Investigator-Initiated Specified Clinical Research Agreement

This Investigator-Initiated Specified Clinical Research Agreement (hereinafter "the Agreement") is entered into by and between [Official Name of the Research Institution] (hereinafter "Research Institution") and XXXX (hereinafter "Company"), in view of the fact that the investigator-initiated clinical research (hereinafter "the Research") set out in the following Research Implementation Particulars (hereinafter "the Particulars") applies to the specified clinical research (hereinafter "Specified Clinical Research") provided for in Article 2, paragraph (2) of Clinical Trials Act (Act No. 16, 2017) (hereinafter "the Act"), under Article 32 of the Act, Article 88 of the Ordinance for Enforcement of the Act (hereinafter "the Ordinance") and other applicable laws and related notifications, concerning implementation of the Research.

[Research Implementation Particulars]

1. Name of the Research

Research name	

2. Matters involving Investigator and Institution to which the investigator belongs (the Research Institution)[1]

Name of Investigator	
Institution to which the investigator belongs (the Research Institution)	

[1] Corresponding to Article 88, items (iii) and (iv) of the Ordinance

In this model agreement, the matters to be set forth in the agreement under Article 88 of the Ordinance for Enforcement of the Clinical Trials Act (Article 88 of the Ordinance) are highlighted in yellow so that readers can see at a glance. For the whole article to be set forth under Article 88 of the Ordinance, only the title of the article is highlighted, while, for some provisions of an article to be set forth under Article 88 of the Ordinance, the whole provisions are highlighted.

The matters to be set forth under Article 88 of the Ordinance are as listed below:
(Matters to be set forth in the agreement)
Article 88 "Matters specified by an Ordinance of the Ministry of Health, Labour and Welfare" as provided in Article 32 of the Act are as listed below:

1 Date of execution of the agreement
2 Implementation period of "Specified Clinical Trial" (limited to the researches specified in Article 2, paragraph (2), item (i) of the Act; hereinafter the same applies in this article, the following article and Article 90).
3 Name and location of Marketing Approval Holder of Drugs which provides research funds and the name and location of the Research Institution.
4 Name of Investigator / Principal Investigator who conducts Specified Clinical Research
5 Timing of payment of research funds for Specified Clinical Research
6 Matters involving "publication of information, etc. on provision of research funds or other benefits" set forth in Article 33 of the Act
7 Matters involving the handling of deliverables of Specified Clinical Research
8 Matters involving the provision of information on side effects, efficacy and safety of pharmaceuticals
9 Matters involving the publication by recording in the database developed by the Ministry of Health, Labour and Welfare as specified in Article 24, paragraph (1) herein.
10 Matters involving the compensation and healthcare provision for any damage to health in a subject of Specified Clinical Research
11 Matters involving the creation of Standards for Conflicts of Interest Management specified in Article 21, paragraph (1) herein and the creation of Plan for Conflicts of Interest Management specified in Article 21, paragraph (3) herein
12 Matters involving the provision of information on the research funds provided to the Research Institutions by the groups which manage the research as specified in item (ii) of the following article herein (only to the extent that Marketing Approval Holders of Drugs and such groups enter into an agreement)
13 Other matters required for the provision of research funds

Location of Institution to which the investigator belongs (the Research Institution)	
Department to which the investigator belongs	
Name of the manager of the Research Institution	

3. Objective of and summary of medical devices for use in the Research

(1) Objective, description and period of the Research [2]

Objective	
Description	
Expected number of subjects	
Period	From the scheduled start date to end date of the research as described below: - Scheduled start date of the research (scheduled date of the publication under Article 24, paragraph (1) of the Ordinance) XX/XX/20XX - Scheduled end date of the research (scheduled date of the publication by recording in j RCT [as defined in Article 1]) XX/XX/20XX

(2) Summary of medical devices for use in the Research

Unapproved/off-label/approved under the Pharmaceutical and Medical Device Act	□ Unapproved	□ Off-label	□ Approved
INN (Enter the development code if unapproved domestically and internationally)			
Trade name (Add country name for a foreign product.) [3]			

4. Term of the Agreement･the Research Funds･Provided Goods･Loaned Goods

Term of the Agreement	From XX/XX/20XX to XX/XX/20XX
The Research Funds	Total XXXXXXXX yen (including consumption tax and local consumption tax, XXXXX yen) Breakdown: XXXXX yen for preparation stage XXXXX yen for implementation stage
With/without Provided Goods and	Without/With (See Annex 6)

[2] Corresponding to Article 88, item (ii) of the Ordinance

[3] For the devices unapproved in Japan, please enter names of countries in which the trade name is used.

description	
With/without Loaned Goods and description	Without/With (See Annex 6)

Article 1 (Definitions)

In the Agreement, the definitions of the terms listed in the following items are as prescribed respectively in those items. In the event of any discrepancy in definition between Applicable Laws and Ordinances and the following items, the former shall prevail.

(1) "Investigator-Initiated Clinical Research" means the clinical research for which the Investigator assumes final responsibility, including proposing the clinical research, preparing the protocol, and conducting the clinical research appropriately.

(2) "Investigator" means the person who conducts the clinical research specified in the Act (including a person who conducts any Specified Clinical Research), and is listed in paragraph (2) of the Particulars as a physician or a dentist who manages operations for the Research in the Research Institution.

(3) "The Research Name" means the name listed in paragraph (1) of the Particulars.

(4) "Sub-investigator" means the physician or dentist who shares operations for the Research under the Investigator's direction in Research Institution.

(5) "The Researchers" mean all persons who engage in the Research, including Investigators and Sub-investigators.

