**この参考英訳はICF共通テンプレートの内容確認や導入手続きなどのための社内利用を想定した参考資料であり、治験参加者への説明や同意取得を意図したものではありません。**

Informed Consent Form Common Template

* Black text: Common text (should not be changed)
* Blue text: Changeable text (change the text according to the details of the clinical trial and then change font color to black)
* Green text: Instruction (remove when preparing the informed consent form [ICF])

The boxes (green background) provide the preparation guide.

Remove the preparation guide before finalizing the document.

|  |
| --- |
| Preparation guide) |

ICF Common Template (Ver.1.2 Mar 28, 2025)

**<<How to prepare an Informed Consent Form>>**

Note the following guidance when preparing an ICF.

Remove “Informed Consent Form Common Template” (the front cover of the common template), “<<How to prepare an Informed Consent Form>>,” and “Reference material: GCP applicable sections” when preparing an ICF.

General

* + - * Use expressions that are easy for study participants to understand.
      * Only the information that is necessary for study participants to consider participation in the study should be described (consider not writing duplicate content or using redundant expressions).
* Technical terms should be annotated. Kanji letters that are difficult to read and English terms should be explained when they appear for the first time, or they should be written in hiragana or katakana.
* Efforts should be made to improve readability (e.g., color text, bold letters, underlining, line-spacing expansion, illustration insertion).
* The template adopts the following specifications, but these may be changed according to the target disease and age of the study participants.
* Font: MS P Gothic (Japanese characters), Arial (alphanumeric characters)
* Font size: 12 pt (as a rule)
* Line spacing: fixed value at 18 pt
* Indentation: indentation (the first line) width of 1 character
* Margins: top 17.5 mm, bottom 15 mm, left 20 mm, right 20 mm
* Paper size: A4
* Punctuation marks: “,” “.”
  + If a single study has multiple parts or cohorts, consider describing each part/cohort in the ICF separately for better differentiation in the document as appropriate (e.g., “C-4-2. Study procedures”).
* When a URL is provided, also consider using a two-dimensional barcode.
* Page numbers of each section in the table of contents may be automatically updated using the option “Update table of contents.”
* The term “clinical research coordinator” is used in the common template, but it may be changed to the study site–specific term (including the addition of abbreviations).
* The term “patient(s)” may be used for whole patients including study participants in the context, but use the term “study participant(s)” as much as possible.
* The first version of the Site ICF should be version 1.0, after which the version numbers should increase as version 2.0, version 3.0, and so on. A branch number (version 0.X) should only be used when the ICF is revised per the instructions of the Institutional Review Board (IRB) (e.g., if the review result of the IRB’s initial review material for ICF version 1.0 is “approval after revision,” the version number of the ICF after revision will be 1.1).

This common template document consists of the following:

Do not change the document structure or the order of headings in each section. Additional items, if any, should be added in “C. Description of this clinical trial” or “E. Additional or detailed information.”

A. Summary of the clinical trial

* This section should not be deleted because study participants can understand the summary of the study by reading this section.
* A summary of the study is provided on 1 to 2 pages based on the description in “B. Participation in the clinical trial,” “C. Description of this clinical trial,” and “D. General description about clinical trials.”
* The study-specific detailed information should be described in “C. Description of this clinical trial.”

B. Participation in the clinical trial

* This is a common explanation section given regardless of the study site, sponsor, or study; therefore, the template main text should not be changed.
* Any necessary study-specific additions or supplements should use “E. Additional or detailed information.”

C. Description of this clinical trial

* This part should be prepared based on the protocol contents, etc.
* The description should be as needed for each study based on a preparation guide, etc. (the title should not be changed, in principle).

D. General description about clinical trials

* This is a common explanation section provided regardless of the study site, sponsor, or study; therefore, the template main text should not be changed.
* Any necessary study-specific additions or supplements should use “E. Additional or detailed information.”

E. Additional or detailed information

* As opposed to “D. General description about clinical trials,” this part should provide the information specific to the study site, the sponsor, or the study (e.g., handling of personal information, summary of the compensation system, matters related to pharmacogenomics, other additional or detailed information).
* Description of the compensation system
  + A document stating a summary of the compensation system should be either included in or attached as a supporting document to the information sheet.

Consent form

* Use a replicate form as necessary (Example: in triplicate in the order of “For filing in the medical record,” “For the file at the secretariat,” and “For the study participant”).
* Modify the number and order of replicates and the financial account number section to match the operation of the study site (If the financial account number section is given, a copy of “For filing in the medical record” is not required.)
* Use the “Witness,” “Legally acceptable representative,” and “Proxy signatory” fields as needed.

When an ICF is used, it is not necessary to explain the contents in order and provide explanation in appropriate order to study participants (especially, for information about costs in Section D, consider an order of explanations so as not to become an unjust incentive).

**Reference material: GCP applicable sections**

Matters specified in Article 51 of the Good Clinical Practice (Ministry of Health and Welfare Ordinance No. 28, 1997, referred to hereinafter as “GCP”) and in the GCP guidance (PSB/PED Notification No. 1226-4 dated December 26, 2023, issued by the Director, Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare, referred to hereinafter as “Guidance”), and matters to be included in the common template are shown in the table below.

| **GCP provisions** | **Guidance** **paragraph 1** | | **Relevant part in the common template\*** | |
| --- | --- | --- | --- | --- |
| Article 51 1-1) | 1- (1) | The clinical trial involves research. | B-1 (P.5) | The 10th line |
| Article 51 1-2) | 1- (2) | Objectives of the clinical trial | A-1 (P.3)  C-3 (P.9) | “Objective”  ― |
| Article 51 1-3) | 1- (3) | The name and contact information of the investigator | A-1 (P.3)  B-3 (P.8) | “Contact information”  ― |
| Article 51 1-4) | 1- (4) | Method of the clinical trial (examinational aspect of the clinical trial) | B-1 (P.5) | The 10th line |
| Article 51 1-4) | 1- (4) | Method of the clinical trial (inclusion criteria of the subjects) | C-4-1 (P.10) | ― |
| Article 51 1-4) | 1- (4) | Method of the clinical trial (probabilities of allocation to each treatment in case of randomization) | C-4-2 (P.11) | ― |
| Article 51 1-5) | 1- (5)  2 | Expected clinical benefits and risks or inconveniences (If there are no expected benefits for subjects, notify the subjects to that effect.) | [1] Benefits: C-5-1 (P.14)  [2] Risks or inconveniences C-5-2 (P.14) | ― |
| Article 51 1-6) | 1- (6) | If the study involves patients, the presence or absence of alternative treatments for patients and the potential significant benefits and risks of such treatments | C-6 (P.16) | ― |
| Article 51 1-7) | 1- (7) | Planned duration of the subject’s participation in the clinical trial | A-1 (P.3)  C-3 (P.9) | “Planned duration of participation and number of visits”  ― |
| Article 51 1-8), 9) | 1- (8) | The fact that participation in the study is voluntary and that the subject or their legal representative may refuse or withdraw the subject’s participation in the study at any time. In addition, refusal or withdrawal will not result in any disadvantage to the subject or loss of benefits to which the subject is otherwise entitled. | B-2-1 (P.7) | From the 1st line to the 12th line |
| Article 51 1-10) | 1- (9) | The monitors, auditors, IRB, and regulatory authorities have access to medical source documents. In such a case, the subject’s confidentiality will be protected. | D-4 (P.23) | From the 1st line to the 10th line |

