**Please note that instructional text is yellow highlighted. All instructional text should be removed prior to submission to WCG IRB.**

**RESEARCH SUBJECT CONSENT FORM**

**TITLE:** Title from first page of protocol/study plan

**PROTOCOL NO.:** Sponsor’s protocol number from protocol/study plan

 WCG IRB Protocol #[will be assigned after submission to WCG]

**SPONSOR:** Name

**INVESTIGATOR:** Name

 Address

 City, Province, Postal Cose

**STUDY-RELATED**

**PHONE NUMBER(S):** Number

 Number (24 hours)

 [24-hour number is required] (for studies that are more than minimal risk)

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

|  |
| --- |
| Instructions for Research Consent SummaryPlease do not include this text box in the completed consent form submitted to WCG IRB.We encourage all research studies whose consent document is longer than 4 pages to include an initial concise summary. The initial summary cannot exceed three pages or one third of the length of the remaining consent document (exclusive of face page and signature blocks), whichever is shorter.The templated statements in the “RESEARCH CONSENT SUMMARY” below provide a guide to the content of the summary. The content should be adjusted to be appropriate for the specifics of the study. Under each heading, limit the description to the key information that is relevant to why one might or might not want to take part in the research. Defer the greater detail to the body of the consent form following the initial summary. For example, with a cancer trial the initial summary should identify the most important risks, like the information that a doctor might deliver in the clinical context in telling a patient how sick the chemotherapy drugs will make them. The initial summary should emphasize how those risks are changed by taking part in the study. Include the complete list of reasonably foreseeable risks in the main body of the consent form. |

# RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

# How long will I be in this research?

We expect that your taking part in this research will last [hours, days, weeks, months, years, or until a certain event].

# Why is this research being done?

The purpose of this research is to [Explain in no more than a few sentences the main purposes of the research].

# What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include [Briefly outline in simple terms the procedures that are key to the research and are most likely to affect someone’s decision about whether to take part in the research study].

# Could being in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include [In simple language, explain the risks and discomforts that are most likely to affect someone’s decision about whether to take part in the research study. Identify the most important risks, like the information that a doctor might deliver in the clinical context. Emphasize how those risks are changed by taking part in the study. Include the complete list of reasonably foreseeable risks in the main body of the consent form].

# Will being in this research benefit me?

The most important benefits that you may expect from taking part in this research include [In simple language, explain the reasonably expected benefits to subjects that are most likely to affect someone’s decision about whether to take part in the research study. If there are no benefits, state: It is not expected that you will personally benefit from this research.]

Possible benefits to others include [In simple language, explain the reasonably expected benefits to others that are most likely to affect someone’s decision about whether to take part in the research study].

# What other choices do I have besides taking part in this research?

Instead of being in this research, your choices may include [List the major approved alternative options that are available that may be advantageous to the subject. If this is a study in which there is no disease or condition being treated, you can eliminate this section from the summary, and include it only in the body of the consent. If there are no alternatives, this section can be omitted].

# What else should I know about this research?

Other information that may be important for you to consider so you can decide whether to take part in this research is [Describe any additional information that may be important in this specific study, such as large out of pocket expenses, subject responsibilities that many people might consider burdensome (e.g., abstinence from sexual relations, cigarettes, or alcohol, inability to drive a car while taking study medication, need for overnight stays or admittance to a secure facility), unusual issues related to privacy or confidentiality (e.g., situations where the subject’s research participation is likely to be reported in the media), or serious implications for future treatment (e.g., taking the study drug may limit future treatments options.) If there is no other information in this category, this section can be omitted].

**DETAILED RESEARCH CONSENT**

Organize the information in sufficient detail relating to the research in a way that facilitates the prospective subject’s or legally authorized representative’s understanding of the reasons why one might or might not want to participate. Do not merely provide lists of isolated facts.

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

When the research involves consent by a legally authorized representative or parent, include the next paragraph:

In this consent form “you” generally refers to the research subject. If you are being asked as the legally authorized representative, parent, or guardian to permit the subject to take part in the research, “you” in the rest of this form generally means the research subject.

# Why is this research being done?

The purpose of this research is to [explain in simple terms the main purposes of the research. You can use simple illustrations, diagrams or figures if they are helpful in the explanation].

About [insert number] subjects will take part in this research.

# How long will I be in this research?

We expect that your participation in this research will last [hours, days, weeks, months, years, or until a certain event].

# What happens to me if I agree to take part in this research?

Tell the subject what to expect using simple terms. Include all procedures done because the subject is taking part in this research, including procedures to monitor subjects for safety.

Do NOT describe procedures that will be performed regardless of whether the subject takes part in this research.

When appropriate for your research, include the following items:

Describe where this research will be done

Provide a time-line description of the tests and procedures that will be done, including screening procedures. You can use tables or charts if they are helpful to explain the schedule

Describe each group or arm

If the research involves random assignment describe this and the probability of assignment to each group, For example:

You will be put into a study group by chance (like a coin toss/like drawing straws). You have a [insert number] out of [insert number] chance of being placed in each group. You cannot choose your study group.

