What's a Clinical Trial?

{name of clinical trial}

A "clinical trial" is different from a normal medical examination. It is a medical study that aims to develop new medicines and treatments. In the following pages, we will tell you more about clinical trials. Please don't hesitate to let us know if you do not wish to participate in this clinical trial.

◆ ◆ ◆

People younger than 20 years will be asked to take part as subjects in this clinical trial. Before they take part, their parents or legal representatives need to submit a consent form, or a legal statement saying that they approve their children's participation in the clinical trial.

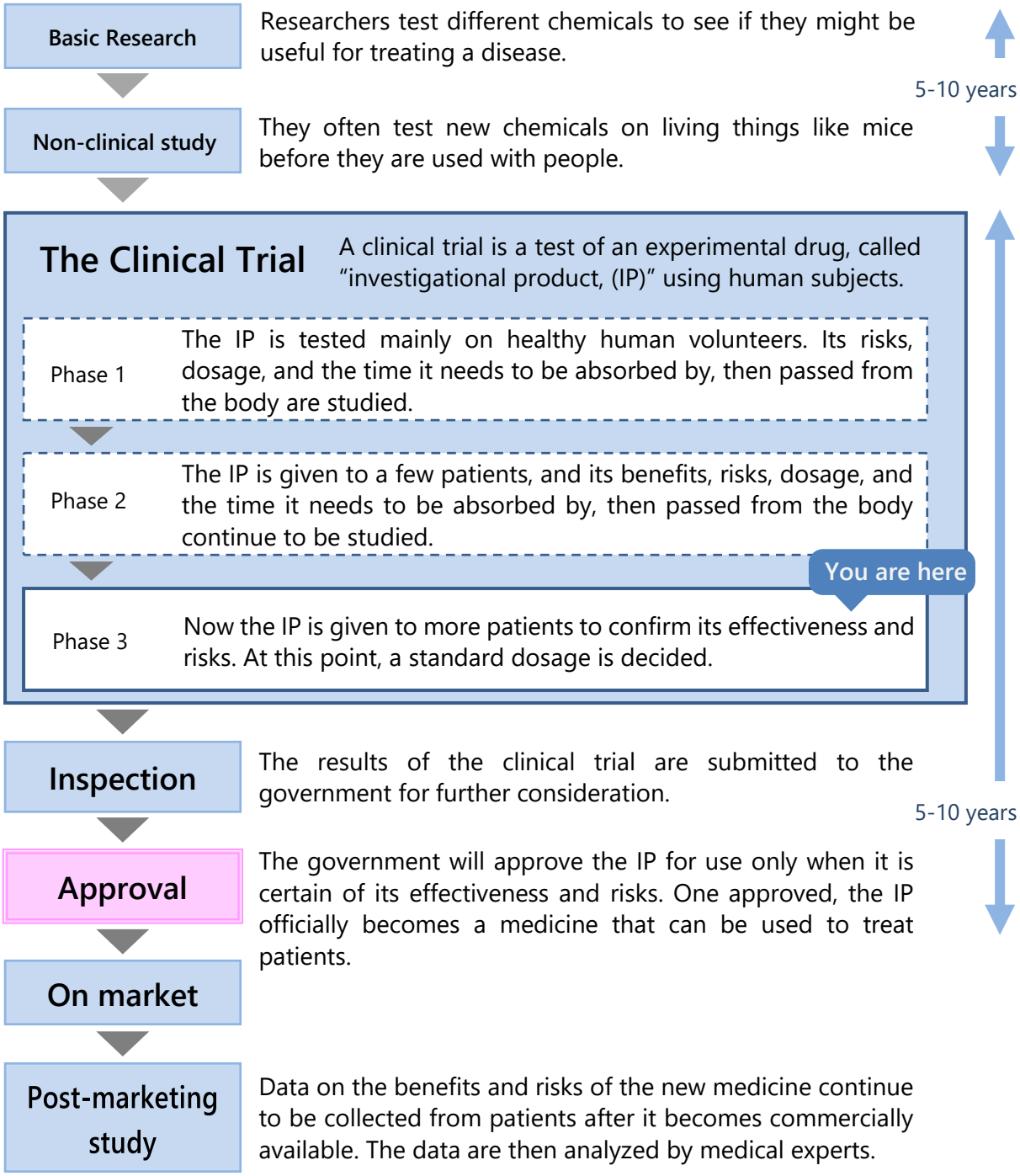
Please ask our staff or doctors if there is anything about this clinical trial that you do not understand. All questions are welcome!
We will explain the clinical trial to you again later to make sure that you still want to participate.

The subjects (or patients) and their parents or legal representatives are free to decide whether or not to participate. No one is required to take part in a clinical trial or can be forced to do so.
If you decide not to take part, your decision will not affect the quality of care you receive in the future.

Contents

1. What's a clinical trial?

Treatments and medicines used today are the result of a lot of study.