**\*The number of lines is counted from the beginning of the main text in the relevant section and does not include blank lines.**

| **GCP provisions** | **Guidance paragraph 1** | | **Relevant part in the common template\*** | |
| --- | --- | --- | --- | --- |
| Article 51 1-10) | 1- (9) | Subjects or their legal representatives will authorize access by affixing their name and seal or signing the consent form. | D-4 (P.23) | From the 41st line to the 42nd line |
| Article 51 1-11) | 1- (10) | Even if the results of the study are published, the confidentiality of the subjects is maintained. | D-4 (P.23) | From the 30th line to the 35th line |
| Article 51 1-12) | 1- (11) | Consultation office of the study site to be referred to or contacted if the subject requests further information about the study or subject’s rights, or if the subject experiences a study-related injury. | A-1 (P.3)  B-3 (P.8) | “Contact information”  ― |
| Article 51 1-13), 14) | 1- (12) | Compensation and treatment that subjects can receive in the event of a study-related injury | D-5 (P.24) | ― |
| Article 51 1-15) | 3, 4 | Matters related to the IRB | A-1 (P.3)  D-3 (P.22) | “Institutional Review Board”  ― |
| Article 51 1-16) | 1- (16)  5 | Details of the expenses needed to be borne by subjects | D-1 (P.20) | “<Costs to be covered by health insurance> You will be responsible for the copayment” listed in the table. |
| Article 51 1-17) | 1- (13)  5 | Planned number of subjects in the study | A-1 (P.3)  C-3 (P.9) | “Planned number of participants”  ― |
| Article 51 1-17) | 1- (14)  5 | Prompt notification of subjects or their legal representatives when information that may affect the willingness of subjects or their legal representatives to continue participation in the study is obtained | B-2-2 (P.7) | ― |
| Article 51 1-17) | 1- (15)  5 | Conditions and reasons for discontinuing study participation | C-7 (P.16) | ― |
| Article 51 1-17) | 1- (17)  5 | Details of payments, if any, to subjects (arrangements concerning calculation of the payment amount, etc.) | D-2 (P.21) | ― |
| Article 51 1-17) | 1- (18)  5 | Matters that subjects must observe | C-8 (P.17) | ― |

**\*The number of lines is counted from the beginning of the main text in the relevant section and does not include blank lines.**

**About the clinical trial of (name of the study drug/identification code) for (disease/condition)**

**Information and Consent Form**

|  |
| --- |
| Study title: |

This booklet describes a clinical trial of XXX.

Please read this information sheet carefully and understand the contents of the clinical trial before making your decision on whether you would like to participate in the clinical trial. You are free to decide whether or not to participate. You will not be disadvantaged in any manner if you decline to participate. You may withdraw from the clinical trial at any time even after you have agreed to participate in the clinical trial or after the clinical trial has started.

If you have questions or concerns about the contents or terms, please feel free to ask the study doctor or clinical research coordinator.

|  |
| --- |
| Preparation guide)   * Insert illustrations as appropriate. The description should be readable in black and white print with consideration for a colorblind person. * Choose illustrations that are appropriate for the study or subjects. * Study title   + When simplifying the title, consider the identifiability of the study during a Web search.     - The Japan Registry of Clinical Trials Portal Site (<https://rctportal.mhlw.go.jp/>), IRB minutes summaries, etc.   + Supplement verbally when it becomes necessary to explain study terms and other information included in the title. * Information such as the department conducting the clinical trial, the Principal Investigator, and contact information may be added to the cover page. (“Contact information” in Section A may be removed if the contact information is provided on the cover page.) |

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# Summary of the clinical trial

## Summary of the clinical trial

This summary is prepared to help you understand the outline of this clinical trial. If this is the first time for you to receive an explanation of a clinical trial, please read from “B. Participation in the clinical trial” onward.

|  |  |
| --- | --- |
| Study Summary (For details, please see the relevant section of the main text.) | |
| Target disease//condition  (C-1) | Disease//Condition |
| Objective  (C-3) | To examine the effectiveness and safety of [study drug name/code] for the treatment of [disease/condition] |
| Dosage form and dosage of the study drug  (C-4-2) | [Dosage form and dosage of the drugs used in the clinical trial] |
| Planned duration of participation and number of visits  (C-3, C-4-3) | * X days from the start to the end of the study (approximately XX weeks) * Approximately X visits |
| Planned number of participants  (C-3) | Approximately XX patients  *(**In case of global studies, also describe the number of participants in Japan, if possible.)* |
| Sponsor  *(The following text in blue will be stated only if applicable: In-country Clinical Caretaker)*  <Company sponsoring the study at this hospital> | XXXX Corporation  *(The following text in blue will be stated only if applicable)*  XXXX Corporation  An In-country Clinical Caretaker is a company that serves as the role of a sponsor in Japan on behalf of a foreign pharmaceutical company that does not have any address in Japan. |
| Costs during the study  (D-1) | *(In the case of studies involving healthy adults, describe as* *“*You will be charged no cost,” *and remove all relevant fields below.)*  < *Sponsor’s coverage (You will be charged no cost)>*  Applicable period:  First day of taking (using) the study drug to the last day of taking (using) the study drug or the day on which discontinuation is decided  Costs covered:   * Costs of the study drug * Costs of all tests * Costs of all imaging examinations * *(The following blue text will be stated only if applicable:* Costs of any medication with the same effect as the study drug*)* * *(The following blue text will be stated only if applicable:* Other costs of the following as necessary to cover the costs of tests performed for the study outside the study treatment period*)*   < Costs to be covered by health insurance (You will be charged copayment.)>   * Initial visit fee, revisit fees * Treatment costs except for target disease/condition |
| Payment to reduce burden  <Payment to you for your participation>  (D-2) | X,XXX yen per visit or admission/discharge for the study  Applicable period: From the date of informed consent to the end of the observation period  Payment method: The money will be transferred in a monthly batch to your designated financial account in the following month. |
| Institutional Review Board  (D-3) | Name: XXXXX Institutional Review Board  Type: Institutional Review Board  Founder: Director of XXXXX  Address: XXX, XXX [prefecture]  The Institutional Review Board’s written procedures, member list, and meeting minute summaries can be found in the following: *(either one should be stated referring to the following:)*   * Website of XX (https://XXX.XXX.jp/) * XXX (storage location) |
| Contact information  (B-3) | Principal investigator  Department:  Name:  Contact number: XXX-XXX-XXXX (main number)  Consultation office  Name of the study doctor:  Contact number: XXX-XXX-XXXX (main number)  Clinical research coordinator:  Contact number: XXX-XXX-XXXX (main number)  Weekdays XX to XX, Study Management Office (extension: XXXX)  Nights XX to XX and holidays (extension: XXXX) |

