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 (CRC):

A "clinical trial" is different from a normal medical examination. In a clinical trial, researchers study new medicines and treatments to see how safe they are and how well they work. As we explain the details about this clinical trial, please tell us at any time if you decide you don't want to take part in it. Please ask us any questions you may have. You can also talk it over with your family before deciding. Your decision not to take part will not change the quality of the care you receive.

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Informed Assent Form C
Protocol Number:
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1 What's a clinical trial?

Medical treatments used today are based on a lot of research.

Pre-clinical test

Researchers test different chemicals to see if they might be useful for treating a disease. They often test new chemicals on living things like mice before they are used with people.

5-10 years

Clinical trial

After a new chemical passes the pre-clinical test, it is tested with human volunteers in a clinical trial. The chemical is now called an "investigational product" (IP) and is tested in three phases.

Phase1

Researchers give the IP to healthy volunteers and/or patients to check its safety. They then measure how much of the IP gets absorbed and how much of it passes through the body.

Phase2

Only a few patients get the IP. After the patients get the IP, the researchers measure the benefits, risks, and the best amount (dosage) for making patients better.

Here ▶ **Phase3**

Now, the researchers give the IP to many more patients to see how well it works, what the risks are, and what the best dosage is.

5-10 years

Inspection/ Approval

After the clinical trial is over, the drug company sends the results to the government to be checked by experts. If the government experts think the IP is safe and effective, it gets approved as a new medicine for use with patients.

Passed

Pre-market study

Researchers continue studying the new medicine after it has been approved. They collect information about its benefits and risks from many patients.

2 Disease and the investigational product

About {name of disease}

→Details

About {name of investigational product}

In this clinical trial, you will be asked to take tablets of *{name of investigational product}*, which doctors believe may have the following effects: *{ 1) effect, 2) effect}*

(Additional information: in case it is not approved in Japan)

{name of investigational product} is commonly used to help patients with *{name of disease}* all over the world, but *{name of investigational product}* has still not been approved for use in Japan.

(Additional information: in case a similar medicine has been approved)

Currently only *{name of similar medicine}* is available in Japan to treat *{name of disease}*, ***but*** *{name of investigational product}* works differently from *{name of similar medicine}*. Here's how:
{difference between the two}
A clinical trial gives researchers a chance to test new drugs so that patients have more choices about their treatment in the future.

3 The purpose of this clinical trial

(Example)

The purpose of this clinical trial is to measure the effectiveness and risks of using the investigational product (IP) in patients with *{name of disease}*. During the trial, researchers will measure how much of the IP is absorbed by the body and how much passes through.

4 Taking part

To qualify to take part in this clinical trial, you must meet the following requirements.

Requirements

1)
2)
3)
4)

You can't take part if you have even one of following.

1)
2)
3)
4)
5)
6)

Even if you have all these requirements, you may still not be able to participate depending on your medical examination results.

5 How will the clinical trial work?

Number of people taking part

Example 1

15 people in Japan

Example 2

15 people in Japan and 60 people from other countries

How long with this clinical trial last?

This clinical trial will last 6 weeks from the time you decide to take part in it.

{Number} days	Screening (Medical examinations to check that you can take part)
{Number} Weeks	Using the investigational product (IP)
{Number} Weeks	Observation (Medical examinations to check for differences before and after taking the IP)

Type of IP and directions for taking it

(Example)

Take one tablet twice a day, once after breakfast and once after dinner.

Insert a photo of investigational product

Dosage

(Example)

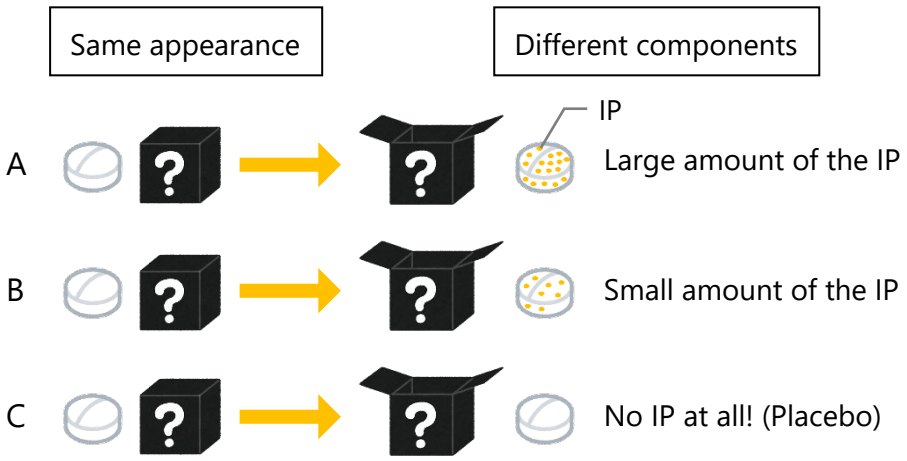
(In case of placebo)

You will help test the IP in one of three ways, called "regimens (REH-ji-menz)."

