) and could be used by this company for a secondary use, such as business or marketing purposes. The research team or the McGill University Health Centre cannot guarantee the security (confidentiality, integrity, and availability) of this data. Assessing the risk to privacy involved in using the services of company name is not part of the mandate of the Research Ethics Board of the McGill University Health Centre. You should therefore make sure that you understand the impact using this name of connected device/application will have on your privacy. If you would like more information, please further discuss it with the research team.~~

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All these study data collected during for this research study (including personal information and samples)

will remain confidential ~~to the extent provided by law.~~ as described in this Informed Consent Form.

You will be identified by a code number only. The key to the code linking your name to your study file will be kept by the doctor in charge of this ~~research study.~~

To ensure your safety, a document indicating your participation in this study, a copy of the Informed Consent Form OR a ~~data information sheet~~ summary of the study, is included in your medical chart. The results of certain tests conducted as part of the research may be included as well, depending on the situation. As a result, any person or company to whom you give access to your medical chart, any person legally authorized, will have access to this information.

The ~~doctor in charge of this research study or a member of the research team~~ will ~~forward~~ share your coded study data ~~to~~ with the sponsor or its representatives.

~~However, This includes sending your coded health information outside of Québec. The sharing will follow the limits set by the agreement with the sponsor and any partners outside of Quebec are required to respect confidentiality rules equivalent to those in effect in Quebec and Canada, regardless of the country to which your data may be transferred.~~

Study data and samples will be stored for at least 15 years following the end of the study by the doctor in charge of this research study and the study sponsor and/or funding agency. Study samples will be stored for at least X years following the end of the study by the doctor in charge of this ~~research~~ study and the study sponsor and/or funding agency.

The study data may be published or shared at scientific meetings; however, it will not be possible to identify you.

For monitoring, control, safety, security, and approval of the study drug by regulatory agencies, your study file as well as your medical charts may be examined by a person mandated by Canadian or international regulatory authorities, such as Health Canada, as well as by authorized representatives of the study sponsor, the institution, or the ~~Research Ethics Board REB.~~ All these individuals and organizations will have access to your personal data, but they adhere to a confidentiality policy.

You have the right to consult your study file in order to verify the information gathered, and to have it corrected if necessary. However, to protect the scientific integrity of this study, you may have to withdraw from the study if you access certain information before the study ends.

CONFIDENTIALITY AND USE OF DEVICE OR APP

To take part in this study, you need to use a device or app provided by a company insert the name of the company. When you use it, your study data will be coded and/or anonymized and shared. The company that provides the device or app will collect, process, store, and delete anonymized study data. The study data might be stored in a cloud outside of Canada, for ex. in the United States. The company might also use this data for other purposes, like business or marketing. The McGill University Health Centre (MUHC)

and the research team cannot guarantee that your study data will be completely secure (kept private, accurate, and available). The REB of the MUHC does not assess the level of risk to your privacy when you use this company's services. You should make sure you understand how using this device or app might affect your privacy. If you want more information, ask the research team.

CONFIDENTIALITY AND SERVICES OFFERED BY THIRD PARTIES

The Sponsor has ~~entered into a contractual agreement with~~asked an independent company insert the name of the company to manage the organization of Adapt as necessary: travel arrangements and or the reimbursement of costs associated with study participation (for e.g., parking fees). The use of the services offered by name of the company is not required in order to participate~~a requirement for your participation~~ in this study or to receive reimbursement of costs associated with your participation. ~~On the other hand, if~~ you choose to use name of the company's services, you will need to provide name of the company with your personal and/or health information~~about you~~. Please note that the ~~evaluation REB of this study by the Research Ethics Board of the McGill University Health Centre MUHC did not include any evaluation of~~evaluate the risks ~~associated with the use of~~ using of the services offered by name of the company. The Sponsor however confirms that name of the company will not share ~~with them~~ personal information that could identify you with them. For more information about the use of name of the company's services, you should ask a member of the study team.

INCIDENTAL FINDINGS

Material incidental findings are findings made in the course of the study that may have significant impacts on your current or future wellbeing or that of your family members. A material incidental finding concerning you in the course of this research will be communicated to you and to a health professional of your choice.

POSSIBILITY OF COMMERCIALIZATION

The results of the research derived in part from your participation in the study may lead to the development of new commercial products. However, you will not be entitled to any financial gain thereof.

FUNDING OF THE RESEARCH PROJECT

The study doctor and the institution have received funding from the sponsor for the completion of the research project.

CONFLICT OF INTERESTS

Click here to enter text

OR

The researchers have no conflict of interest to declare.

COMPENSATION

You will receive an amount of \$ _____ per visit scheduled as per protocol, for a total of _____ visits, for a total amount of \$ _____, as compensation for costs incurred during your participation in this research study. If you withdraw from the study (or are withdrawn) before it is completed, compensation will be proportional to the length of your participation.

AND/OR

Your expenses for choose: travel, meals, parking, etc. related to your participation in this research study will be choose: reimbursed upon presentation of receipts OR paid by a coupon which will be given to you at (specify a time) .

OR

You will not receive financial compensation for participating in this research study.

AND

The research drug name of the drug will be offered to you free of charge for the duration of this research study.

SHOULD YOU SUFFER ANY HARM

Should you suffer harm of any kind following administration of the study drug or any other procedure related to this research study, you will receive all the care and services required by your state of health.

By agreeing to participate in this research study, you are not waiving any of your rights nor discharging the doctor in charge of the study, the sponsor, or the institution of their civil and professional responsibilities.

CLINICAL TRIAL REGISTRATION

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any moment.

CONTACT INFORMATION

If you have any questions or if you have a problem you think might be related to your participation in this research study, or if you would like to withdraw, you may communicate with the doctor in charge of this research study or with someone on the research team at the following number: add phone number .