|  |
| --- |
| Preparation guide)   * The summary of the clinical trial should be prepared with reference to the preparation guide for each section. * Contact information in this section may be removed if the contact information is provided on the cover page. * If the jRCT or other study registry websites are available for reference, add the URLs or two-dimensional barcodes to Section A. |

# Participation in the clinical trial

## What is a clinical trial?

We receive treatment, such as medications, when we are injured or become ill. Before a “drug” can become available to us, it is first necessary to investigate the properties of the compound as a “drug candidate” and examine its activities in animals. Finally, whether the compound is effective in treating human illnesses should be studied with the cooperation of healthy people and patients.

Such studies using a “drug candidate” in healthy people or patients to examine its effectiveness (efficacy) and side effects\* (safety) in humans to seek approval as a “drug” from the government (Ministry of Health, Labour and Welfare) are called “clinical trials,” and the “drug candidate” used in a clinical trial is called a “study drug.” Unlike routine medical practice, clinical trials have a research aspect and are therefore conducted with great caution.

In addition, participation in a clinical trial is based on the free will of the participants, and their rights and safety must be protected to the maximum extent. Accordingly, clinical trials are conducted in accordance with the standards established by the Ministry of Health, Labour and Welfare (Good Clinical Practice [GCP]). In accordance with GCP, the implementation of this clinical trial at this hospital has been reviewed and approved by the IRB (explained in “D-3. Institutional Review Board that has reviewed this study”).

\*A side effect is a reaction for which a causal relationship cannot be ruled out because there is at least a reasonable possibility of a causal relationship between a drug and an adverse event. An adverse event is any unintended or undesirable symptom, disease, or abnormal laboratory value, whether or not caused by the use of a drug or a clinical research study procedure.

Adverse events

[Relationship between adverse events and side effects]

**Processes of clinical trials**

A “drug candidate” is first tested in animals in terms of its efficacy and safety before proceeding to a “clinical trial.” Clinical trials are usually divided into three stages (phases) and they proceed with confirmation of the efficacy and safety in each phase.

The results obtained from clinical trials are then submitted to the Ministry of Health, Labour and Welfare for review for approval as a “drug.”

**\*This clinical trial is Phase X.**

* The following is an illustration explaining the clinical trial process, created by Japan Medical Association and published with permission.



Source: Japan Medical Association

\*Phase 1 trials may be conducted in patients, such as those conducted in the case of anticancer drugs.

## Voluntary participation in the study

### Study participation and withdrawal

Your decision to participate in this study is voluntary. If you agree to participate in the study, please sign the consent form. If you sign the consent form, please keep this information sheet and consent form in a safe place. Even after you have agreed to participate in the clinical trial, you are still free to withdraw your participation at any time for any reason by talking to the study doctor or clinical research coordinator.

*(In the case of studies in which the participants are not healthy adults,* *the following black text should be stated:* Even if you do not agree to participate or if you withdraw your participation after you have agreed, you will not be disadvantaged in any way and you can receive treatment suitable to your medical condition.*)*

*(In the case of studies involving healthy adults, the following black text should be stated:* Even if you do not agree to participate or if you withdraw your participation after you have agreed, you will not be disadvantaged in any way.*)*

If you discontinue your participation during the study, please see “D-4. Protection of personal information” for handling of the data collected up to that point.

### Notification of new information

You will be promptly notified if new important information becomes available about the study drug. Each time, you will be asked whether or not you desire to continue your participation in the study.

## Contact information

If you have any questions, concerns, or worries about this study, please feel free to ask the study doctor or clinical research coordinator. You may discuss with your family or other persons.

|  |  |
| --- | --- |
| Contact information | Principal investigator  Department:  Name:  Contact number: XXX-XXX-XXXX (main number)  Consultation office  Name of the study doctor:  Contact number: XXX-XXX-XXXX (main number)  Clinical research coordinator:  Contact number: XXX-XXX -XXXX (main number)  Weekdays XX to XX, Study Management Office (extension: XX XX)  Nights XX to XX and holidays (extension: XXXX) |
| Preparation guide)   * In the principal investigator’s section, provide the name and department (description of the department is not required by GCP but recommended to be included in this common template for possible inquiries from study participants). Attach reading to name as needed. * Each study site may make additions/changes as appropriate. (The principal investigator and a consultation office must be stated in accordance with GCP.) * In addition, describe the consultation office in case participants would like to know more about the rights of subjects or if participants experience any health injury related to the clinical trial. * A contact point or contact information that allows study participants to establish contact should be listed. * Two-dimensional barcodes should be added, if available. | |

# Description of this clinical trial

## About your disease and treatment

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| Preparation guide)   * In the case of studies involving healthy adults, it should be stated. * Briefly describe the target disease (condition). * Briefly describe the standard treatment. * If there is no standard treatment, describe the widely used general treatments or therapies.   (Details should be stated in “C-6. Alternative treatment methods if you do not participate in this clinical trial.”) |

## About the study drug

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| --- |
| Preparation guide)   * Explain clearly the study drug in relation to the disease, with a focus on differences from existing drugs, features, and other key information. Be careful not to duplicate the contents of “C-5. Foreseeable benefits and disadvantages.” * Specify the status of marketing or clinical trials inside and outside Japan if applicable. * Briefly explain the mechanism of action using a figure, etc. * If there is any reference drug or concomitant medication, it should be stated. * Investigational devices/products should be described according to their use. |

