# Clinical Trial of a New Medicine ({*name of investigational product*})

**- What's a clinical trial? -**


**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!**

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

# 1 What's a clinical trial?

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Many kinds of medicine (drugs) are used to treat different types of disease.

But before a chemical (called a "drug candidate") can be used as a medicine, it needs to be tested for safety.

Researchers do tests to see how well a drug candidate works in a laboratory, often by using animals like mice.

If a drug candidate seems to work well, both healthy and sick people (patients) are asked to volunteer to take the drug candidate to see the good and bad effects it may have in humans. This test of the drug candidate is called a Clinical Trial.


When we do a clinical trial at a hospital, we have strict rules to protect the people taking part. We check if the medical staff are following the rules. We also make sure that this hospital is the right place to do the medical trial.


After a clinical trial, we send the results to the government, where experts check them closely.

If the experts think that the results are good, the candidate drug becomes a "medicine" which can be used safely to help many patients.


Please listen carefully to our explanation about this clinical trial of the drug candidate called *{name of an investigational product}* and think carefully

whether you want to take part. Please ask us any questions you have at any time.

## 2 Drug Candidates


The drug candidate in this trial is called *{name of investigational product}* and was made to treat *{name of disease}*. We're doing this trial to see how well *{name of investigational product}* can help patients like you who have *{name of disease}*. We'll also be checking to see whether it can have any bad effects on your health.

Drug candidates like *{name of investigational product}* that are tested in clinical trials are sometimes called "investigational products".

## 3 Clinical Trials


### Number of volunteers

20 patients with *{disease name}* between 8 to 15 years old will take part in this clinical trial.

### Duration

The clinical trial will last 6 weeks.

## How does a clinical trial work?

You will first get medical examinations so that we can tell the difference before and after using the investigational product.

| Exams | - | Start | 4th week | 8th week | 12th week | 16th week | 20th week | 24th week | 28th week | 32th week | 36th week | 40th week | 44th week | 48th week |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Height<br>Weight  | ○ | ○ | | ○ | | ○ | | ○ | | ○ | | | | ○ |
| Blood Pressure<br>Pulse  | ○ | | ○ | | | ○ | | ○ | | ○ | | | | ○ |
| Examination  | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| Blood and Urine Tests  | ○ | ○ | | ○ | | | ○ | | | ○ | | | | ○ |
| Breathing Function Test  | | | | ○ | | | ○ | | | ○ | | | | ○ |
| Electrocardiogram  | ○ | | | ○ | | ○ | | ○ | | ○ | | ○ | | ○ |

| Exams | - | Start | 4th week | 8th week | 12th week | 16th week | 20th week | 24th week | 28th week | 32th week | 36th week | 40th week | 44th week | 48th week |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Take the investigational product (IP)  | | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | |

***Example***

- **Breathing Function Test**

  This test checks how well you can breathe.

  A tube will be placed in your mouth, and you'll be asked to breathe following the nurse's directions.

  Please tell us if it's difficult for you to breathe or you feel sick so that you can take a break.

- **Investigational product (IP) in your blood**

  Once you take the IP, it gets into your blood and circulates through your body. Using a blood test, we measure how much of the IP stays in your blood and how well it works. We will take a sample of your blood *{number}* times after you start taking the IP at predetermined times and dates. On some days, we may ask you to visit the hospital without taking the IP. In this case, we may take a blood sample once or more than once on the same day. If we decide to take multiple blood samples on the same day, we may do so either by (1) Using a normal injection needle or (2) inserting a soft tube into your vein. You may have some pain or feel a little sick during a blood test.

**What to do at home**

- Take the IP according to the schedule you are given.
- Keep a medical diary *{name of diary}* with your family.

## Directions for taking the IP

Please take *{name of an investigational product}* after each meal, three times a day.

*Insert a photo of investigational product*

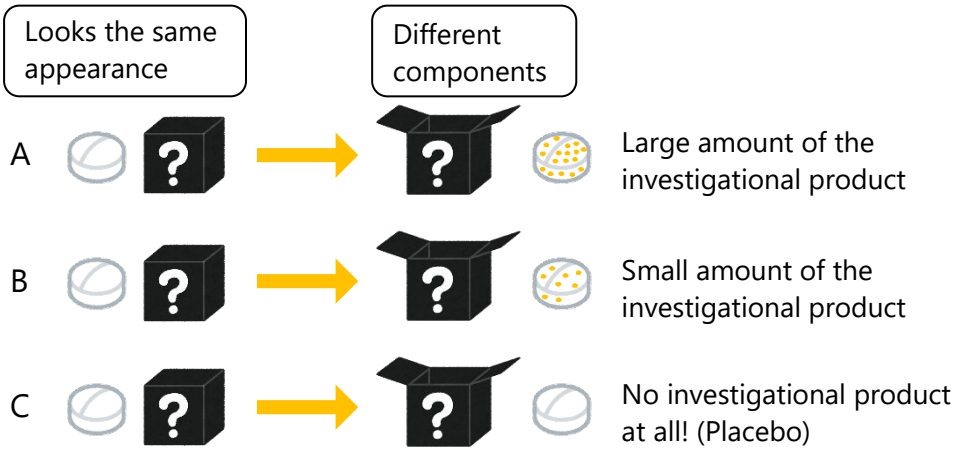
You will help test the IP in one of three ways.

