Please note that instructional text is yellow highlighted.

This text should be removed prior to submission to WCG IRB.

EXPERIMENTAL TREATMENT PLAN

**INFORMATION AND CONSENT FORM**

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

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

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

**SPONSOR:** Name

**MANUFACTURER:** Name

**PHYSICIAN:** Name

Address

City, State, Zip Code

Country

**TREATMENT PLAN**

**PHONE NUMBER(S):** Number

Number (24 hours)

You are being asked to consider the use of [name of drug, biologic, or device]. Although the primary purpose is to treat your disease, this treatment is investigational and the U.S. Food and Drug Administration (FDA) has not determined it to be safe or effective.

In this consent form “you” generally refers to the patient. If you are being asked as the legally authorized representative, parent, or guardian to permit the patient to get the experimental treatment, “you” in the rest of this form generally means the patient.

Participation in this expanded access treatment is voluntary. You may decide to not participate or leave at any time without penalty or loss of benefits to which you are otherwise entitled. If you have questions, concerns, or complaints, or think this treatment has hurt you, talk to the team at the phone number(s) listed in this document.

**INVESTIGATIONAL TREATMENT WITH [INVESTIGATIONAL PRODUCT]**

**CONSENT SUMMARY**

You are being offered to take part in an expanded access treatment with [investigational product] specifically to treat your condition because you have a diagnosis for which there are no therapies beyond those you have been offered or have already received. Although the primary purpose is to treat your disease, this treatment is investigational and the U.S. Food and Drug Administration (FDA) has not determined it to be safe or effective.

**Why is this expanded access treatment with [investigational product] being done?**

The purpose is to provide access to [investigational product] to you, because in the opinion of your treating doctor, you would potentially benefit from treatment with this investigational product. Your condition may stay the same or get worse. The information from this treatment may also help future patients with a similar condition.

**How long will I be in this investigational treatment?**

We expect that your taking part in this treatment will last [duration-treatment courses].

**What happens during the treatment?**

If you decide to take part in this expanded access treatment with [investigational product], [summary of procedures, dosing, cycles].

**Could being in this investigational treatment hurt me?**

This treatment may hurt you in ways that are unknown. These side effects will vary in people and are unpredictable. You should discuss these with the treating doctor. The most common side effects or potential adverse events are:

* [Risks]

**Will being in this treatment benefit me?**

You may or may not receive any medical benefits from this treatment.

**What is my alternative?**

You do not need to be in this expanded access treatment with [investigational product] to receive treatment for your condition. Your doctor can explain alternative treatments for your condition, which may include [medical alternatives], taking part in a clinical research study [if appropriate. Another alternative is to treat any pain or symptoms that you are having, without trying to treat the disease.]

**DETAILED TREATMENT INFORMATION**

# What should I know about this experimental treatment?

* Someone will explain this treatment to you.
* This form sums up that explanation.
* Getting this treatment is voluntary. Whether you take it is up to you.
* You can choose not to get this treatment. There will be no penalty or loss of benefits to which you are otherwise entitled.
* You can get this treatment and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
* If you don’t understand, ask questions.
* Ask all the questions you want before you decide.

# What happens to me if I agree to this experimental treatment?

Tell the patient what to expect using simple terms. Include all procedures done because the patient is getting the treatment, including procedures to monitor patients for safety.

Do NOT describe procedures that will be performed regardless of whether the patient gets the experimental treatment.

Describe the route, frequency and how long the patient will get the treatment. If applicable, you can indicate that the patient will get the treatment for as long as it works. For example: You will continue getting the treatment until you have unacceptable side effects or it stops being helpful.

# What are the side effects of the experimental treatment?

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

Always include:

In addition to these risks, this treatment may harm you in unknown ways.

Include if pregnancy is a possibility:

This treatment may hurt a pregnancy or fetus in unknown ways. Talk to your doctor about whether this applies to you and your treatment.

# Will it cost me money to take this experimental treatment?

You may be charged for the treatment and associated services, such as drug administration, hospitalization, and monitoring. Insurance may not cover the treatment or these associated services. 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 taking this experimental treatment benefit me?

Getting the treatment may treat your disease. However, we cannot promise any benefits. If the information from your using the treatment is used for research, it might help others in the future.

# What other choices do I have besides taking this experimental treatment?

Include a description of the possible alternative treatments.

If appropriate, include the following.

If you decide that you don’t want to the experimental treatment, you may want to be given treatment that only includes pain medication and other support. It aims to maintain your comfort and dignity rather than cure disease. Usually this care can be provided at home. If you think you might prefer this care, please discuss with your family, friends and your doctor.

# What happens to the information about this treatment?

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

* The product manufacturer
* People who work with the treating doctor
* Government agencies, such as the Food and Drug Administration
* WCG IRB, the Institutional Review Board (IRB) that reviewed this treatment
* List others with whom private information will be shared
* When the procedures include communicable disease testing, include any disclosures mandated by state-law.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy. If the results from this use are published, your identity will remain confidential.

# Who can answer my questions about this experimental treatment?

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

The use of this investigational treatment is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may contact them at 855-818-2289 or [clientcare@wcgclinical.com](mailto:clientcare@wcgclinical.com) if you have questions, concerns, or complaints that are not being answered by your doctor or for information about your rights in this treatment plan.

# What if I am injured because of taking this experimental treatment?

If you experience a bad effect of the treatment, call the study doctor immediately. The study doctor will provide emergency medical treatment. You or your insurance will be billed for this treatment. No other payment is routinely available.

# Can the experimental treatment be stopped without my approval?

Your doctor can stop the treatment without your approval if it is in your best interest or the sponsor decides to stop supplying the treatment.

We will tell you about any new information that may affect your health, welfare, or choice to continue to get the treatment.

# What happens if I get the experimental treatment, but I change my mind later?

If you decide to stop getting the treatment, contact your doctor so that you stop safely.

# Statement of Consent:

Example signature block: for an adult able to consent. The signature block will be modified as appropriate for the person being enrolled if they are a child or lack the capacity to consent form themselves.

Your signature documents your consent to take part in this experimental treatment.

Your signature Date

Signature of person obtaining consent Date