***Note (REMOVE THIS TEXT BEFORE SUBMITTING):***

* *Note: this template can be used in paper form or made into an e-consent document.*
* *Grey boxes with black text in brackets are to be completed.*
* *Red, italicized text in brackets is help text and/or a prompt for information that also must be included.*
* Orange text is optional, sample wording.
* *Do NOT delete the paragraph headings.*
* *This template is only to be used for intermediate (small group)-size patient use of a test article.*
* *With the guidance language removed, this template has the following readability scores:*
  + *Flesch Reading Ease: 57.6*
  + *Flesch-Kincaid Grade Level: 8.7*

# Consent for Small Group Use of an Investigational Product

**[Version date]**

*[If for Parental/Guardian Permission]:*

In this document, “I/my/you/your” mean your child [the child]. If your child turns 18 years old while receiving the investigational treatment, your permission for him/her/them to continue receiving the investigational treatment is no longer required. *[Minors should sign the adult consent at that time.]*

*[If use of an LAR]:*

In this document, “I/my/you/your” mean the participant you are giving permission to receive the investigational treatment.

Please read this form or have this form read to you. Take your time to make your decision. Make sure we explain the investigational treatment to you. Ask us any questions. You may also want to talk about the investigational treatment with your doctor and family, loved ones, or friends. The choice to receive the investigational treatment, or not, is yours. If you decide to receive the investigational treatment, please sign and date this form.

## Why am I being asked to receive an investigational treatment?

You are being asked to consider investigational treatment with  [name of drug/device]  because  [state how and why participant was selected] .

*[Choose one]:*

At this time, there is no proven treatment for this type of condition.

*or*

This drug/device is being offered to you as an investigational treatment for  [include details] .

The Food and Drug Administration (FDA) has not approved the use of  [name of drug/device] . Doctors are studying  [name of drug/device]  as a treatment for patients who have problems with  [name disease]  and have failed other treatments. You will not be asked to be in these studies because you do not qualify. We can use  [name of drug/device]  for you because you have  [name disease]  and you have not improved with available treatments.

## Who will receive this investigational treatment?

You will be one of  [number]  possible patients receiving this investigational treatment.

## What will I be asked to do?

You will complete the following tests and procedures:

 [List procedures and their frequency - you may use a table. Include whether a patient will be at home, in the hospital, or in an outpatient setting.]

 [Briefly label and describe any procedures that are part of standard care, including those that may be completed even if the patient does not agree to the investigational treatment nor indicate consent for that procedure.]

 [Lastly, describe all procedures related to the investigational treatment.]

Please tell the doctors involved in this investigational treatment about any drugs you are taking, including over-the-counter drugs or herbal supplements.

## How long will I receive the investigational treatment?

You will receive investigational treatment for  [months/weeks, until a certain event] .

You can stop receiving the investigational treatment at any time. If you decide to stop, we encourage you to talk to your doctor(s) first.

The doctors may stop the investigational treatment at any time if they feel it is in your best interest, if you experience any severe side effects, of if you need more or other treatments.

## Do I have other choices?

You may choose not to participate in the investigational treatment.  [List alternatives including commonly used therapy(ies) - disclose standard diagnostic procedures or treatment being withheld.]

## What are the risks?

We do not know all of the side effects  [name of drug/device]  can cause because is not fully studied or approved by the FDA. The risks and side effects that other patients have experienced are below.

 [List by regimen the physical and nonphysical risks of receiving the investigational treatment in categories of "very likely" and "less likely but serious." You may choose instead to classify risks as "likely," "possible," or "rare." Nonphysical risks may include but are not limited to: inability to work. Highlight or otherwise identify side effects that may be irreversible, long-term, or life-threatening.]

There may also be side effects that we do not know. Some side effects go away shortly after the  [name of drug/device]  is stopped, but in some cases side effects can be serious, long lasting, or permanent. There is always a possibility that you will have a side effect that, if not treated properly, could be life-threatening.

For more information about risks and side effects, contact the doctor named at the bottom of this consent.

## What about pregnancy?

There could be serious harm to unborn children or children who are breast-feeding. You are asked to use a medically accepted method of birth control such as condoms if you engage in sex while you are receiving this investigational  [drug/device] . If you or your partner do become pregnant while undergoing treatment with this  [drug/device] , you must tell the investigator and talk with a doctor.

## Can this investigational treatment help me?

We cannot and do not promise that this investigational treatment will help you. There is no proof that  [drug/device]  might cure or help your disease.

## How will my information be used and protected?

 [Discuss steps that you will take to ensure confidentiality, e.g. where will data be stored, who will have access to the data, how will data be transferred, to whom and where, when will data be de-identified, security of storage, when and how data will be destroyed] . We will take steps to protect all of your personal information, but we cannot promise confidentiality of all of your information. Investigational treatment records will be kept according to legal requirements and will be a part of your medical record. If your information is published or presented at scientific meetings, you name and other personal information will not be used. Once within your medical record, others at WCM may have access to your information. The WCM doctors for this investigational treatment, the WCM Institutional Review Board (IRB), the Office of Human Research Protection (OHRP), Department of Health and Human Services (DHHS), and the Food and Drug Administration (FDA) and/or their representatives, may access your records.

## Will I be paid?

You will not be paid.