IPs become new medicines thanks to the many people who volunteer as subjects in clinical trials. Their help makes it possible for patients to benefit from new alternatives to the standard treatments in the future. In this way, clinical trials are essential for the development of new treatments.

The current clinical trial will continue until the IP is approved for use with patients.
Usually, it takes a few months from when government gives its approval to when the new medicine becomes commercially available. During this period, the clinical trial goes into the "post-marketing phase" when the IP is called a "study drug." Patients can continue to receive the experimental product during this period, and they and their parents or legal representatives will be informed as soon as the experimental product is officially approved as a new medicine.

(Investigator-initiated trials)

In Japan, clinical trials are planned and conducted by pharmaceutical companies. However, a law called the "pharmaceutical affairs law" was established in 2002 to allow medical doctors to plan and conduct clinical trials whenever necessary. Such trials are called "investigator-initiated trials." The current clinical trial is an investigator-initiated trial.

2. {name of disease} and investigational product {name of investigational product}

<{name of disease}>

→Details

<Investigational product called {name of investigational product}.>

(Example 1)

In this clinical trial, you will be asked to take tablets called *{name of investigational product}*. *{name of investigational product}* is categorized *as {name of a compound}*, which earlier studies have found to be potentially effective in treating *{name of disease}*. *{name of investigational product}* is used commonly all over the world for patients with *{name of disease}* but has not yet been approved for use in Japan.

(Example 2)

In this clinical trial, you will be asked to take tablets called *{name of investigational product}*. *{name of investigational product}* is categorized as *{name of a compound}*, which earlier studies have shown to be potentially effective in treating *{name of disease}*. In other countries, *{name of an investigational product}* is being tested in phase *{number}* clinical trials, where it is being assessed for *{effectiveness}*.

(Example 3, In case a similar medicine is approved)

In this clinical trial, you will be asked to take tablets called *{name of investigational product}*. *{name of investigational product}* is categorized as *{name of a compound}*, which earlier studies have shown to be potentially effective in treating *{name of disease}*. Currently only *{name of similar medicine}* is approved as a treatment for *{name of disease}*. *{name of investigational product}* has different effects from *{name of similar medicine}*. Clinical trials offer a chance to create a new alternative to the standard treatment so that patients can have more, possibly better, choices.

3. The purpose of this clinical trial

(example)

The purpose of this clinical trial is to study the *{main/sub purpose}* of *{name of investigational products}* in patients with *{name of disease}*. Researchers will also measure how much of the investigational product is absorbed by the body.

4. Participation selection

A person wishing to participate in a clinical trial needs to meet certain requirements, called "inclusion criteria."

The inclusion criteria for this clinical trial are shown below:

Criteria

1. …
2. …
3. …
4. …

…

Also, you won't be able to participate if any of the following applies to you. These are called "exclusion criteria."

1. …
2. …
3. …
4. …

…

Besides the exclusion criteria above, you may not be able to participate depending on the results of your medical examinations.

5. Clinical trial procedure

<Number of participants>

(Example 1)

20 people in Japan

(Example 2)

20 people in Japan and 60 people from other countries

<Duration>

(Example)

3 weeks (see below)

**Insert a chart if needed*

- Screening: 1 week
  You will receive medical examinations to make sure it is safe for you to take part in this clinical trial.
- Using the IP: 1 week
- Observation: 1 week
  You will receive medical examinations to make sure your health is OK after taking the IP.

(example: The trial will be continued until the IP is approved.)

This clinical trial will continue until *{name of investigational product}* is approved by the government as a treatment for *{name of disease}*. The length of this clinical trial may change depending on the time needed for approval.

<Long-term use of the IP>

You can continue to receive the IP after this clinical trial if you wish and the medical doctors think it will help you. We will explain the long-term use of the IP again later. You can then decide whether you wish to continue taking the product.

<Dose>

(Example)

This clinical trial will test four types of IP, each of which has already been tested in adult subjects. We are now planning to test the same products in children to see if there is any difference in their effectiveness between adults and children.

A: *{name of investigational product}* 3 mg

- This is the largest dosage of the IP.
- This dosage may be the most effective for treating *{condition}*.
- You may experience adverse events or have an adverse drug reaction (both expected and unexpected kinds), as we will explain in "Chapter 6: Potential risks and benefits." You may experience these effects and reactions frequently during this trial.

B: *{name of investigational product}* 2 mg

- This is the second largest dosage.
- This dosage may be effective for treating *{condition}*.
- You may experience adverse events or have an adverse drug reaction (both expected and unexpected kinds), as we will explain in "Chapter 6: Potential risks and benefits."

C: *{name of investigational product}* 1 mg

- This is the smallest dosage.
- This dosage may have little or no effect.
- You may experience adverse events or have an adverse drug reaction (both expected and unexpected kinds), as we will explain in "Chapter 6: Potential risks and benefits."