If the research involves blinding, include language describing a single (subject only) or double (subject and research team) blind, as appropriate. For example:

During the research, you (or you and the study doctor) will not know which group you are in. (Your study doctor can find out in case of an emergency).

* Identify all hospitalizations, outpatient visits, and telephone or written follow-up
* Indicate the length and duration of visits and procedures
* Identify all unapproved drugs, devices, tests, and procedures as experimental
* For studies conducted under an IND, IDE, or abbreviated IDE, state:

[Name of the product or device] is investigational, which means that it is not approved by Health Canada.

* Identify all approved drugs, devices, tests, and procedures being used in a novel fashion as experimental
* If blood will be drawn, indicate how often and the amount in English and metric units
* Identify all questionnaires or diaries by name and explain what they involve and how long and how often they will need to be completed
* For research on investigational drugs or devices, list any options for the subject to get the drug/device after the research, and who will pay for this
* Describe any planned future research (extension study, follow-up study, analysis of specimens). Describe them and whether subjects will be asked to sign a separate consent form.
* Indicate whether the study treatment will be available at the end of the study.

If applicable, explain whether the subject will be told clinically relevant research results, and if so, under what conditions.

If biospecimens will be collected include information about where and how the samples will be stored:

Your samples will be stored in [location] until [time frame or the study is complete].  The samples will be coded and will not directly identify you.  If you withdraw from the study you can request that your samples also be removed from the study.  Any testing done on your samples are for research use only and unlikely to lead to information that will be used for your clinical care. However, if any information is learned from your samples that will have direct clinical impact, you will be notified.

Include if the research may involve whole genome sequencing:

The research might include whole genome sequencing (determining the order of DNA building blocks (nucleotides) in your genetic code). The researchers have [plans/no plans] to tell you about the genetic test results from your samples.

# What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to: [Describe the responsibilities of the subject.

Describe any warning or precautions that the subject needs to know

Describe any warnings regarding becoming pregnant or getting another person pregnant

Describe any requirements to for the subject or the subject’s partner to abstain from sexual relations or use contraception

Describe any requirements to avoid certain activities or refrain from taking certain drugs

Describe any requirements to keep research articles out of the reach of children or others

Describe any requirements to promptly report certain side effects to the investigator

Describe requirements to follow the instructions as provided by the study team and to give them any new information about new medications, new medical issues, etc.

Describe any requirements to avoid or minimize contact with others

Describe any situations where the subjects should immediately contact the investigator or immediately seek medical attention

# Could being in this research hurt me?

In simple language and in a simple bullet format (whenever possible), explain the known possible risks and discomforts.

List risks and discomforts in order of most common and most likely to occur, with least likely to occur listed last. Also, list any rare, but serious risks.

If there are many risks, use a bulleted format. If known, provide the percentage or range of occurrence for the risks.

Describe the duration of the risks and discomforts. Note whether the risks and discomforts will go away when the study drug, device, or procedure is stopped.

Describe the side effects of any comparator drugs.

Describe any risks of washout, withholding treatment, or randomization.

Consider:

Physical risks (for example, medical side effect)

Psychological risks (for example, embarrassment, fear or guilt)

Privacy risks (for example, disclosure of private information, including risks of genetic testing results)

Legal risks (for example, legal prosecution or being reported for child abuse)

Social risks (for example, social ostracizing or discrimination)

Economic risks (for example, having to pay money out-of-pocket for research or medical expenses, losing health insurance, or being unable to obtain a job)

* It is unnecessary to list details of previous clinical trials.

Include for research that involves procedures whose risk profile is not well known, including all research involving an investigational product:

In addition to these risks, taking part in this research may harm you in unknown ways.

Include for research that involves pregnant people or people who can become pregnant potential and known risks to an embryo or fetus:

Taking part in this research may hurt a pregnancy or fetus in the following ways:

Include for research that involves pregnant people or people who can become pregnant and procedures that involve risks to an embryo or fetus or whose risk profile in pregnancy is not well known:

Taking part in this may hurt a pregnancy or fetus in unknown ways. These may be minor or so severe as to cause death.

# Will it cost me money to take part in this research?

Include for research that may result in additional costs to the subjects:

Taking part in this research may lead to added costs to you, such as: [Describe these costs].

Include for research where insurance will be billed:

In some cases, private insurance does not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

# Will being in this research benefit me?

If there are possible benefits to the subject:

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include [Describe any direct benefits to the subject. If benefits from taking part may not continue after this research has ended, describe them]. Possible benefits to others include [Describe any benefits to others].

If there are no expected benefits to the subject but possible benefits to others/ scientific knowledge:

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include [Describe any benefits to others].