A. You will be given lots of *{name of investigational product}*;

B. You will be given a small amount of *{name of investigational product}*;

OR

C. You will be taking something that looks like *{name of investigational product}* but doesn't contain the product at all, called a "placebo" (pluh-SEE-bo).



If you get the placebo (tablet C), your condition will not change or may even become worse because it doesn't do anything.

Which one of the three ways you get to take the IP will be decided randomly (by chance). Not even the researchers will know!

Whatever the case, we'll look after you carefully.

If you feel sick or feel uncomfortable, please tell your family or the researchers right away. You can quit the clinical trial anytime when you want to.

What is a "placebo"?

A placebo looks just like *{name of investigational product}* but doesn't contain it at all! However, some people feel better when they take the placebo because they believe it works. We use the placebo to compare it with *{name of investigational product}* so that we get a better idea of how the IP is working and to check if there are any bad effects on your health.

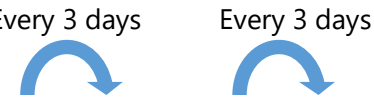
***(Example: Dose titration study)***

***<u>In case a Forced titration</u>***

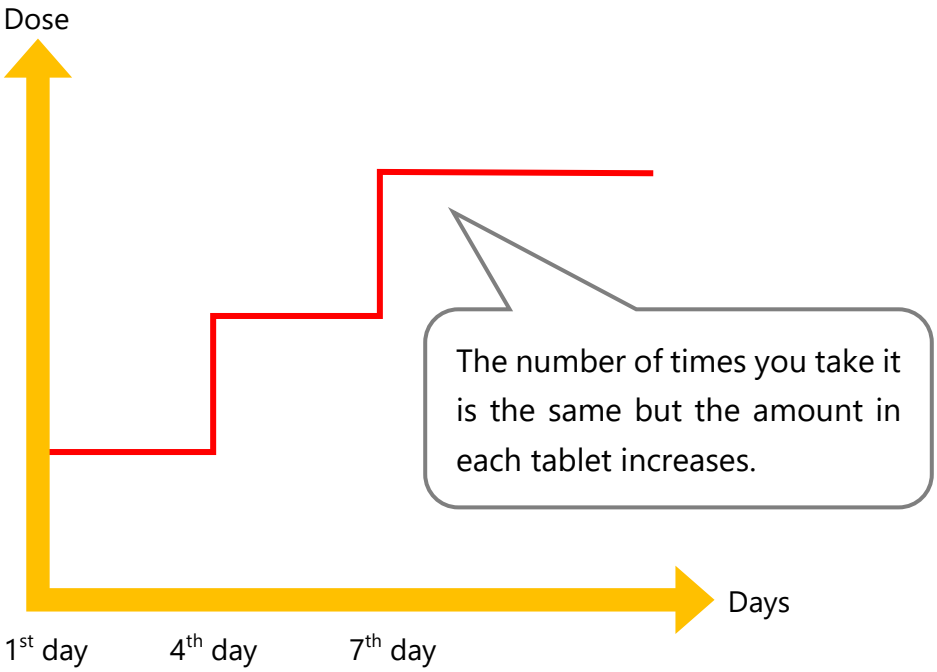
First, you'll be asked to take small amounts of the investigational product, then bigger amounts every three days while we check to make sure that everything is OK with your health. This is important to judge what amount is best for patients the same age and weight as you.

***<u>In case a Dose titration</u>***

First, you'll be asked to take small amounts of the investigational product, then bigger amounts gradually until we can see an effect while we check to make sure that everything is OK with your health.
This is important to judge what amount is best for patients the same age and weight as you.




| | 1st day | 4th day | 7th day | … |
|---|---|---|---|---|
| Dose | | | | |


Dose
The number of times you take it is the same but the amount in each tablet increases.
Days
1st day
4th day
7th day

# 4 Pros & Cons of the Investigational Product

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Each candidate drug has pros and cons. Here are the pros and cons of *{name of an investigational product}* that we know about so far.