(6) "Manager of the Research Institution" means the person who manages and supervises Investigator in the Research Institution to which Investigator belongs and is listed in paragraph (2) of the Particulars.

(7) "The Research Objective" is listed in paragraph (3), item (i) of the Particulars.

(8) "The Medical Device" means the medical device listed in paragraph (3), item (ii) of the Particulars.

(9) "Certified Review Board" is the committee established under the Act and the Ordinance, which reviews and provides opinions for the implementation of clinical researches.

(10) "The Research Funds" are the funds which the company listed in paragraph (4) of the Particulars provides to the Research Institution.

(11) "Protocol" means the protocol which describes the implementation system, background, objective and content of the Research, inclusion and exclusion criteria for subjects of the Research, withdrawal criteria for the Research, treatment in subjects of the Research, safety evaluation, efficacy evaluation, statistical analysis, Access to Source Documents, quality control and assurance, ethical considerations, retention and handling of records (including data), compensation and monetary payment for implementation of the Research, publication of information, implementation period, explanation to and consent by subjects of the Research, and other matters required for proper implementation of the Research in compliance with laws and ordinances.

(12) "Trial Plan" means the form to be submitted to the Director of the Local Bureaus of Health and Welfare in accordance with Form 1 (in relation to Article 39) of the Ordinance.

(13) "j RCT" refers to the database "Japan Registry of Clinical Trials" developed by the Ministry of Health, Labour and Welfare as specified in Article 24, paragraph (1) of the Ordinance, which is a combination of "Application and information disclosure system for Certified Review Board", the system to perform procedures for the application for certification or the notification of change to the Minister of Health, Labour and Welfare under the Act, and "Trial Plan and research summary disclosure system", the system to perform procedures for submission of Trial Plan to the Minister of Health, Labour and Welfare under provisions of the Act.

(14) "Applicable Laws and Ordinances" mean the ethical principles defined in the Declaration of Helsinki, the Act, the Ordinance, and other laws, regulations and notifications applicable to

clinical researches.

(15) "Primary Endpoint Report" means the summary of results collected for primary endpoint of Protocol.

(16) "Clinical Study Report" means the document in which results of the Research are compiled.

(17) "Source Documents" mean records and data on clinical findings, observations and other activities from clinical practices in subjects of the Research (including analysis data and compiled data thereof), as specified in Annex 5.

(18) "Procedures" mean the document in which procedures are specified so that each operation for the Research is performed constitutively and approximately.

(19) "Samples" are defined as parts of the human body including blood, tissues, cells, body fluids and excreta, and DNA extracted from them, to be used in the Research.

(20) "Affiliate" means any corporation controlling, controlled by or under common control with oneself. In this item, "control" means the direct or indirect ownership of more than fifty percent (50%) of the stock or shares entitled to vote.

(21) "The Confidential Information" means the information on the Research disclosed or provided by the other party.

Article 2 (The Research Objective)

1. The Agreement is intended to specify the relationship among Investigator, the Research Institution and Company for Investigator conducting the Research as Investigator-Initiated Clinical Research in the Research Institution and for Company compensating for the expenses for such research, and to specify descriptions required by Applicable Laws and Ordinances.
2. The parties shall confirm that the Research is duly conducted, respecting life, health and human right of subjects of the Research, in accordance with the basic philosophy of clinical research described in the Ordinance, under Investigator's responsibility, for the purpose of accumulation of information on the safety and efficacy for the Medical Device.
3. The parties shall confirm that Company does not provide the Research Institution with the Research Funds as a means of unjustifiably inducing trade with the Research Institution, Investigator and others who engage in the Research.

Article 3 (Payment and handling of the Research Funds)

1. Company shall pay the Research Funds listed in paragraph (4) of the Particulars as fair and reasonable expenses necessary for the Research to Research Institution as described in Annex 1, in accordance with the terms of the Agreement.[4]
2. Company shall pay the Research Funds by wire transfer to the following bank account held by the Research Institution. The cost of the transfer shall be borne by Company.
   XXXXXX Bank, XXXX Branch, Savings/Checking account [No.] [Name of account holder]
3. The Research Institution shall have Manager of the Research Institution and Investigator report to Company that the milestone specified in Annex 1 has been achieved and send the invoice.
4. Company shall confirm the content of the report and the invoice and notify the Research Institution of the results within XX days of the date of receipt of the report and the invoice under the preceding paragraph.
5. Upon the notification under the preceding paragraph, if Company makes an objection or requires

[4] Corresponding to Article 88, item (v) of the Ordinance

additional fact-checking for the report or the invoice under paragraph (3) of this article, in response to the objection or request, the Research Institution shall amend the report or the invoice as necessary, and shall re-send the amended report or invoice to Company, to which the preceding and this paragraphs shall apply mutatis mutandis.

6. Company shall pay the amount of the Research Funds described in the invoice by the end of the month following the month to which the day of notification of no objection to the content of the report and the invoice provided in paragraph (3) of this article belongs, under paragraph (4) of this article.
7. If there is a surplus in respect of the Research Funds that have already been paid upon completion or discontinuation of the Research, the Research Institution shall return this to the Company.[5]
8. The Research Institution shall not, by itself or through Manager of the Research Institution and Investigator, use the Research Funds for any objective other than the Research Objective, in accordance with "Breakdown of the Research Funds" included in Annex 2.
9. The Research Institution shall submit an account report on the breakdown of the Research Funds to the Company within XX days after completion of the final payment, and the Company may audit the accounts of the Research Institution relating to the Research Funds.
10. The Research Institution shall retain documents related to the Research Funds between the first and last payment date and for X years after the last payment date for the Research Funds