D: Placebo

- The placebo looks exactly like *{name of an investigational product}* but does not contain it at all.
- Some people report feeling better even when they have only taken the placebo because of their strong expectation that they will feel better.

  We will compare data we get from the placebo with data from the various dosages of the IP to carefully assess the benefits and risks of *{name of*

investigational product}.

- The placebo is not designed to treat *{condition of disease}*. Your condition may not change or may even become worse if you receive the placebo.

Which tablet/dosage you receive will be decided randomly. This means that you, your parents/legal representatives, and even the doctors will not know which of the four varieties you get. Randomly assigning treatments in a clinical trial is very common and is the best way of studying the risks and benefits of investigational products scientifically.

Type	Probability
{name of investigational products} 3 mg	1/4
{name of investigational products} 2 mg	1/4
{name of investigational products} 1 mg	1/4
Placebo	1/4

If you feel sick or have any concerns, please tell the doctors or medical staff at any time. The doctors will examine you carefully to make sure that you are not in danger and will give you appropriate treatments if you need them. Depending on the results of your examinations, the doctors may decide to stop your participation in the clinical trial.
You can withdraw from the clinical trial at any time without affecting the quality of the care you receive in the future. Please tell the doctors or medical staff if you wish to stop taking part in the clinical trial.
After the clinical trial, we will let you know which of the four treatments you received.

<How to take the IP>

(Insert the photo of investigational products)

(Example)

Take 1 tablet after breakfast and dinner.

<Schedule>

You will receive regular medical examinations to monitor your health before and after taking the IP according to the following schedule. You may need to have additional examinations if something unexpected happens or depending on the results of the

examinations. After this clinical trial is over, you will no longer be allowed to take the IP. For further details, please ask your doctor.

(insert schedule)

<Medical examinations>

1. Blood test/urine test

   You will receive a blood and urine test to check your liver and kidney function, etc. before and after this clinical trial.

   If you are menstruating (having periods), you may need to take a pregnancy test.

2. Pharmacokinetics test (blood test)

   You will take a blood test to measure the concentration of the IP components in your blood to see how they are working inside your body.

   We will also measure the time it takes for the components to be absorbed into and passed out of your blood. When taking a blood test, please follow the directions you are given.

   (If you have dosage instructions)

   We may ask you to visit the hospital without taking the IP.

   (Procedure)

   - *{amount}* ml of blood will be drawn for each test.
   - The blood for the various tests will be drawn at the same time / at different times.
   - You will receive a blood test on *{date of every week / month}*.
   - You will receive a blood test *{number}* times at regular intervals after taking the IP.

     Or

     You will receive a blood test *{number}*hours before / after taking the IP.

   We will draw your blood either by using a normal injection needle each time or by leaving a soft tube in your vein during the test. You be asked to stay in the hospital until all the blood tests are done.

3. ….

4. …

<Prohibitions and restrictions (things you should not do)>

Please let us know if you intend to take any medications that are not included in this

clinical trial during your participation because they may interfere with how the IP works or may interact with the IP to make you ill. On the list below are some of the medications and treatments that you should not take during this clinical trial.

You will be given a "clinical trial card" with a list of what you should avoid or not do. If you need to visit another department, hospital, clinic or pharmacy, please show this card to the doctors or staff there. Please also be sure to check with a doctor before taking any medications that are not on the list.

Once this clinical trial begins, you will not be allowed to continue receiving *{name of treatment}*.

(example)

List1 List of medications and supplements not allowed

Duration	Kind	Name of medicine (example)
2 weeks before screening and 3 weeks after the clinical trial (during the clinical trial)	Medications with enzymes that dissolve *{name of an investigational product}*	
	Other medications	Medications given in the clinical trial except *{name of IP}*

List2 List of treatments not allowed

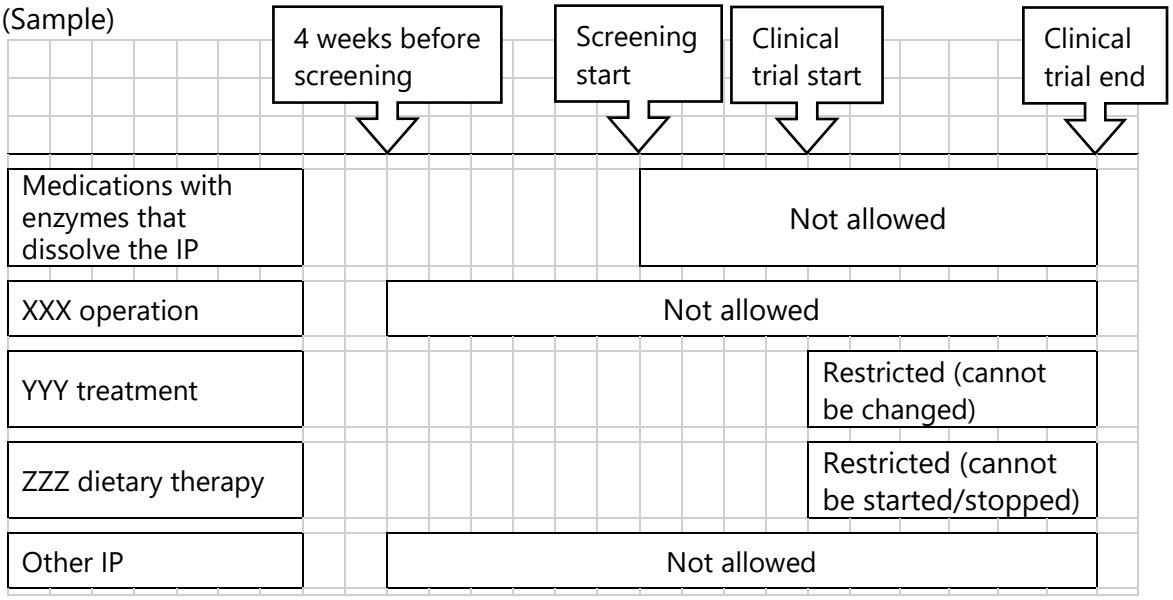
Duration	Kind
Start of screening and 1 month after screening	XXX Operation