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 regimen A, you may get better but you may also become worse, as we will explain in "Chapter 6: Potential risks and benefits."

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

Why use a placebo?

Some people feel better after taking a placebo because they believe it is working. Researchers use placebos so that they can get a better idea of how the IP is working by comparison. In this way, researchers can measure an IP's effectiveness and its health risks accurately.

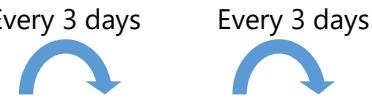
Which regimen you get will be decided automatically and even you, your parents, and the researchers will not know until after the clinical trial.
If you feel sick or feel uncomfortable, please tell your parents or the researchers right away. The researchers will examine you carefully and give you something to make you feel better. Also, if your test results show that it's unsafe for you to continue, the researchers may stop you from taking part any further.
You can quit the clinical trial anytime when you wish. Your decision to quit will not affect the quality of the care you receive. Please tell the researchers or the CRC if you want to quit.

(In case a Forced titration)

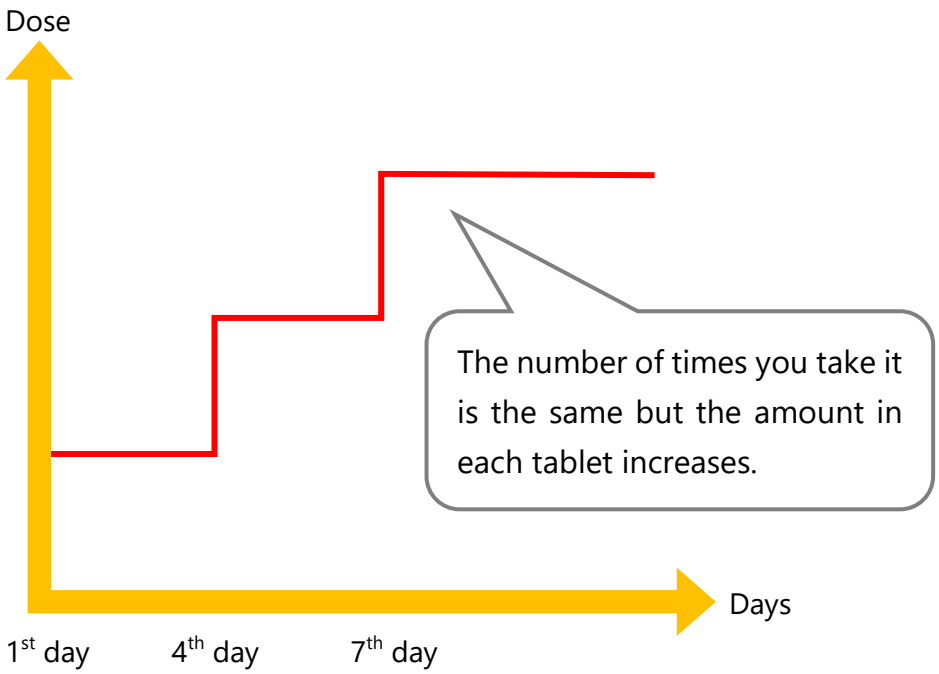
First, you'll be asked to take small amounts of the investigational product, then bigger amounts every three days while we check to make sure that everything is OK with your health. This is important to judge what amount is best for patients the same age and weight as you.

(In case a Dose titration)Example

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

Schedule

You will be asked to take the following medical examinations according to the schedule below.

	Screening	During IP use							Observation
Time		Start	2nd week	4th week	8th week	12th week	20th week	28th week	36th week
			(±3days)						
Explanation/ Consent									
Medical examination									
Blood pressure									
Pulse									
Body temperature									
Urine test									
Blood test									
IP in blood									
Lung function test									
Diary									
Genetic testing *									

*We will explain the details in Chapter 12.

Example

- **Lung function test**

This test checks the size and movement of your lungs when you breathe. A mouthpiece (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 you can take a rest.

- **Measuring the IP in your blood**

A blood test tells how much of the IP stays in your blood and how much of it is working. Shortly after you begin taking the IP, you will be asked to take a blood test using either (1) a normal injection needle or (2) a soft tube inserted into your vein. You can choose whichever you like better. You may have some pain or feel a little sick during a blood test. There will be about five blood tests during the clinical trial.
To measure the amount of the drug in your blood, you may be asked to visit the hospital even on a day when you haven't taken the IP.

6 Potential risks and benefits

Potential benefits

You may or may not get benefits from taking *{name of investigational product}* because research on this IP is not over yet. The effectiveness of the treatment depends on the person taking it.