Article 4 (Implementation of the Research)

1. The Research Institution shall implement the Research, Specified Clinical Research, in accordance with Applicable Laws and Ordinances, the Agreement and Protocol (Article 10, paragraph (3) of the Ordinance; hereinafter the same).
2. The Research Institution shall have Manager of the Research Institution and Investigator perform Investigator's duties specified in the following paragraph and duly conduct the Research, in compliance with Applicable Laws and Ordinances, the Agreement and Protocol.
3. Investigator's duties shall be as described in Annex 3. Annex 3 organizes the duties provided in Applicable Laws and Ordinances for Investigator's convenience. Even if any insufficient or wrong description in Annex 3 does not allow Investigator to comply with the Act and the Ordinance, Company shall not be liable for anything.
4. If the Research Institution shall, by itself or through Manager of the Research Institution and Investigator, entrusts part of the Research operations[6] to a third party (hereinafter "Contract Organization"), the Research Institution shall supervise and assume responsibility for the execution of operations entrusted to such parties. In this case, the Research Institution shall have Contract Organization assume the obligations hereunder, shall immediately report to Company if the Research Institution becomes aware of Contract Organization's act in violation of applicable laws, the Agreement and Protocol, and, upon the responsibility of itself, Manager of the Research Institution or Investigator, shall rapidly execute or have the manager or Investigator execute corrective measures and also shall report the content of such corrective measures to Company.

Article 5 (Reporting the progress of the Research to Company)

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[5] Corresponding to Article 88, item (xiii) of the Ordinance. This item would be added to ensure that the surplus in respect of the Research Funds is not considered as offering profits to the Research Institution.

[6] Entrusting the Research itself in target number of subjects partially to other institutions shall be handled as "multicenter model" and shall not be covered by the Agreement.

The Research Institution shall have Manager of the Research Institution and Investigator report the following matters set forth in each item to Company promptly at Company's request:

(1) Trial Plan number of the Research
(2) Certification number of Certified Review Board
(3) First Patient First Visit
(4) Last Patient Last Visit
(5) ---

Article 6 (Safety Information)[7]

1. Company shall provide the Research Institution, the manager of the Research Institution and Investigator with up-to-date information regarding safety and safe usage of the Medical Device.
2. The Research Institution shall, by itself or through Investigator, report to Company timely the information regarding safety of the Medical Device in the Research, in accordance with Protocol (including, without limitation, serious adverse events; see Protocol for details).
3. The Research Institution shall, by itself or through Manager of the Research Institution and Investigator, cooperate as far as possible with Company in taking action related to the safety information on the Medical Device.

Article 7 (Provision of Medical Device or Goods)[8]

1. Company shall provide Medical Device or goods prescribed in Annex 6 (hereinafter collectively "Provided Goods") to the Research Institution free of charge, to the extent necessary for the Research.
2. The Research Institution shall, by itself or through Investigator, assume responsibility for managing and storing the Provided Goods in accordance with applicable laws and regulations and information stated in accompanying documents, and shall use the Provided Goods solely for the purpose of executing the Research. the Research Institution shall, by itself or through Investigator, take responsibility for use of the Provided Goods, and shall prepare and retain up-to-date records regarding the receipt and usage of the Provided Goods.
3. The Research Institution shall not use the Provided Goods received from the Company in connection with the Research for any purpose other than the Research, and shall not provide the Provided Goods to the Researchers, Contract Organizations or other third parties for any purpose other than the Research.
4. If the Research is completed or discontinued, or if the Agreement is cancelled, the Research Institution shall return to the Company any surplus of Provided Goods (including general-purpose goods that can be used for purposes other than the Research) received from the Company in their present, existing condition as of completion or discontinuation of the Research or cancellation. If the Company opts for the Provided Goods to be destroyed rather than returned, the Research Institution shall destroy the Provided Goods in accordance with the Research Institution's prescribed procedure and then record this, and if the Company requests the issuance of a certificate of disposal, the Research Institution shall promptly comply with this request.[9]

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[7] Corresponding to Article 88, item (viii) of the Ordinance
[8] This article assumes the case of medical devices or goods being provided. Please delete it if no medical devises or goods are provided.
[9] Each company should determine whether words indicating that provided medical devices shall not be reimbursed by insurance need to be added. Some companies appear to take measures such as labeling the devices as not being reimbursed by insurance.

Article 8 (Loan of Medical Device or Goods)[10]

1. During the term of the Agreement, the Company shall loan the Medical Device or Goods, etc. prescribed in Annex 6 (hereinafter the "Loaned Goods") to the Research Institution free of charge for up to twelve (12) months for execution of the Research.
2. If the Loaned Goods are the Medical Device, the Company shall receive separately from the Medical Institution the "Letter of Confirmation Concerning Loan of Medical Device" prescribed by the Japan Fair Trade Council of the Medical Devices Industry.
3. The right of ownership and other rights pertaining to the Loaned Goods shall belong to the Company, and the Research Institution shall manage the Loaned Goods with the duty of diligence of a good manager. The Research Institution shall not invalidate the Loaned Goods by, for example, removing name plates or labels indicating the Company's right of ownership or their manufacturing or management number etc., and it shall not dismantle, repair, remodel or alter the Loaned Goods, transfer, loan or assign them to another Center, nor pledge them as security.
4. The Research Institution shall not use the Loaned Goods for purposes other than the Research nor allow the Researchers, Contract Organizations or other third parties to use them for purposes other than the Research.
5. If the Loaned Goods are lost or damaged, the Research Institution shall compensate the Company for such damage; provided, however, that this shall not apply if such loss or damage is not attributable to the Research Institution.
6. If the Research is completed or discontinued, if the Agreement is cancelled, or if the loan period for goods ends, the Research Institution shall promptly return the Loaned Goods to the Company in their present and existing condition as of the time of completion or discontinuation of the Research, cancellation, or the end of the loan period.[11]

Article 9 (Handling of Personal Information)

Each party shall comply with Applicable Laws and Ordinances and applicable Act on the Protection of Personal Information for implementation of the Research.