List3 Procedures that cannot be changed during the clinical trial

Duration	Treatment
1 month before screening and 3 weeks after the clinical trial (during the clinical trial)	YYY treatment → The treatment cannot be changed 4 weeks before screening or during the clinical trial.
2weeks before screening and 2 weeks after the clinical trial (during clinical trials)	ZZZ dietary therapy → The treatment cannot be started/stopped.

Some medications and treatments are not mentioned on the list above. Your doctors will explain the details to you.

(Sample)



6. Potential risks and benefits

<Potential benefits>

By participating in this clinical trial, you may or may not have the following benefits: *{potential benefits}*.

Please note that the placebo does not contain any of the active ingredients in the IP that can give you any of the above benefits.

<Potential risks>

You will receive medical examinations (blood test, X-ray etc.) frequently.

You may experience adverse events [*1)] or adverse drug reactions [*2)].

*1) Adverse event: Any time you feel ill for whatever reason while taking the IP.
*2) Adverse drug reaction: An adverse event that directly results from taking the IP.

(Insert safety information)

=Influence on reproductive functions=

(example)

In animal tests, the cells of reproductive organs have been shown to become abnormal when a large amount of the IP is given *{number}* times. However, we cannot be certain whether the same thing will happen in humans. If it does, your reproductive organs (ovary, uterus, testes) may be damaged. If you are concerned about the possibility of your reproductive organs being damaged, please tell your doctor.

7. Requirements for participants

1. Please follow any instructions you are given during this clinical trial.

2. Please see your doctor with your parents / legal representatives according to the schedule you are given.
   Please take your medical examinations according to schedule. Please tell us immediately if you are unable to receive an examination for any reason.
   Your parents / legal representatives also need to be present at the hospital to be informed about the clinical trial.

3. Please bring all the IP you have with you to the hospital.
   Please bring any leftover IP, including empty containers and bags, with you.

4. Prohibition against participating in other clinical trials
   For your own safety and the success of this clinical trial, you are not allowed to take part in other clinical trials.

5. Please tell us about any medications or treatments you are currently receiving.
   Please tell us if you are receiving or intend to receive a treatment for any another illness, including dental treatments. The doctors in this clinical trial will arrange with the doctors in charge of your other treatments to protect you from adverse events caused by mixing treatments. If you are hospitalized for any reason, please tell your doctor as soon as possible.

6. Birth control
   During this clinical trial, you will be asked to practice birth control because we are not certain about the effect of the IP on the health of unborn babies and breastfeeding babies.

(In case of a long-term trial)

Even if you cannot become pregnant now, you may be able to become pregnant as your body matures during this clinical trial.
Please tell the doctor or medical staff when you begin having your period.

7. If you find that you are pregnant, please let the doctors or medical staff know immediately so that you can withdraw from the clinical trial.

8. …

8. Other treatment options besides this clinical trial

(Example1)

Below are other medications and treatments that you can receive for *{condition name}* if you decide to withdraw from this clinical trial. Please ask your doctor for details.

1. …
2. …
3. …

You can receive appropriate treatment for your condition even if you decide not to take part in this clinical trial.

(Example2)

No medications have yet been approved in Japan for the treatment of *{name of disease}*.
Your condition may improve with treatments using *{name of alternative treatment}*.
You can receive appropriate treatment even if you decide not to take part in this clinical trial.

9. Compensation and/or treatment of trial-related injuries

Please tell your doctor immediately if you feel ill or uncomfortable.
We will examine you and give you an appropriate treatment if you suffer any trial-related injury, such as an adverse drug reaction. You can also receive compensation based on the

terms and conditions provided by the pharmaceutical company. Please note that you will be ineligible to receive compensation if any of the following applies to you: 1) the clinical trial is not the cause of the adverse event; 2) the adverse event resulted from your not following the instructions given to you; 3) the adverse event resulted from an intended or unintended action or omission by you or your parents/legal representatives.
Please refer the document entitled, "Compensation in the clinical trial" for details.