## Objectives of the clinical trial

|  |
| --- |
| Preparation guide)   * Briefly describe why this clinical trial is necessary and state the objectives of the clinical trial (what it intends to clarify). * Briefly describe what is compared (what is the difference) between the general standard treatment and the study treatment. * For a First in Human (FIH) study, describe that it is a “first study where the drug is taken (used) by humans.” * Describe the planned duration of participation and the planned number of participants in the clinical trial. * For a clinical trial of antineoplastic agents, explain the purpose of the tolerability evaluation period and the purpose of the subsequent extension treatment period (see PMDA 30-day review inquiries checklist (antineoplastic agent field) Reference: <https://www.pmda.go.jp/files/000252155.pdf>). |

**Planned duration of participation in the clinical trial and planned number of participants**

Approximately XX patients with [disease/symptom] will participate in this study around the world. *(In the case of global studies, also describe the number of participants in Japan, if possible.)*

*(If the duration of participation is already decided,* *include the following blue text:* Your participation in this study will last up to XX weeks.*)*

*(In the case of antineoplastic agents, include the following blue text:* The duration of participation in the study depends on the participant. You may take (use) the study drug until it is revealed that your cancer has worsened or until the study doctor determines that you will not receive benefits even if you continue to take (use) the study drug.

Even after you stop taking (using) the study drug, your condition will be checked as follow‑up through telephone calls or hospital visits every XX weeks.*)*

## Clinical trial design

### Criteria for participation in the study

|  |
| --- |
| Preparation guide)   * List the inclusion and exclusion criteria by section. * Mainly state the criteria involving an interview with the study participants, study-specific criteria, and criteria involving invasive testing, etc. |

If you agree to participate in this study, you will first be asked to undergo the specified tests to check whether you are eligible to participate in this study.

<< Patients who can participate in this study >>

*(Include the following contents:*

* *Age and sex*
* *Criteria specific to the disease being studied [severity, treatment resistance, test values, etc.])*

<< Patients who cannot participate in this study >>

*(Include the following contents:*

* *The washout period of the previous treatment*
* *Criteria for pregnancy or breastfeeding*
* *Criteria for contraception*
* *Criteria for serious complications, test values, etc.*
* *Criteria for participation in another study)*

Please note that there are some other requirements, and you may not be able to participate in the study depending on the results of your physical examination by the study doctor or tests.

If you are currently visiting other departments or medical institutions, inform the study doctor thereof. The study doctor may inform the departments or medical institutions of your participation in the study and request medical information to check your health condition.

### Study procedures

|  |
| --- |
| Preparation guide)   * Set subsections as needed.   Examples of subsections: “Study design,” “How to take (use) the study drug”  **Study design**   * Explain the treatment groups, assignment, and probability for random assignment in an easy‑to-understand manner, using a table, figure, etc. * If the study has multiple parts or cohorts, clearly state the part/cohort applicable to the study participants. * Briefly describe to the participants any tests, procedures, surgeries, premedications, etc., that are not routinely used in standard medical care, if they will be used. * Explain the terms placebo; randomized, open-label; randomized, double-blind, if applicable. In case of a study with randomization, the probability should be stated, and it should also be noted that neither the study participants nor the study doctor can choose the treatment group.   **Dosage form and dosage of the drugs used in the clinical trial**   * Describe the dosage form, route of administration, dose, number of doses, dosing interval, and handling method at home in an easy-to-understand manner. The information that duplicates that in “C-2. About the study drug” or “C-8. Your responsibilities during the study period” is not required to be described. * Describe the information that allows participants to understand the dosage form and appearance of drugs used in the clinical trial (a figure, picture, etc.) if the study participants take (use) the drugs used in the clinical trial by themselves. * If this information is better understood when described together with the treatment assignment, then, depending on the study design, they may be described together. * If participants take (use) a combination of placebo and the active drug, describe it in an easy-to-understand manner. * Describe premedication and supportive care, if applicable. |

*(If a placebo is used in the study, include the following blue text:* A placebo is a product that looks like a study drug but does not contain an active ingredient. Patients may feel that they are “doing better” as a result of being administered the placebo by believing that the placebo is a drug. This is called the “placebo effect.” The objective of this study is to scientifically evaluate the efficacy of the study drug itself by subtracting the “placebo effect.”*)*

*(In the case of randomized, open-label studies, include the following blue text:* Neither you nor the study doctor can choose which group you will be in. You will be assigned to one of the treatment groups with a probability of X in X (a XX% chance) using a method called “randomization.” “Randomization” is widely used in clinical trials as an effective method for fair comparison of the efficacy, safety, etc.*)*

*(In the case of randomized, double-blind studies, include the following blue text:* Neither you nor the study doctor can choose which group you will be in. You will be assigned to one of the groups with a probability of X in X (a XX% chance) using a method called “randomization.” In addition, neither the study doctor nor you will know which group you are in, to enable accurate evaluation of the effects of the study drug. This is because if the type of the drug to be used is known, the study doctor’s or patient’s preconceived notion and imaginary assumption will make it impossible to accurately evaluate the drug. The technical term for this method is “double-blind comparative study” and it is widely used in clinical trials of drugs. However, in the event of an emergency where the study doctor needs to know the treatment group, the group will be revealed immediately.*)*

### Study schedule

|  |
| --- |
| Preparation guide)  **Schedule**   * Clearly explain the schedule using a table and text, considering the target disease of the study. * Use language with consideration to study participants (e.g., words such as “prognosis research” and “survival confirmation” should be avoided). * If blood is collected, include the approximate amount of blood collected (if frequent pharmacokinetic [PK] blood draws are performed, prepare a separate schedule table, etc., to help understanding). * Foreseeable risks of invasive testing should be stated in “C-5-2. Foreseeable disadvantages.” * Distinguish between mandatory items and optional items (e.g., mandatory ●, optional ○). In Japan, “X” should be avoided wherever possible. * If hospitalization is specified in the protocol, describe the length of hospitalization. * For optional additional research (including storage location, storage period, and disposal timing of the sample, and disclosure of the results of the genome/gene analysis), consider describing it as a separate item.   **Test items**   * Uncommon tests in medical care for target diseases should be explained in such a way that study participants can visualize them. For tests performed in routine medical care, describe items that are considered to be particularly important. |

[Schedule Table]