Article 10 (Handling of Samples)[12]

If Samples are handled in the Research, they shall be appropriately handled in compliance with Applicable Laws and Ordinances and the Act on the Protection of Personal Information (Law No. 57, May 30, 2003).

Article 11 (Compensation and Other Measures)[13]

For implementation of the Research, the Research Institution shall, by itself or through Manager of the Research Institution and Investigator, shall beforehand establish the system to provide insurance and medical care and take other necessary measures in preparation for compensation and medical care for subjects of the Research in the event of injuries associated with the Research.

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[10] This article assumes the case of medical devices or goods being loaned. Please delete it if no medical devises or goods are loaned.

[11] An article needs to be added accordingly for any provision of service besides provision or loan of medical devices or goods.

[12] If Samples are not specifically required, it may be specified that Samples shall "not be received" or "not be provided" by the Research Institution.

[13] Corresponding to Article 88, item (x) of the Ordinance

Article 12 (Change to Protocol and Trial Plan)

1. The Research Institution may have Investigator change Protocol within the scope of the Research Objective. With a prior written consent of Company for the content of the change, the Research Institution shall have Investigator take necessary measures such as submitting Trial Plan in compliance with Applicable Laws and Ordinances. Company shall not reject the consent unless there is good reason.
2. Each party may consult about and correct the amount and payment method of the Research Funds set forth in Article 3 herein in accordance with the content of revised Trial Plan.

Article 13 (Replacement of Investigator)

1. If Investigator turns out to become unable to continue his/her duties at the Research Institution because of his/her resignation, dismissal, transfer, or any other reason, the Research Institution shall immediately notify Company thereof in writing.
2. In the case of the preceding paragraph, the Research Institution shall take measures such as replacement of Investigator to avoid the absence of Investigator of the Research, and shall immediately notify Company thereof in writing.
3. If Company makes an objection to the replacement of Investigator under the preceding paragraph, Company may consult with the Research Institution about whether or not the Research may be continued or procedures.
4. For measures such as the replacement of Investigator, the Research Institution shall have the Investigator to be replaced notify Certified Review Board before replacement in compliance with Applicable Laws and Ordinances.

Article 14 (Procedures at the end of the Research)

1. The Research Institution shall have Investigator address each of the following items:
   (1) Prepare and publish within the following periods Primary Endpoint Report, and Clinical Study Report and its summary.[14] Publication under this article means recording in j RCT.
      A) Primary Endpoint Report
         In principle, one (1) year after the end of the period for data collection for primary endpoints
      B) Clinical Study Report and its summary
         In principle, one (1) year after the end of the period for data collection for all endpoints
   (2) When preparing documents under the preceding item, submit them to Company without delay for confirmation as follows:
      A) Company shall examine Primary Endpoint Report, and Clinical Study Report and its summary from ethical viewpoint, and the viewpoints of appropriate use of the Medical Device pursuant to the Agreement, Handling of Personal Information (Article 9), Handling of Intellectual Property Rights (Article 17), and Confidentiality (Article 19), and shall respond to Investigator within XX days thereafter. Provided, however, that Company should not be involved in the interpretation of results of the Research.
      B) Investigator shall be responsible for determining the content of Primary Endpoint Report, and Clinical Study Report and its summary, taking the Company's response

[14] Corresponding to Article 88, item (ix) of the Ordinance

under the preceding A) into consideration in good faith.

(3) For publication under item (i), seek the opinion of Certified Review Board in advance and publish it within one (1) month of the date on which it is issued by the Certified Review Board.

(4) When submitting the summary of Clinical Study Report to Certified Review Board, promptly submit to the Minister of Health, Labour and Welfare the following documents additionally:

A) Protocol

B) Statistical Analysis Plan (only if prepared)

2. The Research Institution shall have Investigator submit Primary Endpoint Report, Clinical Study Report and its summary, and Statistical Analysis Plan (only if prepared) for the Research, to Company, within X months of publication.

Article 15 (Publication of the Research Results)[15]

1. If Investigator issues journal articles, presentations at academic conferences, press releases, etc. regarding the Research (hereinafter collectively "Publications"), each party shall confirm that they are based on Primary Endpoint Report and Clinical Study Report.
2. Under the preceding item, if Investigator issues Publications, the Research Institution shall have Investigator address each of the following items:
   (1) If Investigator prepares materials for Publications, Investigator shall follow Annex 4 "Materials for Publications and Schedule" and submit materials for Publications to Company.
   (2) Company shall examine Materials for Publications under the preceding item from ethical viewpoint, and the viewpoints of appropriate use of the Medical Device pursuant to the Agreement, Handling of Personal Information (Article 9), Handling of Intellectual Property Rights (Article 17), and Confidentiality (Article 19), and shall respond to Investigator by the deadline specified in Annex 4. Provided, however, that Company should not be involved in the interpretation of results of the Research
   (3) Investigator shall be responsible for determining the content of final Publications, taking the Company's response under the preceding item into consideration in good faith. Company shall not reject Publications unless there is good reason.