10. Updates on information

If we find any important information about adverse drug reactions, etc. related to the IP during your participation in this trial, we will let you and your parents/legal representatives know immediately. Based on this information, you can decide whether or not to continue participating in this clinical trial. Please do not hesitate to tell us if you wish to withdraw from this clinical trial.

11. Terminating your participation in this clinical trial

If any of the following applies to you, you will be asked to withdraw from this clinical trial. Your participation will also be terminated if you do not comply with the requirements in Chapter 7.

1) You and your parents/legal representatives decide you should withdraw.
2) A doctor has decided that you are not qualified to continue for medical reasons, such as having an adverse drug reaction.
3) A doctor has decided that you should withdraw because the IP is not working sufficiently.
4) Continuing participation is not possible because you cannot visit the hospital (because you have moved, etc.) or your doctors are unable to contact you.
5) You have become pregnant.
6) The pharmaceutic company has decided to halt the clinical trial.
7) The "Institutional Review Board" has decided to halt the clinical trial.

Your doctors will give you an appropriate treatment even if you decide to withdraw from this clinical trial.

You may receive additional examinations to monitor your condition when/after you withdraw from this clinical trial.

12. Genetic testing

You will be asked to undergo genetic testing in this clinical trial. Your genetic information is uniquely yours and will never change during your lifetime. Some of your genetic characteristics can be passed on to your children.

<What does genetic mean?>

Children inherit the color of their eyes and hair from their biological parents. These are examples of what we call "genetic characteristics or traits," which are transmitted from parent to child by various parts of your DNA called "genes". Genetic information lies in the DNA within the nucleus of cells throughout your body and is a kind of blueprint containing information on how a living creature grows, develops, and reproduces. Some genetic information is linked to specific diseases and can influence your risks and benefits in treatments.

<The purpose of genetic testing>

(Example 1)

A medication may work well for some people but not for others. The purpose of genetic testing in this clinical trial is to see how well the IP works in different people, each with a different genetic "blueprint." All the subjects in this clinical trial will be asked to undergo genetic testing to help us understand which type of medication is most effective and safest for different patients.

(Example2 : in case to diagnose)

The target population in this clinical trial are subjects whose gene type is *{name of type}*. You will be asked to undergo a genetic test to identify your gene type and determine your eligibility to participate in this clinical trial.

<The aims of genetic testing>

(Example1)

The sole aim of genetic testing in this clinical trial is to find specific genetic information thought to be related to *{name of disease}*. Studying this genetic information may help researchers better understand how the gene functions and what if any importance it may have in developing treatments. Other genes will not be analyzed.

(Example2)

The sole aim of genetic testing in this clinical trial is to find specific genetic information thought to be related to *{name of disease}*. At this point, the details and timing of the genetic test have not been decided. As our knowledge of genetics increases with progress in genetic testing technology, the number of research topics may increase as well.

<Procedure>

{quantity} ml of blood will be collected for genetic testing at week *{number}* along with samples for other tests.

<Potential risks and benefits>

(Example 1)

The aim of genetic testing in this clinical trial is to study the relationship between the effectiveness of the treatment and genes. There is almost no direct benefit to you. However, your cooperation may help in the development of new methods of diagnosing the disease and in establishing a dosage that is best for each patient (tailor-made treatment).

If you are told the results of your genetic test, you may experience anxiety about your health or unexpected and undesirable impacts on your social life. Furthermore, the facts discovered by genetic testing (i.e., your genetic information) may be transmissible to your children. For these reasons, the sponsor will strictly control the results of your genetic test so that the information is not leaked.

{quantity} ml of blood will be collected for genetic testing at week *{number}* along with samples for other tests. The total number of blood tests you need to take will remain the

same.

(Example 2)

The results of the genetic testing may enable your condition to be diagnosed more accurately and may be helpful in developing future treatments.

If you are told the results of your genetic test, you may experience anxiety about your health or unexpected and undesirable impacts on your social life. Furthermore, the facts discovered by genetic testing (i.e., your genetic information) may be transmissible to your children. For these reasons, the sponsor will strictly control the results of your genetic test so that the information is not leaked.

<Disclosure of genetic test results>

(Example1)

Because of *{reason}*, you will not be told the results of your genetic test.

The results of your genetic test will be securely protected by the sponsor.

(Example2)

The results of your genetic test will be securely protected by the sponsor.

Please tell your doctor if you wish to know the results of your genetic test. The doctor and your parents/legal representatives will discuss whether you should be shown the results of your genetic test. If you wish, you may talk to a genetic counselor at that time. It may take some time before the results become available.

The information from your genetic test will never be disclosed to anyone besides you and your parents/legal representatives.