Potential risks

You may have to get frequent medical exams.
You may also get one or more of the following symptoms.

Percentage	Symptoms
%	Itching and hives
%	Feeling sick
%	Sweating
%	
%	

You may get other symptoms.
If you think something's not right, please tell the researchers right away.
They will give you something to make you feel better.

7 Promises for you to keep during the clinical

1. See the researcher when you're supposed to

A researcher will examine you often to check the effectiveness of the IP and to 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 or guardians to write down) the name of the medicine and the date you took it in your medical diary.

3. Tell us about any other treatments

Please tell your parents and the researchers if you intend to have another treatment for any other illness, including dental treatments.

4. Bring your "clinical trial card" whenever you go to another hospital or pharmacy

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

5. Keep a diary for during your clinical trial

Please keep a diary with your family to write down each time you take the IP and how you feel. Please bring the diary with you whenever you visit the hospital and show it to the researchers and the CRC.

6. Bring all the IP you have to the hospital

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

7. Birth control during the clinical trial

The researchers cannot say yet how taking the IP may affect your ability

to have a baby or breast feed it. Please be sure not to get pregnant during the clinical trial.

-For girls

If you discover that you are pregnant, please tell your parents or the researchers right away so that you can stop taking part in the clinical trial.

-For boys

If you find that your partner has become pregnant, please tell your parents or the researchers right away so that your partner and her baby can be examined to make sure they're OK.

** Add an explanation about contraception by referring to the text suggestions as necessary (see: For women, For men, Contraception).*

8 Other treatment options if you don't take part

You can receive other treatments that have already been approved even if you decide not to take part in this clinical trial.

{name of treatment}

9 If you have side effects

If you feel uncomfortable, please tell your parents and the researchers right away. The researchers will watch you closely and give you treatments to make you feel better.

10 Updates

If a new health risk, etc. of the IP is discovered while you are taking part in this clinical trial, the researchers will inform you and your family right away. Based on this new information, you can decide whether or not you want to quit the clinical trial. Please let us know if you'd like to quit.

11 Withdrawing from participation

A clinical trial may be stopped for any of the following reasons.
Also, you may be asked to stop taking part if you do not follow the rules in Chapter 7.

1. You and your parents or guardians decide to stop your participation.
2. The researchers say you should stop for some health reasons.
3. (If you are a girl) You are pregnant.
4. The researchers think the IP is not working or that you may be at risk of severe effects or injuries related to this trial.
5. The drug company conducting this clinical trial decides to stop the trial.
6. The Institutional Review Board decides to stop the trial.

The researchers will continue to examine you and give you other treatments even if you stop taking part in the trial. You may receive additional medical examinations to make sure your health is OK when you withdraw or afterwards.

12 Genetic testing

This clinical trial includes genetic testing. Your genetic test concerns your family and your future children.

What does "genetic" mean?

Genes, which contain your body's "blueprint," make it possible for parents to pass traits like eye color and hair color on to their children. Each of us carries genetic information from each of our biological parents. Some genes are related to certain diseases and can affect the effectiveness and health-related risks of medical treatments.

Genetic testing: purpose and procedures

(Example 1)

The purpose of the genetic test in this trial is to find out how well the IP is working in patients depending on specific differences in their genetic information. This is the only reason for doing the genetic tests in this trial.

(Example 2)

The researchers in this trial will ask you and other volunteers to take a genetic test to diagnose *{name of disease}*. Those who receive a diagnosis of *{name of disease}* can then take part in the clinical trial.

(Example 3)

The researchers in this trial will do genetic tests to get specific genetic information that they need to measure how well the IP is working. Once we have decided when and how the genetic tests will be conducted, we will let you know.

On week *{number}* of your hospital visits, you will receive several tests, and *{quantity}* ml of blood will be collected for testing. The blood used for genetic testing will be kept by a special agency for a maximum of *{period}*, then will be safely disposed of.

Potential risks and benefits

(Example 1)

Genetic testing will not give any benefits to you personally, but it may be used to develop new treatments and medicines that can help many people in the future. Some people feel anxious about their genetic test results. Also, there is a risk that your genetic test results, which are part of your private information, might be leaked. However, the drug company sponsoring the clinical trial has promised to control your genetic test information strictly so that it doesn't become public.

Disclosure of your genetic test results

(Example 1)

The researchers cannot tell you the results of your genetic test.

(Example 2)

Please ask your parents or the researchers if you want to know the results of your genetic test.
It may take some time until the results of your test are available. You may talk to a genetic counselor if you wish.

Before you take a genetic test

(In case of required screening)

To take part in this clinical trial, you need to take a genetic test. Before you agree to take part in the trial, please consider carefully whether you want to receive a genetic test and take part in the trial.
You can withdraw from the trial at any time if you change your mind. If you quit the trial, your blood sample will be safely disposed of, but any data we get before you quit will be kept for further study related to this trial.