Article 16 (Ownership, Retention and Use of Source documents)[16]

1. Ownership of Source Documents resulting from the Research shall be as specified in Annex 5 "Ownership and Use of Source Documents".
2. The Research Institution shall, by itself or through Manager of the Research Institution or Investigator, retain Source Documents for five (5) years after the date of completion of the Research in compliance with Applicable Laws and Ordinances, and ensure Contract Organization if necessary.
3. The Research Institution shall, by itself or through Manager of the Research Institution and Investigator, manage and supervise to keep Source Documents from being used for any purposes other than the Research before Investigator issues Publications under the preceding article;

[15] Corresponding to Article 88, item (vii) of the Ordinance
[16] Corresponding to Article 88, item (vii) of the Ordinance

provided, however, that this shall not apply if Source Documents are used in clinical practice for subjects of the Research.

Article 17 (Handling of Intellectual Property Rights)[17]

If any patent right or other intellectual property right (however, except copyright; hereinafter the same applies in this article) appears to arise in connection with the Research, the Research Institution shall notify Company promptly thereof. Any patent right or other intellectual property right arising in connection with the Research shall belong to Company.

Article 18 (Conflicts of Interest Management)

1. The Research Institution shall have Investigator prepare the Conflicts of Interest Management Standards and Conflicts of Interest Management Plan describing the following items:
   (1) Provision of research funds and other involvement in the Research by Company
   (2) To those who obviously benefit from the implementation of the Research, the provision of donations, and rewards for writing and speaking, and other involvement by Company
2. The Research Institution shall confirm the fact of involvement by Company in accordance with Conflicts of Interest Management Standards and Conflicts of Interest Management Plan, and submit the report describing the results to Investigator.
3. The Research Institution shall have Investigator seek the opinion of Certified Review Board about Conflicts of Interest Management Standards and Conflicts of Interest Management Plan and manage conflicts of interest in accordance with such standards and plan.[18]
4. The Research Institution shall, by itself or through Investigator, properly release or publish information about the provision of the Research Funds by Company under the Agreement in accordance with "Guidelines on COI Management of the Japanese Association of Medical Sciences" etc., including in the case of Publications of results of the Research, to ensure transparency of its relationship with Company.
5. Company shall also properly disclose the Research Funds in accordance with "Guidelines for Transparency of the Relationship Between Corporate Activities and Medical Institutions"[19] established by Company according to the Transparency Guidelines prescribed in Article 33 of the Act and Article 90 of the Ordinance and by the Japan Federation of Medical Devices Associations, and the Research Institution shall agree such publication. The Research Institution shall provide the information required for such publication by Company (including but not limited to the information on the institution to which Investigator belongs and his/her transfer, and identification numbers recorded in j RCT) promptly at Company's request.[20]

Article 19 (Confidentiality)

1. Each party shall hold and maintain the Confidential Information in strictest confidence, and shall

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[17] Regarding handling of intellectual property rights, we have created the draft of article indicating that intellectual property rights shall belong to Company. If the draft is not appropriate in practice, please consider to change the draft to the one containing "separately consulted" as specified below:
(Draft of article indicating that handling of intellectual property rights shall be "separately consulted")
If any patent right or other intellectual property right (however, except copyright) appears to arise in connection with the Research, the Research Institution shall notify the company promptly thereof and consult with the company in good faith about ownership and handling of the right.

[18] Paragraphs (1) to (3) of this article correspond to Article 88, item (xi) of the Ordinance.

[19] Please replace "Guidelines for Transparency …" with the title of the guidelines of each company.

[20] Paragraph (5) of this article corresponds to Article 88, item (vi) of the Ordinance.

not disclose, divulge or provide the information to a third party without prior written consent of the other party. However, Company may disclose and provide the Confidential Information to its Affiliates provided that Company shall impose on the Affiliates the obligations equivalent to Company's ones hereunder and shall be responsible to the Research Institution for performing such obligations.

2. Each party may disclose and provide the Confidential Information only to its executives or employees who need the information for the performance of the Agreement (including those who engage in the Research); provided, that the party shall impose on these persons the obligations equivalent to the party's ones hereunder and shall be responsible to the other party for performing such obligations.
3. The party receiving such information shall not be under the obligations provided for in this and the following articles if such information:
   [1] is publicly known/used at the time of disclosure or provision by the other party;
   [2] becomes publicly known after disclosure or provision by the other party without the responsibility of the receiving party;
   [3] was in the receiving party's possession at the time of disclosure or provision by the other party;
   [4] is obtained by the receiving party from a duly authorized third party without any secrecy obligation; or
   [5] was independently developed by the receiving party without the use of the information disclosed or provided by the other party.
4. Notwithstanding provisions of paragraphs (1) and (2), if requested or ordered by a regulatory authority or court in compliance with laws and ordinances, each party may disclose and provide the Confidential Information to the regulatory authority or court. However, in this case, each party receiving such request or order shall immediately notify the other party of being requested or ordered to the extent accepted by laws and ordinances, and consult with the other party about the scope of information to be disclosed or provided.
5. Unless otherwise provided for hereby, on completion of the Research or termination of the Agreement, whichever occurs sooner, the receiving party shall either return all the Confidential Information to the other party or destroy it, in accordance with the other party's instructions.

Article 20 (No Unintended Use)

Each party shall not reproduce or copy the Confidential Information beyond necessity and the scope of the Research Objective, and should not use it beyond the Research Objective.