# What other choices do I have besides taking part in this research?

If there are alternatives:

Instead of being in this research, your choices may include:

List the major approved alternative options such as drugs / devices / procedures

Consider, based on the indication and population, whether an alternative might include no active treatment but support and management of pain and other symptoms to be as comfortable as possible through the remainder of life

If there are no alternatives:

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

# What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

* The research sponsor
* People who work with the research sponsor
* Government agencies, such Health Canada and the U.S. Food and Drug Administration (FDA)
* WCG IRB, the Research Ethics Board (REB) that reviewed this research
* List others with whom private information will be shared
* When the procedures include communicable disease testing, include any disclosures mandated by provincial law.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

For all applicable clinical trials, add the following language verbatim. If the research does not require listing on www.clinicaltrials.gov, but will be listed anyway, you may include this language. The REB does not require this information when not required by FDA, even if the study will be listed.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

# Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number(s) listed in this document.

This research is being overseen by WCG IRB, the Research Ethics Board overseeing the study. An REB is a group of people who perform independent review of research studies. You may contact them at 855-818-2289 or clientcare@wcgclinical.com if:

1. You have questions, concerns, or complaints that are not being answered by the research team.
2. You are not getting answers from the research team.
3. You cannot reach the research team.
4. You want to talk to someone else about the research.
5. You have questions about your rights as a research subject.

# What if I am injured because of taking part in this research?

Modify the following language to reflect your study:

If you are injured or get sick because of being in this research, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your, your provincial health plan, or your private insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by insurance policy or the government, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the study doctor or sponsor.

You have not waived any of your rights to legal recourse, including if you are harmed as a result of the research, by participating in this research.

# Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

Describe reasons why the subject may be withdrawn. Include all reasons for withdrawal described in the protocol. For example:

It is in your best interest

You have a side effect that requires stopping the research

You need a treatment not allowed in this research

You become pregnant

The research is canceled by the health authorities or the sponsor

You are unable to take the research medication

You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

# What happens if I agree to be in this research, but I change my mind later?

Include if there are procedures for orderly termination of taking part in the research.

If you decide to leave this research, contact the research team so that the investigator can: [Describe the procedures for orderly termination by the subject].

Include if there are potential adverse consequences to a subject who withdraws:

If you decide to leave the research early, there may be risks with this decision. These may include: [Describe the adverse consequences].

# Will I be paid for taking part in this research?

If subjects will be paid:

For taking part in this research, you may be paid up to a total of $[Amount]. Your compensation will be broken down as follows:

Describe payment schedule in terms of amount

Describe when payments will be made

Describe the amount of payment if the subject drops out

If subjects will not be paid, include the following or a similar statement:

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

The results from this study may lead to new commercial products or tests.  If this happens you will not receive any compensation.

# Statement of Consent:

Example signature block: for studies that only involve adult subjects able to consent. Board will modify the signature block as appropriate for the study population being enrolled.

Your signature documents your consent to take part in this research.

Signature of subject Date

Signature of person obtaining consent Date

Example signature block: for studies that may or will involve adult subjects unable to consent and may also include adult subjects that have capacity to consent Board will modify the signature block as appropriate for the study population being enrolled.

* All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted
* If assent is obtained, have the person obtaining assent document assent on the consent form

Signature of subject/legally authorized representative Date

I confirm I have explained the study to the extent compatible with the subject’s capability, and the subject has either agreed to be in the study, or is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

Signature of person obtaining consent Date

**If the following language is provided in the body of the consent form, it is not required to also be submitted here.**

**Confidentiality and the Collection, Use and Disclosure of Your Personal Information**

This consent form also tells you about your privacy rights. If you sign this form, you will be giving your permission for the collection, use and disclosure of your personal information for the purposes of this study.

If you decide to be in this study, the study doctor and study staff will collect information about you. This may include your name or initials, date of birth, gender, ethnic origin, medical history and health-related information such as results of laboratory tests, x-rays and physical examinations and medical records. The information collected from you will be kept for at least 15 years as required by law.

When possible, the information sent to the sponsor and those working for the sponsor will not identify you directly. Other indirect identifiers will be used instead. Your personal information will be used to confirm your eligibility for this study, to assess the results of this study, for purposes of safety and to meet legal and regulatory requirements.

For the purposes set out above, the study doctor and study staff may share and disclose information about you to the sponsor. "Sponsor" includes any persons or companies contracted by the sponsor to have access to the research information during and after the study.

The information will be given to Health Canada. It may also be given to the U.S. Food and Drug Administration (FDA) and governmental agencies in other countries where the study drug may be considered for approval. Information, including your medical records, which identifies you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

* the sponsor, including anyone working for or with the sponsor, or owned by the sponsor;

and may be looked at and/or copied for research or regulatory purposes by:

* Health Canada;
* the FDA;
* governmental agencies in other countries; and
* WCG IRB.

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

There may be other circumstances where your information may be disclosed if required by law or for your benefit in the event of an emergency.

You have access rights to your information and the possibility to correct your information according to local law and procedures. You can discuss this with your study doctor. There is no expiration for your permission. You may take away your permission to collect, use and share information about you at any time by providing reasonable notice to the study doctor. If you do this, you will not be able to stay in this study. No new information about you will be gathered after that date. However, the information about you that has already been gathered may still be used and given to others as described in this form.

**Signature of Subject Date**