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Screening period | Treatment (use) period | | | | | | | | End of treatment (use) | Follow-up period | |
| Cycle  (1 cycle =  [● days]) |  |  |  |  |  |  |  |  |  |  |  |  |
| Day | -●● to-● | ● | | | | | ● | ● | ● |  | - | - |
| Allowable window |  | ±●day(s) | | | | |  |  |  |  |  |  |
| Consent for study participation | ● |  |  |  |  |  | ● | ● | ● |  |  |  |
| Taking (using) study drug |  |  | ● |  |  |  | ● | ● | ● |  |  |  |
| Concomitant medication review | ● | ● |  |  |  |  | ● | ● | ● | ● | ● | ● |
| Investigation of adverse events, etc. | ● | ● |  |  |  |  | ● | ● | ● | ● | ● | ● |
| Blood test | ● | ● |  |  |  |  | ● | ● | ● | ● |  |  |
| Urine test | ● | ● |  |  |  |  | ● |  |  | ● |  |  |
| Pregnancy test (urine/blood) | ● | ● |  |  |  |  | ● | ● | ● | ● |  |  |
| Pharmacokinetics (blood)/time |  | ●  -1 hour | ●  0 hours | ●  10 minutes | ●  30 minutes | ●  1 hour | ○ | ○ | ○ | ● |  |  |
| Genetic test (blood) |  |  | ○ |  |  |  | ○ | ○ | ○ | ○ |  |  |
| Questionnaires | ● | ● |  |  |  |  | ○ | ○ | ○ | ○ | ○ | ○ |
| Review of physical condition |  |  |  |  |  |  |  |  |  |  | ● | ● |

●: Items that are mandatory

○: Items that are performed only for those who have given consent separately or for whom the study doctor deems it necessary

The approximate amount of blood collected per visit will depend on whether or not you give consent for the optional additional tests, and it should be stated as XX mL at least and XX mL at most.

Please note in advance that you may be asked to visit the hospital more than the number of visits specified in the protocol to perform additional tests if the study doctor deems it necessary due to the onset of an adverse event, etc.

[Explanation of test items]

*(Describe the following items, etc.)*

• Urine collection: XXX

• Electrocardiogram: XXX

• Health condition questionnaire: XXX

## Foreseeable benefits and disadvantages

### Foreseeable benefits

|  |
| --- |
| Preparation guide)   * Specify the available results of previous phase studies if they can be presented, distinguishing between Japan and other countries and clarifying the treated population. * Clinical benefits should be described objectively based on the protocol, etc., in each treatment group (including the placebo group). * Describe the possibility that participants may not receive the expected benefits. * Describe specific therapeutic benefits, if any. * For a study that lacks data, such as an FIH study, describe that because of the lack of data, it is unknown whether participants will receive the expected benefits. |

Your [disease/symptom] may or may not improve by taking part in this study. However, data obtained from this study may help other patients suffering from the same disease in the future.

*(In the case of placebo‑controlled studies, include the following blue text:* If you are assigned to the placebo treatment (use) group, you may not receive a direct benefit.*)*

*(In the case of studies involving healthy adults, remove the previous blue text and include the following blue text:* Taking part in this study may not benefit you directly, but data obtained from this study may help patients in the future.*)*

### Foreseeable disadvantages

**C-5-2-1 Side effects or adverse events**

|  |
| --- |
| Preparation guide)   * A tabular form should be used to present information (event terms, frequency, etc.). * In the case where tabular presentation is unsuitable (such as global studies or previous phase studies with a complex design), an overview (summary) of the study can be included at the beginning. * Describe risks based on nonclinical trials as well as adverse events and side effects based on clinical trials as appropriate. Regarding the range of description (criteria for frequency of events to be listed, etc.), it is not regulated by the GCP Ordinance or related notifications. * For events that can easily worsen, it is preferable to describe their early symptoms, etc., as a warning. * Annotate difficult medical terms. |

For side effects and adverse events, please see the following:

*(Insert [describe] data for side effects and adverse events)*

Side effects other than those listed above may also appear. If you experience any unusual symptoms in your body after you participate in this study, please tell the study doctor immediately.

If you experience any health injury related to this study, the study doctor will provide you with the best possible and appropriate treatment.

**C-5-2-2. Risks other than side effects**

|  |
| --- |
| Preparation guide)   * Describe any risks, other than side effects, that may result from participation in the study, as needed. * Describe the risks related to contraception, sperm donation, and partner’s pregnancy, if any (this can be described in another section). * If there is a difference in pregnancy risks between men and women, add this information to clearly indicate the risks for each sex. |

The safety of this study drug in pregnant women and fetus/infants has not yet been established. In addition to side effects, there could be the following risks to you if you participate in the study:

*(Describe the following:)*

* Risks associated with blood sampling: XXX
* Risks associated with diagnostic imaging: XXX

**C-5-2-3. Limitations associated with study participation**

|  |
| --- |
| Preparation guide)   * Describe limitations that result from participation in the study. In addition, clearly state the restricted period as much as possible (e.g., during the period you are taking the drugs used in the clinical trial, during the period you are hospitalized, or the day before you take the drugs used in the clinical trial). * If the waiting time in the hospital is long for PK sampling or for other reasons (e.g., PK sampling at 4 hours post dose), this should be stated. * If there is any test that cannot be measured according to the provisions of the study, it should be stated. * If premedication is administered to prevent side effects, it should be stated. |

Participation in the study may lead to the following:

*(Describe the following, etc.)*

* Daily life and lifestyle including diet and physical exercise may be restricted.
* Some limitations may apply to treatment and concomitant drugs.
* The number of visits and tests may be increased.
* For the test specified for this study, you may need to stay at the hospital for more than X hours.
* You may take (use) premedication to prevent side effects caused by the study drug.
* You may not be able to participate in a clinical trial or clinical research other than this study.

## Alternative treatment methods if you do not participate in this clinical trial

|  |
| --- |
| Preparation guide)   * Regarding the presence or absence of alternative treatment methods and specific treatment methods, state not only the drug name or treatment method but also details including expected benefits and foreseeable side effects. * If an alternative treatment is not a standard treatment, it should be stated. * When alternative medications or treatment methods are indicated, summarize them to be easy to understand by using a table, etc., as needed. * In the case of studies involving healthy adults, it should be stated. * In the case where treatment methods or medications not covered by insurance are described, it should be stated. |

If you decide not to participate in this study, the following treatment options are available. Please consult your study doctor or your primary physician about these alternative treatments.

* You will receive a treatment that has already been approved for [disease/symptoms].
* You will participate in another clinical trial.

## Possible discontinuation of the study

|  |
| --- |
| Preparation guide)   * State that the study may be stopped even after informed consent to participate in the study is provided. * State the discontinuation criteria to the extent that participants can understand, add, and change the information to be consistent with the discontinuation criteria in the protocol. |

You may be withdrawn from the study even after you have given consent to participate in the study. Please follow the study doctor’s instructions in the following instances:

1. If you request to discontinue
2. If your condition is found not to meet the requirements for participation in the study
3. If the study doctor judges that it is difficult to continue the study because of your condition
4. If you are unable to comply with the study instructions and procedures
5. If you need a treatment that is not allowed in this study
6. If it is determined that you are pregnant
7. If the sponsor judges that it is difficult to continue the study
8. If the study doctor, the regulatory authority, or the IRB judges that the study should be stopped for other reasons

Please understand that if your participation in the study is discontinued after you take (use) the study drug, you may need to undergo tests to check your health condition. In addition, if you are withdrawn from the study, investigations and tests may be performed to check your health condition even after discontinuation of the study.