<Preservation and disposal of samples>

If you agree to take a genetic test, your blood sample will be preserved in a special test center for a maximum of *{term}*. After this period, the sponsor will dispose of your blood samples safely.

<Agreeing to be genetically tested>

(Example1)

You need to take a genetic test to participate in this clinical trial. Please carefully consider all aspects of this clinical trial, including the genetic testing, before deciding whether or

not to participate. By signing the agreement, you are consenting to the conditions of this clinical trial.

(Example 2)

Participating in this clinical trial is completely up to you and your parents/legal representatives. Please let your doctor know if you do not wish to take part or if you change your mind after joining this clinical trial. Even if you decide that you do not want to take a genetic test, you will never be treated unfairly and will be able to continue taking part in this clinical trial. You may also withdraw from this clinical trial at any time after submitting your consent form.

<Disposal of blood samples and test data after withdrawal>

(Example1)

If you withdraw from this clinical trial, your blood samples will be disposed of safely. However, any data obtained from the analysis of your blood samples before your decision to withdraw will be kept for further use in this clinical trial.

(Example2)

All blood samples for genetic testing will be kept without the name of the subjects and other private information that can lead to their identification. Because no one will know which blood samples belong to which subjects, your blood samples cannot be disposed of even if you decide to withdraw from this clinical trial.

<Use of information from your genetic testing>

The sponsor has legal ownership over the results of the genetic tests and has the right to use them for *{purpose}*. In this clinical trial, the sponsor will use the genetic test data for *{purpose detail}*. The sponsor also has intellectual property rights and ownership rights over any profits generated by this clinical trial. This means that the subjects and their parents/legal representatives will not be paid for taking the genetic test in this clinical trial.

13. Long-term preservation of blood samples

If you and your parents/legal representatives agree, your blood sample will be preserved for a long time and be used in tests again whenever necessary. Regardless of whether or not you consent to the preservation of your blood samples, you will continue receiving all the services you are entitled to in this clinical trial and will be able to continue participating. If you wish to stop participating, please let your doctor know even after you have already signed the consent form. Remember, you can withdraw at any time.
Additional research related to this clinical trial will examine what may be useful for diagnosing *{name of disease}* and the risks and benefits of the IP. The topics of this additional research will become clearer with progress in this clinical trial and advances in the various technologies that can be used for the research. At this moment, however, the topics and procedures of these additional studies have not yet been decided. These additional studies may analyze your genetic data for other kinds of information.

If you agree, your blood samples will be preserved for a maximum period of *{term}* in a special test center, and the sponsor (the pharmaceutical company providing the IP) will dispose of them safely after the agreed upon period. If the sponsor judges that the samples are not needed anymore, the sponsor may dispose of them before the end of the agreed upon period.

Your blood samples will be disposed of if you withdraw from participation or decide to take back your consent for their long-term preservation. However, any data obtained before you changed your mind will be retained as part of the data of this clinical trial and for additional research. Your doctors will tell you the results of the additional studies if you wish. However, these additional studies may not be conducted or completed during this clinical trial.

The sponsor has intellectual property rights and ownership rights over any profits generated by the additional studies. You and your parents/legal representatives will not be paid for cooperating in the additional studies.

14. Disclosure of medical records and privacy policy

<Anonymized data>

The information collected in a clinical trial is called "clinical trial data" and includes the subjects' birthday, medical records, and examination results. Data from usual medical examinations before enrollment may also be used in this clinical trial.

An alphanumeric code (a code made up of letters and numbers) will be used instead of the subjects' name to catalogue their data. This method ensures that no one will be able to identify the subjects by their data.

e.g., Taro Chiken →A001

Codifying data in this way is called "anonymizing" the data, and the anonymized data are officially called "anonymous clinical trial data."

Table1

	Clinical trial data (Before anonymous)	Anonymous clinical trial data
Access right/Users	1. Doctors and medical staff engaged in the clinical trial. 2. Government agencies (PMDA (Japan), FDA (USA), etc.) 3. Institutional Review Board 4. Sponsor (pharmaceutical company producing the IP), their partner companies, companies with a patent license, and their affiliates 5. Sponsor and their partner companies (testing centers, etc.) 6. Medical staff at other hospital where the subjects are treated	● See 1～6 in the left column. ● Persons concerned with the clinical trial at other medical institutions.
Purpose	● To administer treatments during the clinical trial and perform other procedures in the hospital. ● To ensure that the clinical trial is being conducted properly. ● To check on the health of patients if they cannot be contacted	● For use in trials and studies involving the same IP. ● For use in other trials and studies of the same disease or a disease related to this trial. ● To obtain approval as a new medicine. ● For use in scientific reports or dissertations.

Description of data	● Medical records ● Examination results ● Patient diary, etc.	● Anonymous data reported to the sponsor ● Analysis of anonymous data, etc.