Article 21 (Exclusion of Anti Social Forces)

1. Each party shall represent and warrant that it does not and will not fall under any of the following items or does not and will not perform the act coming under any of the following items:
   (1) It falls under any of an organized crime group, an organized crime group member, a person for whom five years have not passed since the day on which the person ceased to be an organized crime group member, a quasi organized crime group member, an organized crime group-associated company, a corporate extortionist, rogue persons or groups proclaiming itself as a social activist or an organized special intellectual crime group, and any other person equivalent to the above (hereinafter collectively referred to as "Anti Social Forces");

(2) Its officer or a person substantially involved in its management falls under Anti Social Forces;
(3) A person who controls its financial and business policy decisions falls under Anti Social Forces;
(4) Unfair use of the Anti Social Forces for the purpose of gaining dishonest profits for itself or a third party or of damaging a third party;
(5) The act of providing funding or accommodation to Anti Social Forces with knowledge of the act encouraging the activities of Anti Social Forces; or
(6) Its officer or a person substantially involved in its management is engaged in socially condemnable relationship with Anti Social Forces.

2. Each party shall not make an unreasonable demand, by itself or through the use of a third party, by the use of violence, force, intimidating words or fraudulent means.
3. Where a fact falling under any of items of paragraph (1) or a fact of the act falling thereunder is found in any of the contractors, suppliers and other business associates used for performance of the Agreement by the Research Institution, Manager of the Research Institution or Investigator, Company may request the completion of such trade and other necessary measures to the Research Institution. The Research Institution which receives such request shall take necessary measures to a reasonable extent except when there are justifiable grounds.

Article 22 (Legal Compliance)[21]

1. Each party shall comply with Japanese laws, U.S. Foreign Corrupt Practices Act, and other laws related to corruption prevention (hereinafter "Corruption Prevention Laws"), and shall not provide or propose to provide government officials or other third parties involved in trade with money or facilities in a manner that violates Corruption Prevention Laws.
2. The Research Institution shall supervise Manager of the Research Institution or Investigator to ensure that they comply with insider trading regulation under the Financial Instruments and Exchange Act (Act No. 25, April 13, 1948; including amendments).

Article 23 (Effective Period and Discontinuation and Cancellation of Agreement)

1. The term of validity hereof shall be the term of agreement listed in paragraph (4) of the Particulars.
2. If the Research is discontinued, the Research Institution shall inform Company thereof and whether or not results of the Research are scheduled to be published at the time of the discontinuation, within XX days of decision on the discontinuation.
3. In any of the following cases, each party may cancel all or part of the Agreement by notifying the other party in writing.
(1) If the Research is not started during a reasonable period after notification to the Minister of Health, Labour and Welfare;
(2) If, based on adverse events during implementation of the Research or safety information notified by Company, the Ministry of Health, Labour and Welfare or any party hereto judges that it is impossible to ensure the safety of the Research Subjects;
(3) If the Research is significantly behind the schedule prescribed in Protocol;
(4) If the milestone specified in Annex 1 is not achieved;

[21] As AMDD, the article pertaining to FCPA and insider trading regulation is added. Words in this article are assumed to be replaced with any words designated by each company as appropriate.

(5) If the other party violates the Agreement and there is no sign of improvement after a reasonable period stipulated notwithstanding a demand for rectification;
(6) If continuation of the Agreement becomes difficult due to an ethical reason for discontinuing the Research or a legitimate reason which hinders the continuation of the Research;
(7) If the Research is discontinued pursuant to the preceding paragraph;
(8) If the other party violates Applicable Laws and Ordinances;
(9) If the other party breaches representations and warranties provided in paragraph (1) of the preceding article, violates paragraph (2) of the same article, or does not respond to the request under paragraph (3) of the same article.

4. Paragraphs (7), (9) and (10) of Article 3 (Payment and handling of the Research Funds), paragraphs (3) and (4) of Article 4 (Implementation of the Research), paragraph (3) of Article 6 (Safety Information), Article 9 (Handling of Personal Information), Article 10 (Handling of Samples), Article 11 (Compensation and Other Measures), Article 15 (Publication of the Research Results), Article 16 (Ownership, Retention and Use of Source documents), Article 17 (Handling of Intellectual Property Rights), paragraphs (4) and (5) of Article 18 (Conflicts of Interest Management), Article 19 (Confidentiality), Article 20 (No Unintended Use), Article 22 (Legal Compliance), Article 24 (Damages), Article 25 (Assignment), Article 27 (Governing Law and Jurisdiction), Article 28 (Consultation in Good Faith), and any other provisions which by their nature are expected to remain valid shall remain valid even after cancellation, discontinuation or expiration of the Agreement.[22]

Article 24 (Damages)

1. The Research Institution shall assume indemnity liability for the damage incurred by the intention or fault of the Research Institution or the Researchers to subjects of the Research; provided, however, that this shall not apply in cases where the Company must directly assume product liability or tort liability towards third parties including the Research Subjects, such as when there is a defect in the Medical Device.
2. If the other party violates the Agreement, each party shall be entitled to request compensation for the damage incurred thereby.
3. The exercise of the right of termination under the preceding paragraph shall not preclude the terminating party from seeking damages.

Article 25 (Assignment)

Neither party hereto may assign rights or obligations arising from the Agreement to any third party, with the exception of Affiliates of the Company, without prior written consent of the other party.

Article 26 (Changes to Agreement)

The Agreement including annexes may only be revised, changed or extended based on a document that bears the signatures and seals of authorized representatives of each party.

Article 27 (Governing Law and Jurisdiction)

[22] If any article for the provision or loan of medical devices and goods is added, No. of article which remains valid shall be changed. Please accordingly coordinate article No. as appropriate.

The Agreement shall be governed and construed in accordance with the laws of Japan, and the ** District Court shall be the court of first instance with exclusive jurisdiction over any dispute arising in connection with the Agreement.

Article 28 (Consultation in Good Faith)
The parties hereto shall consult with each other in good faith to determine any matters not provided for in the Agreement or other doubts arising in connection herewith.