## < Pros >

Some patients got better but some did not.

Researchers haven't finished studying *{name of an investigational product}* yet.

Its effectiveness is different for each person.

## < Cons >

You may have one or more of the following.

- 1 out of 3 patients may feel itchy or get hives.

- 1 out of 10 patients may feel ill.

- 1 out of 100 patients may get sweaty.

- A very few patients may have trouble breathing.

You may also get other symptoms, but we'll look after you carefully.

Please tell your family or us if you feel sick or uncomfortable.

Everything you can tell us about how you feel will be very helpful.

We will give you a treatment to feel better if needed.

# 5 Promises for You to Keep during the Clinical Trial


## 1) See your doctor when you're supposed to

Your doctor will examine you often to check the effectiveness of the investigational product and make sure that your health is OK.

## 2) Ask your family before you take any other medicine

Some medicines can't be taken during the clinical trial.
If you feel sick, before you take another medicine be sure to ask your family if it's allowed. And please write down (or ask your parents to write down) the name of the medicine and date you took it in your medical diary.

## 3) Bring your "clinical trial card" whenever you go to another hospital or pharmacy

If you go to another hospital, please show your "clinical trial card" to the doctors there and tell them that you are taking part in a clinical trial and are not allowed to take certain kinds of medicine.

## 4) Keep a diary during your clinical trial

Please use a diary with your family to write down each time you take the investigational product and how you feel. Please bring the diary with you whenever you visit the hospital and show it to the doctors.

## 5) Bring all the investigational product you have to the hospital

Please don't throw away any leftover investigational product, including the empty cases and bags. Give them to your parents and bring all of it to the hospital.

## 6) Our request to young people growing up

- **For girl**

  Body and mind, you are on your way to becoming a grown-up. If you are a girl, you may start having your period, which happens at different times to different girls and is a normal part of becoming an adult.

  We cannot say how the IP will affect the part of your body where babies grow.

  If you have already begun having your period, please make sure not to get pregnant during the clinical trial. If you become pregnant, please tell your family or the researchers right away so that we can make sure that you and your baby are OK.

- **For boys**

  Body and mind, you are on your way to becoming a grown-up. If you are mature enough, you may already have sperm. When your body starts growing sperm is different for different boys and is a normal part of becoming an adult.

  We cannot say if the investigational product will affect the part of your body where your sperm is made. If you are physically mature enough to have sperm, please make sure that you don't get your girlfriend

pregnant. If your girlfriend becomes pregnant, please tell your family or the researchers right away.

## 6 Withdrawing from the Clinical Trial

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You can quit the clinical trial in the following cases.

1) You and your family decide to stop.
2) The doctors decide you should not continue because something is wrong with your health or the investigational product is not working for you.
3) The drug company that makes the investigational product has decided to stop the trial.
4) The hospital has decided to stop the trial (each hospital can decide to do a clinical trial or not).

## 7 Personal Information

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After the trial, we will send the results to the government, but your name, address, and other information about you will not leave the hospital.

Personal information is information about you like your name, address, phone number, and so on.

## 8 Taking Part in the Clinical Trial


Please think carefully if you want to take part in this clinical trial or not. Your decision is the most important thing. Of course, you can ask the advice of your family and the researchers. If you decide not to take part, we will give you another treatment that's already been approved for use. Please ask the researchers for details.

You can quit the trial at any time after discussing your feelings with your family and us.

Whenever we find any new information about the investigational product during the trial, we'll let you know right away. Based on this new information, you can decide whether or not to continue.

Please don't hesitate to ask us anything at all!

## 9 Contact


| | |
|---|---|
| Hospital | (Example) ○○Hospital |
| Contact to | (Example) Clinical trials division |
| Phone number | |

Name of Hospital:
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Protocol Number:
Version:
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:** ____ / ____ / ____
Year Month Date

**Name:** _____

• • • Doctor • • •

Explanation date: ____ / ____ / ____
Year Month Date

Name: _____

• • • Clinical Research Coordinator • • •

Explanation date: ____ / ____ / ____
Year Month Date

Name: _____

Name of Hospital:
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**Copy (clinical trial)**

# ... Letter of Assent ...

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• • • Doctor • • •

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• • • Clinical Research Coordinator • • •

Explanation date: ____ / ____ / ____
Year Month Date

Name: _____

Name of Hospital:
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**Patient copy**

# ... Letter of Assent ...

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**Name:** _____

• • • Doctor • • •

Explanation date: ____ / ____ / ____
Year Month Date

Name: _____

• • • Clinical Research Coordinator • • •

Explanation date: ____ / ____ / ____
Year Month Date

Name: _____