*(Although a description of data handling after discontinuation of the study is stated in “B-2-1. Study participation and withdrawal,” if there are study-specific rules for handling of samples, the following should be stated:* If you discontinue your participation during the study, please see “D-4. Protection of personal information” for handling of data collected up to that point.*)*

## Your responsibilities during the study period

|  |
| --- |
| Preparation guide)   * The description should be modified with additions or changes as appropriate for each study, considering the provisions of the protocol and dosage form of the study drug. * Statements that are also given in another section and are in duplicate can be deleted from this section as appropriate. * If possible, items should be classified and not only enumerated. * Avoid expressions that restrict lifestyleexcessively. |

Please make sure to observe the following while you participate in this study in order to secure your safety and to ensure that the efficacy and safety of the study drug are properly evaluated:

**Undergo examinations and tests as instructed**

1. Follow the study doctor’s instructions to receive/undergo examination and tests. When you are unable to make a scheduled visit, make sure to contact the study doctor or clinical research coordinator.

**Take (use) the study drug properly**

1. Take (use) the study drug properly as instructed by the study doctor. If you do not take (use) the drug as instructed, please contact the study doctor or clinical research coordinator immediately.
2. The study drugs that you do not take (use) (remaining study drug, remaining missed doses) and empty containers should be returned to the hospital. Make sure to bring them to the hospital at the next visit without discarding them at home.
3. Combined use with other drugs may intensify or weaken the effects of the study drug. If you are currently seeing another doctor or are under the care of another medical institution, or if you are currently taking any drugs (including over-the-counter drugs and medicines prescribed by other medical institutions), health foods, supplements, etc., please inform the study doctor or clinical research coordinator before participation in the study. Please also let them know before using any new medication during participation in the study.
4. Please complete the “dosing diary” while you are participating in the study. The “dosing diary” should be returned to the hospital. Make sure to bring it with you at the next visit.

**Prevent pregnancy**

1. The safety of the study drug for fetuses has not been established. Make sure to prevent pregnancy by using medically appropriate contraception, such as birth control pills and multiple contraceptives (condoms, intrauterine devices, etc.) during participation in this study and until at least XX days after you have stopped taking (using) the study drug. The proposed methods of birth control have been approved or certified in Japan. Please follow your study doctor’s instructions regarding specific contraceptive methods. *(If the contraceptive period is set for the drugs used in the clinical trial other than the investigational product, describe it for each drug.)* Notify us immediately if you or your partner becomes pregnant during participation in the study. In such cases, you may be asked to provide further information about the pregnancy including its subsequent course.

**Communicate with each other**

1. If you experience any unusual symptoms related to your physical condition, please contact the study doctor or clinical research coordinator immediately.
2. If you plan to see another doctor, visit another medical institution, or purchase medication or health foods at a pharmacy during participation in this study, please first talk to the study doctor in advance. If you are unable to talk to the study doctor in advance, for example, in an emergency, make sure to present your “Clinical Trial Participation Card” and inform them that you are participating in a study. Next, please inform the study doctor or clinical research coordinator.
3. Be sure to inform the study doctor or clinical research coordinator of any change in your address, telephone number, or other contact information.

**Information about the study should not be disclosed to unspecified persons**

1. Information about this study is confidential and belongs to the sponsor. You can talk about the study with your family and people at work who need the information. However, do not post any information about this study on social media (including posting photos of the study drug, etc.).

# General description about clinical trials

## Costs during the study

*(In the case of studies involving healthy adults, describe as* *“*You will be charged no cost,” *and remove all relevant fields below:)* You will not be charged for the study drug taken (used) in this study. Thus, while you are taking (using) the study drug, your medical expenses may be partly reduced. However, for the costs of general medical care, including initial visit fee, revisit fee, hospitalization fee, or medications for diseases other than the target disease of this study, you will need to pay the copayment portion of your health insurance.

|  |  |
| --- | --- |
| <Sponsor’s coverage>  You will be charged no cost. | Applicable period: First day of taking (using) the study drug to the last day of taking (using) the study drug or the day on which discontinuation is decided  Costs covered:   * Costs of the study drug * Costs of all tests * Costs of all imaging examinations * *(The following blue text will be included only if applicable:* Costs of any medication with the same effect as the study drug*)* * *(The following blue text will be included only if applicable:* Other costs of the following as necessary to cover the costs of tests performed for the study outside the study treatment period*)* |
| < Costs to be covered by health insurance >  You will be charged the copayment. | * Initial visit fee, revisit fees * Treatment costs except that for the target disease/condition |

|  |
| --- |
| Preparation guide)   * If study participants are responsible for the costs of a concomitant drug used after participating in the study (including a concomitant drug that has been used since before participating in the study) in accordance with the regulations and operations at each study site, it should be stated. In addition, if a drug needs to be changed from a generic product to the original product, this should be clearly stated because the costs borne by the study participants will increase. |

## Payment to reduce burden

If you participate in the study, you will need to make visits according to the study schedule *(In the case of studies involving healthy adults, remove the following blue text:* and you may have to more frequently visit the hospital compared with your usual medical care*).* Thus, to reduce the burden associated with participation in the study, such as transportation expenses, you will be paid a prespecified amount of money per visit or admission/discharge for the study.

This is called “Payment to reduce burden,” which is optional and you are free to decide whether or not to receive it.

As Payment to reduce burden is considered miscellaneous income for tax purposes, you may need to file a tax return.

Payment to reduce burden for this study is as follows.

|  |  |
| --- | --- |
| Payment to reduce burden  <Payment to you for your participation> | X,XXX yen per visit or admission/discharge for the study  Applicable period: From the date of informed consent to the end of the observation period  Payment method: The money will be transferred in a monthly batch to your designated financial account in the following month. |
| Preparation guide)   * Enter the period, amount, and time of payment in accordance with the regulations and operations at each study site. | |

## Institutional Review Board that has reviewed this study

Clinical trials must be conducted in accordance with the standards for clinical trials established by the Ministry of Health, Labour and Welfare (GCP). For the conduct of this clinical trial, the head of the medical institution conducting director of the trial (director of this hospital) is required to obtain the opinions of the IRB.