In witness whereof, the parties hereto have caused this Agreement to be executed by their representatives in duplicate, each party retaining one (1) copy thereof respectively.

XX/XX/20XX[23]

Research Institution
[Address]
[Organization]
[Title/Name]

Company[24]
[Address]
[Organization]
[Title/Name]

I read, understood and will comply with all terms of the Agreement above.

XX/XX/20XX
Investigator
(Signature)
[Organization]
[Title/Name]

[23] Corresponding to Article 88, item (i) of the Ordinance
[24] Corresponding to Article 88, item (iii) of the Ordinance

Annex 1. Milestone

Description/amount of payment	Milestone
First: Expenses necessary for the review by Certified Review Board XXXXX yen (including consumption tax and local consumption tax) (Scheduled completion date: XX, 20XX)	In application to Certified Review Board [or] Within XX days after the execution of the Agreement
Second: Expenses necessary for implementation of the research XXXXX yen (including consumption tax and local consumption tax) (Scheduled completion date: XX, 20XX)	When, after submission of Trial Plan to the Minister of Health, Labour and Welfare, the implementation of the Research is approved by Manager of the Research Institution (however, after registered in j RCT)
Third: Expenses for implementation stage XXXXX yen (including consumption tax and local consumption tax) (Scheduled completion date: XX, 20XX)	Setting up payment depending on the progress of enrollment of subjects
Xth: Expenses for completion stage XXXXX yen (including consumption tax and local consumption tax) (Scheduled completion date: XX, 20XX)	When completion of the Research is reported to Certified Review Board [or] When database for statistical analysis is fixed
Final: Expenses for completion stage XXXXX yen (including consumption tax and local consumption tax) (Scheduled completion date: XX, 20XX)	When Primary Endpoint Report, and Clinical Study Report and its summary for the Research are received by Company and results of the Research are recorded in j RCT.

Annex 2. Breakdown of the Research Funds[25]

Payee	Item	Detail		Total (Direct cost)	Remark
		Unit price	Person/day/unit		
	Contract Organization			yen	Registration, Office, DM service
	Insurance premiums			yen	
	Expenses for the examination not covered by insurance			yen	XX
	Expenses to be reimbursed to subjects			yen	XX
	Expenses for storage of materials			yen	
	XX				
Total		----		yen	

[25] Corresponding to Article 88, item (xiii) of the Ordinance

Annex 3. Investigator's Duties

Matter	Applicable Law/Ordinance
Description	
1. Duties of Investigators	Article 4, paragraph (2) of the Act; Articles 10 and 11 of the Ordinance
(1) Have scientific knowledge and medical experience and knowledge, and receive adequate education and training. (2) Fully consider from an ethical and scientific perspective. (3) Conduct the Research in compliance with ordinances and Protocol. (4) Confirm from time to time that the research is appropriately conducted and take measures necessary to ensure appropriate research implementation. (5) When entrusting part of the operations of the Research, perform necessary and appropriate supervision. (6) At the request of Manager of the Research Institution, submit materials required by the manager and provide other necessary cooperation.	
2. Responses at the onset of diseases	Article 4, paragraph (2) of the Act; Article 13 of the Ordinance
(1) Prepare Procedures for responses at the onset of diseases suspected of being caused by implementation of the Research in compliance with Protocol, and respond according to the Procedures. (2) At the onset of diseases suspected of being caused by implementation of the Research, take necessary measures including discontinuation of the Research.	
3. Preparation of Protocol	Article 4, paragraph (2) of the Act; Article 14 of the Ordinance
Prepare Protocol of the Research, which describes the matters listed in Article 14, items (1) to (18) of the Ordinance.	
4. Control of nonconformity	Article 3, paragraph (2), item (i) of the Act; Article 15 of the Ordinance
(1) When becoming aware of the Research not complying with Applicable Laws and Ordinances or Protocol, promptly report that to Manager of the Research Institution. (2) In the case of (1), if particularly significant incompliance is found, promptly seek the opinion of Certified Review Board.	
5. Buildings and other facilities	Article 3, paragraph (2), item (ii) of the Act; Article 16 of the Ordinance
Depending on the content of the Research, confirm that the Research Institution has facilities or equipment necessary for emergency medical service unless cooperation with other medical institutions ensures in advance the system necessary for emergency medical service in subjects of the Research.	
6. Monitoring	Article 3, paragraph (2), item (iii) of the Act; Article17 of the Ordinance
(1) Prepare Procedures for monitoring for implementation of monitoring as specified in the Procedures and Protocol. (2) Do not have the Researchers monitor the operations of which the parties are directly in charge. (3) Have those who engage in monitoring report results of the monitoring to Investigator.	
7. Audit	Article 3, paragraph (2), item (iii) of the Act; Article 18 of the Ordinance