<Users and purpose>

Table1 shows who can access and use the normal/anonymous clinical trial data. Persons who use the data have a legal obligation to protect the subjects' privacy and never to disclose the data to other persons with no right of access.

<Agreeing to the use of your clinical trial data>

By signing the consent form to take part in this clinical trial, you agree that the parties listed in table1 can access and use the normal/anonymous clinical trial data to the extent allowed by law.

<Accessing and correcting the data>

You can ask to see your clinical trial data and to correct any errors. Please ask the doctors or medical staff if you wish to do either.

<Samples>

We may send your samples (blood, skin, etc.) overseas for analysis. The persons overseas who use your samples must do so according to the laws in their respective country. Your identity will never be revealed because the information will have been anonymized.

After the samples are analyzed, they will be preserved for *{period}*, then disposed of. The data collected from the samples will be used as part of the clinical trial data.

<Samples after withdrawal from clinical trial participation>

Please let your doctor know if you wish to withdraw from this clinical trial. The sponsor will dispose of your samples according to their own rules, but the data collected before your withdrawal will be kept as part of the clinical trial data.

<Results and disclosure>

The results of this clinical trial will be made available to the public at *{web address}*.

The information on this site will not include data that can be used to identify you.

Anybody will be able to access this website at any time.

The site will be in English. Please ask your doctor if you have any questions.

15. Cost and Reimbursement

<Expense>

The sponsor will pay part of the cost of tests and medications that you receive during this clinical trial (see 1-5 below). With assistance from the sponsor, the cost of your medical care may be lower than before your enrollment in this clinical trial.

You are responsible for other expenses, like the cost of re-examinations, patient referral charges from other hospitals, hospital admission, submission of information requested by other hospitals, and medications and treatments unrelated to this clinical trial. The amount you need to pay may vary depending on your insurance coverage.

In the case of an investigator-led clinical trial

{name of provider} will provide you with *{name of investigational products}* free of charge. You are responsible for other costs, including hospital admission and medications unrelated to the IP. The amount you need to pay may vary depending on your insurance coverage. To help with your copay, you may be eligible for financial assistance from Services Related to Research into Treatment for Specific Pediatric Chronic Diseases or from your local government.

Costs paid by the sponsor

1) Cost of the IP
2) All medical examinations you receive while taking the IP
3) Medical examinations needed for the clinical trial before/after the clinical trial (such as during the screening and observation periods)
4) Medications you receive for the disease related to this clinical trial while taking the IP
5) If you are hospitalized, your copayment amount (not including additional payments for a regular room and special food or services unrelated to the clinical trial)

<Reimbursement for expenses incurred>

You may need to visit the hospital frequently. You are eligible to receive financial assistance to pay for the transportation fees, etc. you incur by these visits. Transportation fees for visits for normal medical examinations unrelated to the clinical trial are not included.

Amount	*(example)* 7,000 yen
Description	*(example)* Each visit for the clinical trial (1 hospitalization)
How	*(example)* Via bank transfer
When	*(example)* Last day of the next month after your visit

Reimbursements are considered "miscellaneous income" by the tax office and become reportable income if they exceed ¥200,000.

If you are currently receiving public assistance, reimbursements may be regarded as income, and the amount of your public assistance may be decreased.

It is completely up to you whether or not to have your expenses reimbursed. Whichever you choose, you will never receive unfair treatment.

16. Voluntary participation and withdrawal

Your participation in this clinical trial is entirely voluntary. Whether you participate or not is entirely up to you. Of course, you can ask other people's advice if you wish.

You also have the right to stop participating even if you have already given your consent. Regardless of whether you decline participation or choose to withdraw later, the quality of care you receive in the future will not be affected in any way, and you will continue receiving all the services you are entitled to in this clinical trial.

If you withdraw after taking the IP, you may need to receive medical examinations to make sure that your health is OK. In this case, please follow your doctor's instructions. The data obtained from your tests, etc. before your withdrawal will be retained as part of the clinical trial data.

17. Financial assistance from the sponsor

This clinical trial will be conducted at the request of *{name of sponsor}*, who will supply the IP and pay for all costs related to this clinical trial. The sponsor has ownership rights over the results of this clinical trial and any intellectual property, patents, etc. generated by this clinical trial.

(If there is no conflict of interest)

The doctors in this clinical trial and *{name of sponsor}* guarantee that they do not have a relationship that corresponds to any of the following descriptions:

1) The doctors have received grants or donations from *{name of sponsor}* unrelate to this clinical trial.
2) The doctors own shares of *{name of sponsor}*.
3) The employees of *{name of sponsor}* are also researchers at this hospital or the staff employed by this hospital are also employed by *{name of sponsor}*.

If the sponsor and doctors have a relationship corresponding to any one of the descriptions above, there is a danger that the researchers may collect only the data that will profit their employer or modify the data to suit their purpose. This hospital will follow the established rules for conducting a clinical trial and do the utmost to manage the trial to obtain accurate and impartial results.