For any question concerning your rights as a research participant in this study, or if you have comments or wish to file a complaint, you may communicate with the local service quality and complaints commissioner at : add the name of the site and the phone number .

OVERVIEW OF ETHICAL ASPECTS OF THE RESEARCH

The ~~Research Ethics Board~~REB of the ~~McGill University Health Centre~~MUHC has given ethics approval to this research study and is responsible for its ongoing ethics oversight at all participating institutions in the health and social services network in Quebec.

OR

The ~~Research Ethics Board~~REB of the ~~McGill University Health Centre~~MUHC has given ethics approval to this research study and is responsible for the ongoing ethics oversight of the study.

Research Study Title:

Click here to enter text.

I have reviewed the Informed Consent form. Both the research study and the Informed Consent form were explained to me. My questions were answered, and I was given sufficient time to make a decision. After reflection, I consent to participate in this research study in accordance with the conditions stated above, including the use of all personal data and samples collected.

I authorize the study team to have access to my medical chart.

In addition, I authorize the researcher or research team to inform my family doctor or treating physician, in writing, that I am taking part in this research study, and to send them all relevant information.

Yes Initials _____

No Initials _____

I authorize the researcher in charge of this study to communicate with me to see if I am interested in participating in other research studies.

Yes Initials _____

No Initials _____

Name of participant

Signature

Date

SIGNATURE OF PERSON OBTAINING CONSENT

I have explained the research study and the terms of this Informed Consent form to the research participant, and I answered all questions asked.

Name of the person obtaining consent

Signature

Date

SIGNATURE OF WITNESS

Yes No

A witness' signature is required in the following cases:

- Reading disability or inability to read – The witness (impartial) signing below attests to the fact that they read the Informed Consent Form, that the study was precisely explained to the participant, and that the participant seems to have understood it.
- Foreign language (participant does not understand the language in which the Informed Consent Form was written) – The signatory attests to acting as interpreter for the participant throughout the consent process.
- Inability to write (participant is capable of providing consent, but unable to write).

Name of the witness Signature Date

COMMITMENT OF THE PRINCIPAL INVESTIGATOR

I certify that this Informed Consent form was explained to the research participant, and that the participant's questions were answered.

I undertake, together with the research team, to respect what was agreed upon in the Informed Consent form, and to give a signed and dated copy of this form to the research participant.

Name of the principal investigator Signature Date

CONSENT OF THIRD PARTY LEGALLY AUTHORIZED TO CONSENT IN LIEU OF A PARTICIPANT WHO IS INCAPACITATED

As the legal representative of the participant (guardian, trustee, mandatory; or in cases of sudden incapacity, spouse, close relative, or person close to the participant), I have reviewed the Informed Consent Form. The study and the Informed Consent Form were explained to me. My questions were answered, and I was given sufficient time to decide.

I was also informed that in the event that the person I represent becomes able to give consent for themselves while this research study is underway, that person will be invited to sign the Informed Consent Form.

After reflection, I consent that the person I represent may participate in this research study in accordant with the conditions stated above, including the use of personal data and samples. I will receive a copy of this form, signed and dated.

I authorize the research team to access the medical chart of the person I represent.

I also authorize the researcher or their team to inform the person’s family doctor or treating physician that that the person I represent is taking part in this research study and to send them all relevant information.

Name of research participant represented

Name of legal representative: _____

- Trustee
- Guardian
- Mandatary
- Spouse
- Close relative
- Person close to the participant

Signature of legal representative

Date

SIGNATURE OF PERSON OBTAINING CONSENT

I have explained the research study and the terms of this Informed Consent Form to the legal representative, and I answered all questions asked.

** The signature of a witness is required: 1) in addition to the participant's, if the informed Consent Form is read to the participant; or 2) instead of the participants', if the participant is legally capable of consent but is unable to read or write (e.g., the witness signs beside the participant's thumbprint).*

SIGNATURE OF PERSON OBTAINING CONSENT

I have explained the research study and the terms of this Informed Consent Form to the legal representative, and I answered all questions asked.

Name of the person obtaining consent	Signature	Date
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COMMITMENT OF THE PRINCIPAL INVESTIGATOR

I certify that this Informed Consent form was explained to the research participant, and that the participant's questions were answered.

I undertake, together with the research team, to respect what was agreed upon in the Informed Consent form, and to give a signed and dated copy of this form to the research participant.

Name of the principal investigator	Signature	Date
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Additional Information on Data Privacy Following the Application of the *General Data Protection Regulation (GDPR)*

Research Study: Insert name of the study

Sponsor: Insert name of the sponsor and address of sponsor's head office in Europe

Dear Sir/Madam,

The international sponsor of this research study, insert name of sponsor , has a head office in Europe. As such, the sponsor must comply with the *European Union General Data Protection Regulation (GDPR)*. The GDPR gives you additional rights that are not specified in Canadian and Quebec legislation and that therefore do not appear in the Informed Consent Form that you signed for the research study stated above. For more information, see below.

As per the GDPR, you have the following rights to data privacy, in addition to those specified in the Informed Consent Form you signed:

- Should you request corrections to the data collected about you during the project, please note that you have the **right to restrain** the processing and use of that data while your request is being evaluated. For example, you may ask that your data not be processed until your request has been reviewed.
- You have the **right to request a transfer of** your study data to yourself or to anyone else in any commonly used, and accessible format, such as a computer-readable.
- You have the **right to file a complaint** with a European data protection authority, such as insert the name and contact information of a competent European authority designated by the study sponsor .
- You have the **right to request the deletion** of your study data. These will be deleted if no longer needed or if there is no other legal requirement for their use.

If you have any questions, please contact the doctor in charge of this study.