## Do I have to receive the investigational treatment? Can I quit the investigational treatment?

It is your decision whether to receive the investigational treatment or not. You have the right to choose not to receive the investigational treatment or to stop your participation at any time. Your decision to receive the investigational treatment or stop participating will not affect your regular care nor your relationship with Weill Cornell Medicine, your doctors, or other employees. *[If applicable, discuss the process for participants to withdraw once the investigational treatment has begun, including how participants can request their data not be stored, and state data already collected will remain in the medical record. Describe the process and option to continue with follow-up of their condition if applicable – how often and when this will end.]*

You will be told about new information that may affect your health, wellbeing, or willingness to participate.

## What are the costs?

You will not have to pay for the investigational treatment.

The treatment,  [name of drug/device] , will be paid by  [name of sponsor/company] .

Examinations, tests, evaluations, and diagnostic procedures are part of the standard care for patients with your disease.  The costs for these procedures will be charged to you or your insurance. You or your insurance provider will be responsible for these costs.   You will be billed for all costs or co-payments that are not paid by your insurance provider.

## What happens if I am injured?

If you are injured from the investigational  [drug/device] , we will offer you care to treat your injuries. WCM may bill your insurance company or other third parties for the costs of the care. You may also be responsible for some of them.

There are no plans for WCM to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured because of taking the investigational  [drug/device] , tell your doctor as soon as possible. The doctor’s name and phone number are listed below.

## What if I have questions or problems?

If you have any questions, problems, unexpected discomforts, concerns, complaints, or think that something unusual or unexpected is happening, please contact:

 [Physician's name]

 [Department]

 [Address]

 [Phone - this must be a 24-hour telephone number. On call number should be provided.]

 [Email address]

Be sure to tell the doctor about the investigational treatment you have received.

If you have questions regarding your rights as a participant, about what you should do in case of any injury or illness because of your participation, or if you want to get information or give feedback, please contact the WCM Institutional Review Board (IRB) at:

WCM IRB, (646) 962-8200, [irb@med.cornell.edu](mailto:irb@med.cornell.edu)

Website: <https://research.weill.cornell.edu/irb>

You may also submit questions or complaints without giving your name by calling (866) 293-3077 or visiting http://www.hotline.cornell.edu/.

# HIPAA Authorization for Use and Disclosure of Your Protected Health Information

We will be collecting health information about you and sharing it with others. This information is “protected” because it identifies you

## Protected Health Information (PHI)

By signing this Consent Document, you are allowing the following people to use or release your protected health information:  [list all people or class of people (i.e. researchers and their staff) that will access PHI or you can also create a document to give participants that lists these people] .

This information may include:  [list PHI, e.g. results of physical exams, medical history, body mass index, sensitive diagnoses if applicable, etc.] . We will use this information to:  [include the purpose and describe each use of the requested information] . The health information listed above may be used by and/or released to:  [name or class of persons involved] .

In addition to the people listed in this form, there is a chance that your health information may be shared outside of the investigational treatment and no longer be protected by federal privacy laws. Examples of this include releases to law enforcement, legal proceedings, health oversight activities and public health measures.

## Right to Withdraw Your Authorization

Your permission for the use and disclosure of your health information for this investigational treatment shall not expire unless you cancel it. Your health information will be used or disclosed as long as it is needed. However, you may stop your permission at any time by notifying the WCM Privacy Office in writing. To do this, please send a letter to:

Privacy Office

1300 York Avenue, Box 303

New York, NY 10065

Email: [privacy@med.cornell.edu](mailto:privacy@med.cornell.edu)

If you have questions about this and would like to discuss them, please call (646) 962-6930.

Please note that the doctors involved in the investigational treatment do not have to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

If you have questions about the privacy practices of the institution, you can request a Notice of Privacy Practices from your provider.

## Refusal to Sign

If you choose not to sign this consent form and permission for the use and disclosure of your PHI, you cannot receive the investigational treatment. Your decision to sign this consent form or stop participating will not affect your regular care, benefits, nor your relationship with Weill Cornell Medicine, your doctors, or other employees.

## Signature

I have been told about the investigational treatment, its purpose, procedures, benefits, and risks. I agree to receive the investigational treatment and agree to immediately tell the doctor listed above if I experience any unexpected or unusual symptoms. My questions have been answered. I will get a signed copy of this form.

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Name of Adult Participant Signature of Adult Participant Date

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

Name of Parent/Guardian Signature of Parent/Guardian Date

## Legally Authorized Representative

I am making a decision on behalf of the participant who signed above whether to receive the investigational treatment. My questions have been answered. I will get a signed copy of this form.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of legally authorized representative (LAR) or healthcare proxy |  | Print Name and relationship to participant (when appropriate) |  | Date |

## Witness to Consent of Participants Who Cannot Read or Write

I confirm that the consent form was presented orally to the participant in the participant’s own language, the participant was given the opportunity to ask questions, and the participant has communicated consent to participate:

* Making his/her mark above
* Other means; Indicate here: \_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of witness for adults unable to read or write |  |  |  | Date |

#### **Participant Medical Record Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

#### **Physician Signature** (to be completed at time of informed consent)

I confirm that the investigational treatment was thoroughly explained to the participant. I reviewed the consent form and answered all questions. The participant appeared to have understood the information.

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Name of Physician Signature of Physician Date