The IRB has been established to investigate and deliberate, from scientific and ethical viewpoints, whether there are any problems with the rights and safety of study participants in the clinical trial. It consists of professionals with expertise in medical care or clinical trials, nonprofessionals, and individuals who are independent of the study site.

If you have any questions regarding the IRB, please ask the study doctor or clinical research coordinator.

This study has been reviewed and approved by the following IRB.

|  |  |
| --- | --- |
| Institutional Review Board | Name: XXXXX Institutional Review Board  Type: Institutional Review Board  Founder: Director of XXXXX  Address: XXX, XXX [prefecture]  The Institutional Review Board’s written procedures, member list, and meeting minute summaries can be found in the following: *(either one should be stated referring to the following:)*   * Website of XXXX (https://XXX.XXX.jp/) * XXX (storage location) |

## Protection of personal information

In this hospital, we will collect various data (including images, audio data, or videos) from you before and during your participation in the study and store the data at this hospital as medical records (medical charts) or laboratory test records. To see whether the clinical trial is properly conducted and data are accurately recorded, the study-related personnel (qualified sponsor personnel, etc.); domestic and overseas regulatory authorities, such as the Ministry of Health, Labour and Welfare, US Food and Drug Administration (FDA), and the European Medicines Agency (EMA) and their related agencies; and the IRB that reviews this study may have access such records. However, these persons are obligated to abide by laws, regulations, and guidelines to protect personal information to ensure that your name, address, and other privacy information is not leaked to others.

The study doctor or clinical research coordinator may use the records to contact your family or relatives to confirm your safety if a major disaster occurs or if we cannot suddenly reach you.

The hospital will provide data collected from you to the sponsor (the company sponsoring the study at this hospital). In such cases, your name, address, and other personal information will not be disclosed. Specifically, your data will be provided after your name is replaced by an alphabetic or numeric identification code (coding). Your contact information including your address, phone number, or email address will not be provided to the sponsor. *(In case of clinical trials where no sample is generated, remove the following black text*: Your blood and urine samples obtained in the study will be analyzed for data collection. When this hospital provides the sponsor with samples, the samples will be provided after replacing your name with a code, as done for data.*)*

The sponsor will prepare materials for obtaining approval as a pharmaceutical product or a medical device using coded data and samples, and submit the materials to domestic and overseas regulatory authorities such as the Ministry of Health, Labour and Welfare or share with the sponsor’s group companies in domestic and overseas countries.

*(If information is added to Section E, state the following black text:* There is a detailed explanation in “E-1. Handling of personal information” about how your coded data and samples will be used and with whom they may be shared, so please read it.*)*

A description of this study and results to be obtained in the future may be publicly available on the website of the sponsor (\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*) and on the website, etc., of the regulatory authority of each country (such as <https://www.ClinicalTrials.gov> [English] and jRCT [<https://jrct.mhlw.go.jp>] [Japanese]); however, these websites will not include information that can identify you. These websites may include a summary of the results of the study, and you can view this information.

The hospital and the sponsor are required to store the study data by law. Please note that even if you request to delete your data or if you leave the study early, data (*In case of clinical trials where no sample is generated, remove the following blue text:* [including data obtained from the analyses of samples provided from you]*)* obtained up to that point will continue to be stored and used.

Your signed informed consent for participation in the study indicates that you agree to the above.

|  |
| --- |
| Preparation guide)   * The template main text should remain unchanged as a general description. Additional items, if any, should be stated in “E. Additional or detailed information.”   Example) Description of cross-border transfer of study data during the study, sharing of information with vendors contracted by the sponsor associated with direct delivery of the drugs used in the clinical trial from the study site to the study participant’s home, or introduction of home medical care, as well as the storage period (including the starting period of storage), storage location, and purposes (future secondary use, genetic research, etc.) of personal information (including samples and data of tests including optional tests)  [Points to Consider when Collecting Genomic Samples in Clinical Trials During Drug Development]  Reference: <https://www.jpma.or.jp/basis/guide/lofurc0000001zhr-att/phamageno.pdf> |

## Compensation in the event of health injury

This study is scientifically planned based on available results and will be carefully conducted; however, if you suffer health injury related to this study, the study doctor will provide the best possible and appropriate treatment. Moreover, depending on the nature and extent of your health injury, you may be compensated by the sponsor. However, no compensation may be paid for health injury that is unrelated to this study or caused by your intentional act or gross negligence such as failure to follow instructions provided by the study doctor.

This compensation system does not affect your right to claim damages.

For details of the compensation system, please see the “Summary of Compensation System” attached to this information sheet.

*(If information is added to Section E, state the following black text:* There is additional information in “E. Additional or detailed information” about compensation in case of health injury.*)*

If you have questions about compensation, please ask the study doctor or clinical research coordinator.

|  |
| --- |
| Preparation guide)   * The template main text should remain unchanged as a general description. Additional items, if any, should be stated in “E. Additional or detailed information.” |

# Additional or detailed information

## (Example) Handling of personal information

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Preparation guide)   * Any additional items to “D-4. Protection of personal information” should be stated here.   Example) Purpose of use, description of study data provided to third parties, description of cross-border transfer of study data, sharing of information with vendors contracted by the sponsor associated with direct delivery of the drugs used in the clinical trial from the study site to the study participant’s home, or introduction of home medical care, as well as the storage period (including the starting period of storage), storage location, and purposes (future secondary use, genetic research, etc.) of personal information (including samples and data of tests including optional tests), and handling of personal information at the time of remote monitoring  [Points to Consider when Collecting Genomic Samples in Clinical Trials During Drug Development]  Reference: <https://www.jpma.or.jp/basis/guide/lofurc0000001zhr-att/phamageno.pdf>  [Description of cross-border transfer of study data during the study]  Provision of information will be divided into the following 4 patterns depending on whether the names of countries and third parties to whom personal data are provided are identified (Article 17 of the Ordinance for Enforcement).   |  |  | | --- | --- | | Identified pattern | Information to be provided | | Name of the destination country○  Third party of the destination○ | * Name of the foreign country * Information about the system for protection of personal information in the foreign country obtained by an appropriate and reasonable method * Information about the measures taken by the third party to protect personal information | | Name of the destination country×  Third party of the destination○ | * The fact that the name of the country cannot be identified, along with the reasons * If information to serve as a reference for the person instead of the name of the country is available, such information should be provided. * Information about the measures taken by the third party to protect personal information | | Name of the destination country○  Third party of the destination× | * Name of the foreign country * Information about the system for protection of personal information in the foreign country obtained by an appropriate and reasonable method * The fact that the third party cannot be identified, along with the reasons | | Name of the destination country×  Third party of the destination× | * The fact that the name of the country cannot be identified, along with the reasons * If information to serve as a reference for the person instead of the name of the country is available, such information should be provided. * The fact that the third party cannot be identified, along with the reasons |   Reference: <http://www.fpmaj.gr.jp/about/committees-list/committee/personal-information/_documents/guideline.pdf>  JPMA April 2023 Q&A on “Points of attention regarding personal information protection in pharmaceutical development and secondary use of data”  <https://www.jpma.or.jp/information/evaluation/results/allotment/g75una0000001dbq-att/CL_202304_TP3.pdf>  Model draft for AMED information sheet:  <https://www.amed.go.jp/koubo/data_sharing_template.html>  [Secondary use of data]  Reference:  Consent Form for Whole Genome Sequencing (National Center of Neurology and Psychiatry)  <https://www.ncnp.go.jp/nin/guide/r1/kokudohan_ICF.html>  Consent Form for Cancer Genome  <https://www.ncc.go.jp/jp/c_cat/use/download/index.html> |