(In case pf voluntary screening)

Having a genetic test is completely up to you. Please think it over carefully with your parents before deciding either way.

Please let your parents and the researchers know right away if you don't want to take part or if you change your mind after starting the trial. Again, you can quit this clinical trial anytime you wish.
If you quit the trial, your blood sample will be safely disposed of, but any data we get before you quit will be kept for further study.
You can continue to take part in this clinical trial even if you choose not to take a genetic test or decide to stop the test after it has started.

13 Keeping your blood samples over the long-term

Your blood sample will be preserved for the long term and tested again in the future if additional research is needed to find out the parts of the IP that are effective against *{name of disease}* and their risks and benefits. The additional research study may include tests where your genetic information is disclosed (Please refer chapter 12, Genetic testing). At the moment, however, no additional studies are being planned nor can we say when such studies may be done or what their purpose will be.

You and your parents should decide if you agree to long-term preservation of your blood samples and its use in additional research. You can take part in this clinical trial even if you decide your blood samples should not be preserved in the long-term.

We will safely dispose of your blood sample at any time you wish during this clinical trial, but any data we get before you quit will be kept for further study.

Please ask the researchers if you wish to know more about the additional studies. Please remember that these additional studies may not be done or may not be completed while you are taking part in this trial.

14 Privacy policy

"Personal information" is information about people, like their name, address, phone number, and so on.
The information collected in this clinical trial will include things that are unique to individuals, like their birthday, medical history, and test results that can be used to find out who they are. Your personal information will be given to the pharmaceutical company for protection and be used in studies after removing information that can lead back to you.

An alphabet and number code will be used instead of your name.
Example:
John Doe→A001

The people at the pharmaceutical company who are in charge of this clinical trial and workers at the Ministry of Health, Labour and Welfare may check your medical records to make sure that this clinical trial is being done properly. However, when they check your medical records, they will follow strict rules to keep your information from becoming public. Your personal information will never be leaked.

15 Voluntary participation and withdrawal

Please think carefully whether or not you wish to take part in this clinical trial. Your decision is the most important thing. Even if you choose not to take part, the researchers will give you other, standard treatments to help you feel better.

If you change your mind during this clinical trial, please discuss your feelings with your parents and the researchers before deciding. Whether or not you choose to continue taking part, you will go on receiving all the services you have been getting.

If you decide to quit after taking the investigational product (IP), you may receive a medical examination to make sure your health is OK. Please follow the researchers' directions and ask them or the CRC (Clinical Research Coordinator) if you have any questions or if something is bothering you.

16 Institutional Review Board (IRB)

Clinical trials are done following strict regulations to protect patients' safety and human rights. All clinical trials need to be approved by the Institutional Review Board (IRB). The IRB monitors the researchers to make sure that they are following the rules, protecting the patients' rights, and conducting the clinical trial safely. The IRB has already reviewed this clinical trial and has given permission for it to be conducted.

17 Consultation service

If you want to know more about anything related to the clinical trial or you feel anxious, you can talk to your parents, the researchers or the consulting service below any time you wish. We will be happy to explain everything to you until you and your parents understand completely.
If you experience anything unusual during or after this clinical trial, please tell us right away.

Name of institution	(Example) ABC hospital
Contact	(Example) clinical trial office
Phone number	

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

Hospital Copy

... Letter of Assent ...

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

I agree to be genetically tested.

- ☐ Yes (I agree to disclose the results □ Yes □ No)
- ☐ No

Regarding the use of my blood samples for additional studies:

- ☐ I agree to have my blood samples preserved for the long term.
- ☐ I agree to have my blood samples preserved for the long term without tests disclosing my genetic information.
- ☐ I wish my blood samples to be disposed of safely.

Date: _____ / _____ / _____ /
Year month date

Name: _____

• • • Investigator • •

Date: _____ / _____ / _____ /
Year month date

Name: _____

• • • CRC • • •

Date: _____ / _____ / _____ /
Year month date

Name: _____

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

Clinical Trial Office Copy

... Letter of Assent ...

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Date: _____ / _____ / _____ /
Year month date

Name: _____

• • • Investigator • •

Date: _____ / _____ / _____ /
Year month date

Name: _____

• • • CRC • • •

Date: _____ / _____ / _____ /
Year month date

Name: _____

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

Patient Copy

... Letter of Assent ...

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

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- ☐ Yes (I agree to disclose the results □ Yes □ No)
- ☐ No

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Date: _____ / _____ / _____ /
Year month date

Name: _____

• • • Investigator • •

Date: _____ / _____ / _____ /
Year month date

Name: _____

• • • CRC • • •

Date: _____ / _____ / _____ /
Year month date

Name: _____