(If there is a conflict of interest)

The doctors in this clinical trial are receiving or have received grants from *{name of sponsor}*.

If the sponsor and doctors have a relationship corresponding to any of the descriptions given below, the doctors may collect only the data that will profit their employer or modify the data to suit their purpose. This hospital will follow the established rules for conducting a clinical trial and do the utmost to manage the trial to obtain accurate and impartial results.

1) The doctors are receiving or have received grants or donations from *{name of sponsor}* unrelate to this clinical trial.
2) The doctors own shares of *{name of sponsor}*.

3) The employees of *{name of sponsor}* are also researchers at this hospital or the staff employed by this hospital are also employed by *{name of sponsor}*.

1)-3) above may apply to this hospital. However, whatever the case may be, this hospital will follow the established rules for conducting a clinical trial and do the utmost to manage the trial to obtain accurate and impartial results, such as by not allowing the sponsor to manage the clinical trial data.

18. Institutional Review Board (IRB)

Clinical trials are conducted in accordance with the government's "Good Clinical Practice (GCP)" regulations to ensure the safety and human rights of the subjects.
All clinical trials require approval by an IRB, which consists of medical staff, specialists, non-specialists, and disinterested parties who are tasked to make sure that the trials are justified from both a scientific and ethical standpoint and that they are well-designed, conducted properly, and protect the subjects' human rights. The current clinical trial has been duly reviewed and approved by the IRB below, which will continue monitoring this trial to ensure that it is being done properly.
The operating procedure, membership, and meeting minutes of the IRB can be viewed at the website below.

Central Institutional Review Board in Pediatric Clinical Trials Network
Installer: Directors of medical institutions registered in the Pediatric Clinical Trials Network (joint establishment)
Type: Jointly established Central Institutional Review Board
Address: 2-10-1 Okura Setagaya Tokyo
(National Center for Child Health and Development)
Web site: https://pctn-portal.ctdms.ncchd.go.jp

19. Clinical trial investigators and consulting service

You can talk to the doctors or consultation service below whenever you have any worries or concerns. They will explain everything until you and your parents/legal representatives are satisfied. Please let us know immediately if you experience anything uncomfortable during or after this clinical trial.

Principal investigator in this clinical trial	*(example)* Seiiku Taro / Director, General Medical Treatment Division
Doctor in charge of the clinical trial	(blank)
Contact	*(example)*ABC Children's Hospital 03-1234-5678 Weekdays: 9:00-17:00 *Nighttime hours, weekends (except above times) 03-8765-4321

Name of Hospital:
Protocol Number:
Informed Consent Form
Version:
Date:

Institution/Clinical copy

Consent Form

Title of clinical trial: …

To the Hospital Director

I, (name of patient_____), have received a full explanation of this clinical trial and understand the conditions of participation. I consent to participate in this clinical trial of my own free will by signing the consent form below and agree to receive the explanation packet along with a copy of my consent form.

<Parent/Legal representative>

Date	Year Month Date Time :		
Name		Relationship	

Do you consent to allowing your child to undergo genetic testing in this clinical trial?

- ☐ Yes, I do. (Permission to disclose genetic test results: □Yes □No)
- ☐ No, I do not.

Do you consent to the long-term preservation of your child's blood samples?

- ☐ Yes, I do.
- ☐ Yes, I do, as long as the samples are NOT genetically analyzed.
- ☐ No, I do not.

Do you wish receive reimbursement for costs related to participation in this clinical trial?

- ☐ Yes, I do.
- ☐ No, I do not.

Patient's intent to participate	☐ By assent form ☐ By oral agreement ☐ Not possible due to age or developmental status

<Patient's signature>

Date of agreement	Year Month Date
Name	

<Signature of explaining investigator>

Explanation date	Year Month Date	Name	

<Signature of explaining CRC>

Explanation date	Year Month Date	Name	

<Signature of confirming investigator>

Confirmation date	Year Month Date	Name	

Clinical trials div. copy

Consent Form

Title of clinical trial: …

To the Hospital Director

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<Parent/Legal representative>

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- ☐ Yes, I do.
- ☐ No, I do not.

Patient's intent to participate	☐ By assent form ☐ By oral agreement ☐ Not possible due to age or developmental status

<Patient's signature>

Date of agreement	Year Month Date
Name	

<Signature of explaining investigator>

Explanation date	Year Month Date	Name	

<Signature of explaining CRC>

Explanation date	Year Month Date	Name	

<Signature of confirming investigator>

Confirmation date	Year Month Date	Name	

Patient copy

Consent Form

Title of clinical trial: …

To the Hospital Director

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<Patient's signature>

Date of agreement	Year Month Date
Name	

<Signature of explaining investigator>

Explanation date	Year Month Date	Name	

<Signature of explaining CRC>

Explanation date	Year Month Date	Name	

<Signature of confirming investigator>

Confirmation date	Year Month Date	Name	