Transfer of Information

*(If the names of countries and third parties to whom personal data are transferred are not identified [the last pattern in the table above], state the following blue text:)*

The data collected about you during this study may be transferred to or provided to study‑related personnel, regulatory authorities, partner companies, contractors, academic research institutes, academic conferences, or researchers in domestic and overseas countries.

It will vary to which country’s study-related personnel, regulatory authorities, partner companies, contractors, academic research institutes, academic conferences, or researchers your data will be transferred or provided, depending on the study results or the results of future research and development. Accordingly, please note that at this point we cannot provide you with a definite list of countries and third parties to which your data will be transferred. As the destination of transfer/provision of your data may be decided after some time following the end of the study, we need to obtain your consent in advance at this point. Your data may be transferred or provided to a country that has less rigorous laws and regulations related to personal information or privacy than those in Japan. However, as your data will be coded and processed, nobody involved in data transfer or at the submission destination except the regulatory authorities will have access to your contact information including your name and address.

## (Example) Summary of the compensation system

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| --- |
| Preparation guide)   * Any additional items to “D-5. Compensation in the event of health injury” should be given here. * A detailed document of the compensation system should be incorporated in this section or attached to the information sheet as an appendix. |

## (Example) Matters concerning pharmacogenomics

|  |
| --- |
| Preparation guide)   * Describe the sponsor-specific matters related to pharmacogenomics (if applicable).   Reference: [Points to Consider when Collecting Genomic Samples in Clinical Trials During Drug Development]  <https://www.jpma.or.jp/basis/guide/lofurc0000001zhr-att/phamageno.pdf>   * For optional additional research, etc., (including storage location, storage period, and disposal timing of the sample and disclosure of the results of the genome/gene analysis), consider describing it in “C-4-3. Study schedule” or in Section E as a separate item depending on the content. |

# Consent Form

For filing in the medical record

Study title: XXX

I have received a sufficient explanation of the contents of the above-mentioned clinical trial from the study doctor based on the information sheet. I fully understand the explanation and the contents of the information sheet. I provide consent of my own will to participate in this study and have signed below. I will receive this information sheet and a copy of the consent form.

|  |  |  |  |
| --- | --- | --- | --- |
| A. | 1. Summary of the clinical trial  (including planned duration of participation and flow, planned number of participants, and sponsor details) | D. | 1. Costs during the study  2. Payment to reduce burden  3. Institutional Review Board that has reviewed this study  4. Protection of personal information  5. Compensation in the event of health injury |
| B. | 1. What is a clinical trial?  2. Voluntary participation in the study  3. Contact information |
| C. | 1. About your disease and treatment  2. About the study drug  3. Objectives of the clinical trial  4. Clinical trial design  5. Foreseeable benefits and disadvantages  6. Alternative treatment methods if you do not participate in this clinical trial  7. Possible discontinuation of the study  8. Your responsibilities during the study period |
| E. | 1. Handling of personal information  2. Summary of the compensation system  3. Matters concerning pharmacogenomics |

|  |
| --- |
| **About the payment to reduce burden** (Please check either box)**:**  □I want to receive payment. □I do not want to receive payment. |

*(The list of items above [green box] and the intention confirmation field are not mandatory.)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Participant |  | Date of consent:  Month Day, 20XX |  | Signature: | |
| Legally acceptable representative  (if applicable) |  | Date of consent:  Month Day, 20XX |  | Name of the study participant: |  |
| Background of the representative signature: |  | Signature of the legally acceptable representative: | Relationship:  ( ) |
| Proxy signatory  (if applicable) |  | Date of proxy signature:  Month Day, 20XX |  |  |  |
| Background of the proxy signature: | Signature of the proxy: | Relationship:  ( ) |
| Witness  (if applicable) |  | Date of witness:  Month Day, 20XX |  | Signature: | |
| The study doctor who obtained consent |  | Date of signature:  Month Day, 20XX |  | Signature: | |
| The person who provided supplementary explanation  (if applicable) |  | Date of signature:  Month Day, 20XX |  | Signature: | |

|  |
| --- |
| Preparation guide)   * Make copies as needed, for example “For the file at the secretariat” and “For patient.” * Consider adding a checkbox if there is an agreement for items such as optional tests, provision of samples, etc. * Change the “Legally acceptable representative,” “Proxy signatory,” and “Witness” fields as appropriate. * Consider adding time fields if necessary. * “Date of providing consent form,” etc., can be added as appropriate. * “Contact information” can be added to the consent form as needed. |

**Financial account information to receive payment to reduce burden**

Study title: XXX

In the consent form for participation in the study, you indicated to receive payment to reduce burden. Accordingly, please specify the financial account below to receive payment.

Please fill in the information correctly, because an error in the provided information will prevent or delay the transfer.

For verification, you may be asked to submit a copy of the passbook cover or cash card, or the clinical research coordinator may check the number.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Financial institution | Bank/Shinkin bank/ Agricultural cooperatives | Branch | (Branch) | | | | | | | |
| Deposit type | Savings account/Checking account | Account number  (other than Japan Post Bank) |  |  |  |  |  |  |  |  |
|  |  | Account number  (Japan Post Bank) |  |  |  |  |  |  |  |  |
| Account holder’s name | Reading | | | | | | | | | |
|  | | | | | | | | | |
| **\*If the account holder is different from the study participant, the account holder should sign below.** | | | | | | | | | | |
| Reason:  Signature: (Relationship: ) | | | | | | | | | | |

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| --- |
| Preparation guide)   * Use this form as needed if the financial account is not given in the consent form (prepare the original only). Prepare separately from the ICF or bind at the end of the ICF so that this portion can be detached. |