



# Clinical Trial of a New Medicine

(*{name of investigational  
product}*)

- What's a clinical trial? -

**Pay attention!**



**Name of your doctor:**

**Name of your clinical research coordinator:**

A "clinical research coordinator" is someone who tells you about the medicine that's going to be tested and helps you with your medical examinations. Ask your clinical research coordinator if you have any questions about this trial!



# 1

## How New Medicine is Made



A lot researchers spend a lot of time studying a new medicine before people are able to use it.



Sick people (patients) help test new medicines to see how they work in a "clinical trial."

All the researchers make sure nothing bad happens to the sick people in a trial.

The new medicine that's being tested is called an "investigational product (IP)."



Like at other hospitals, the doctors at this hospital plan and do clinical trials after discussion.



After a clinical trial proves that a new medicine is safe and works well, it can be used to help many patients.

## 2

## The Investigational Product (IP)



Do you have *{disease name}* or cough often or find it hard to breathe?



**Difficulty breathing**



**Difficulty breathing**

The IP in this trial, called *{name of investigational product}*, was made to cure these symptoms.

First, let's think about a few important things to decide if you should or should not take part in this clinical trial of *{name of investigational product}*.

Please ask any questions you have at any time.

### 3

## What Happens in a Clinical Trial?



### How many people get to take part in this clinical trial?

20 patients with *{disease name}* who are between 5 and 9 years old will take part.

### What will you be checking during the clinical trial?

We'll be checking to see how *{name of investigational product}* works and whether anything bad happens to the patients' health as a result of taking the product.

### What kind of IP will I be taking?

You will be taking an IP called *{name of medicine}* during the trial by breathing it in twice a day, once in the morning and once in the afternoon.



*Insert a photo of  
investigational product*

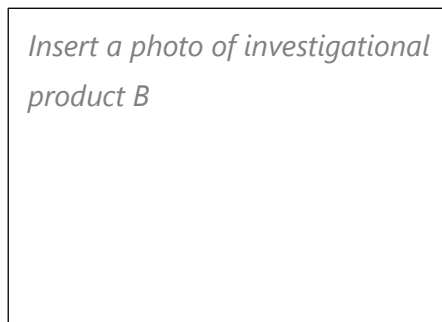
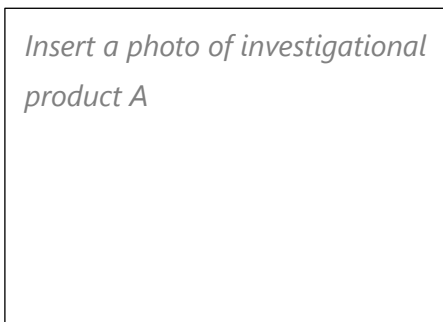
Name of Hospital:  
Informed Assent Form A  
Protocol Number:  
Version:  
Date:

**(Example: Parallel-group comparison study)**

You'll be asked to take either:

- A. (IP) or
- B. (IP)

Both IP's may help cure your sickness and make you feel better.



**(Example: Dose titration study)**

**In case a Forced titration**

First, you'll take a small amount of the IP.

Then, the amount will be increased every ( ) days while researchers keep checking to see that your health is OK.

**In case a Dose titration**

First, you'll take a small amount of the IP.

Then, the amount will be increased every ( ) days while researchers keep checking to see that your health is OK.

## How Does This Trial Work?

You will have medical examinations at the hospital as scheduled, then receive the IP.



Height



Weight



Blood pressure and pulse



Take a blood and urine test



Get a check-up



Receive the IP



Breath test

Breathe in and out as strongly as you can following instructions.

Please tell us if it's hard for you to breathe or if you feel sick.



Other researchers may use your test information but we won't tell anyone your name or other personal information.

## What to Do at Home

Morning



Please check your peak flow soon after you wake up and write it down in your medical diary.

Then inhale (breathe in) the IP.

Don't forget to wash out your mouth after inhaling the IP !



Evening



Check your peak flow just before sleeping and write it down in your medical diary.

Then inhale the IP.

Again, don't forget to wash out your mouth after inhaling the IP !



## Promises for You to Keep during the Clinical Trial

1. Please don't eat *{name of forbidden food etc.}* when you take the IP because eating may stop it from working properly.



2. Please follow the directions you're given when taking the IP.



3. Make sure to visit your doctor when you're supposed to (on your appointment day).

You may have to visit the hospital often.





## 4 What Happens When I Take the IP?



Both good and bad things may happen to your health.

### < Good things >

**You may get better.**

### < Bad things >

**You may get a stomachache, need to go to the bathroom more often or get a rash.**



The researchers at the hospital will check you more often than usual during this clinical trial. If you feel sick or don't feel well, please tell your family right away. We will give you a different treatment so you feel better soon!



## 5 If You're Worried about Anything, Tell Us!



Please talk with your family and think hard if you want to take the IP in this trial or not. It's OK if you don't want to take part in this trial! If you decide not to, we will give you other treatments to help you feel better.

Please let us know at any time if you change your mind about taking part. You can quit this clinical trial at any time after talking with the researchers and your family.

If the researchers find out anything new during the clinical trial, they'll tell you right away.

If you have any questions at all, please don't feel shy about asking us. We can talk about anything you like!



Contact	
Phone number	

Name of Hospital:  
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Date:

Hospital copy

## ... Letter of Assent ...

I have learned everything I want to know about *{name of an investigational product}* and agree to take part in this clinical trial.

**Date of your decision:** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
Year / Month / Day

**Your name:** \_\_\_\_\_

**Doctor**

**Explanation date:** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
Year / Month / Day

**Name:** \_\_\_\_\_

**Clinical Research Coordinator**

**Explanation date:** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
Year / Month / Day

**Name:** \_\_\_\_\_

Name of Hospital:  
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Copy (clinical trial)

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**Clinical Research Coordinator**

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Patient copy

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