(1) As necessary, prepare Procedures for audit for each Protocol for implementation of audit as specified in the Procedures and Protocol. (2) Do not have the Researchers and those who engage in the monitoring conduct audit. (3) Have those who engage in audit report results of the audit to Investigator.	
8. Instructions for those who engage in monitoring and audit	Article 3, paragraph (2), item (iii) of the Act; Article 19 of the Ordinance
For monitoring and audit conducted by those who engage in monitoring and those who engage in audit, provide necessary instructions and management.	
9. Compensation to subjects of the research	Article 3, paragraph (2), item (iv) of the Act; Article 20 of the Ordinance
For implementation of the Research, beforehand establish the system to provide insurance and medical care and take other necessary measures in preparation for compensation and medical care for subjects of the Research in the event of injuries associated with the Research.	
10. Preparation of Conflicts of Interest Management Plan	Article 3, paragraph (2), item (v) of the Act; Article 21 of the Ordinance
(1) Develop standards for appropriate handling for the following involvements (hereinafter "Conflicts of Interest Management Standards"): A) Provision of research funds and other involvement by Company (including special parties concerned) for the Research B) The provision of donations, and rewards for writing and speaking and other services, and other involvement by Company for medical devices for use in the Research, to 1) Investigator, 2) Sub-investigator, 3) persons responsible for statistical analysis and 4) persons listed in Protocol, who obviously benefit from implementation of the Research (2) Seek the opinion of Manager of the Research Institution or the head of the institution about involvements under the preceding paragraph, and receive the report describing results of the confirmation. (3) In the light of the content of the report under (2), prepare the plan specifying the method of appropriate handling for the involvement by Company (hereinafter "Conflicts of Interest Management Plan"). (4) Seek the opinion of Certified Review Board about Conflicts of Interest Management Standards and Conflicts of Interest Management Plan. (5) For involvement by Company, in accordance with Conflicts of Interest Management Standards and Conflicts of Interest Management Plan, perform appropriate management.	
11. Response to opinion of Certified Review Board	Article 3, paragraph (2), item (vi) of the Act; Article 22 of the Ordinance
(1) When receiving any opinion from Certified Review Board, promptly report the content of the opinion to Manager of the Research Institution. (2) In the case of (1), take necessary measures respecting the opinion of Certified Review Board.	
12. Response to complaints and inquiries	Article 3, paragraph (2), item (vi) of the Act; Article 23 of the Ordinance
For appropriate and prompt response to complaints and inquiries about the Research, establish the contact for complaints and inquiries, prepare procedures for the response to complaints and inquiries, and develop other necessary systems.	
13. Publication of information	Article 3, paragraph (2), item (vi) of the Act; Article 24 of the Ordinance
(1) Publish the matters set forth in Applicable Laws and Ordinances by recording in the database developed by the Ministry of Health, Labour and Welfare (Japan Registry of Clinical Trials: j RCT). The same is true when they are amended.	

(2) Prepare Primary Endpoint Report within one year in principle of the end of the period for collecting data for primary endpoints, and Clinical Study Report and its summary within one year in principle of the end of the period for collecting data for all endpoints.

(3) Under the provision of (2), when preparing Primary Endpoint Report or Clinical Study Report and its summary, submit it to Manager of the Research Institution without delay and, under the provision of (1), publish Primary Endpoint Report or the summary of Clinical Study Report.

(4) In submission under the provision of (3), seek the opinion of Certified Review Board in advance and publish as specified in (1) within one month of the date of the opinion. In this case, when submitting the summary of Clinical Study Report as specified in (1), promptly submit the following documents being attached to the summary of Clinical Study Report to the Minister of Health, Labour and Welfare.

A) Protocol

B) Statistical Analysis Plan (if prepared)

14. Ensuring the quality of medical devices	Article 3, paragraph (2), item (vi) of the Act; Article 25 of the Ordinance

(1) Depending on the content of the clinical research, conduct the Research with the medical devices manufactured, taking necessary measures to ensure the quality of the Medical Device.

(2) If a clinical research with an unapproved or off-label Medical Device is conducted or if determined to be necessary depending on the content of the clinical research, create or obtain the records on the Medical Device as listed below.

A) Manufacturing date, number and code of the Medical Device, and other records on manufacturing of the Medical Device.

B) If the Medical Device is obtained, records of quantity and date thereof.

C) Records on disposal of the Medical Device

15. Considerations for environment	Article 3, paragraph (2), item (vi) of the Act; Article 26 of the Ordinance

Make necessary considerations not to have an adverse impact on environment.

16. Handling of personal information	Article 10 of the Act; Articles 27 to 38 of the Ordinance

(1) For handling personal information, identify the purpose of use as specifically as possible.

(2) Do not obtain personal information through deception or by other wrongful means.

(3) Do not handle the personal information obtained associated with implementation of the Research beyond the scope of consent given by subjects of the Research in advance.

(4) Keep personal information accurate and updated within the scope necessary for achievement of the purpose of use.

(5) Take necessary measures for the prevention of the leaking, loss or damage and for the proper management of personal information, and set implementation rules specifying the method.

(6) When using personal information to conduct the Research, comply with Applicable Laws and Ordinances, and obtain consent from subjects of the Research.

(7) If a subject of the Research requests the purpose of use of the personal information possessed by himself/herself and the Research Institution (hereinafter “Possessed Personal Information”) to be notified, notify the requesting person thereof without delay (excluding exceptions provided in Applicable Laws and Ordinances).

(8) If a subject of the Research requests the information identifying the subject of Possessed Personal Information to be disclosed, disclose such personal information to the requesting person without delay (excluding exceptions provided in Applicable Laws and Ordinances).

(9) If it is determined not to disclose all or part of requested personal information because of falling within any exception under (8) or if there is not the personal information requested to be disclosed, notify the requesting subject of the Research thereof without delay.

(10) If a subject of the Research requests the correction, addition or deletion (hereinafter “Corrections”)

of the information identifying the subject of Possessed Personal Information for the reason that the content of the information is not true, perform necessary examinations and make Corrections to the content based on the results without delay. (11) If a subject of the Research requests the suspension of use or erasure (hereinafter "Suspension of Use" for the matter) of Possessed Personal Information for the reason that the information was inappropriately obtained or that the information is handled for any purpose other than the purpose of use, and such request is appropriate, suspend the use of the personal information to the extent necessary to correct the violation without delay (excluding exceptions provided in Applicable Laws and Ordinances). (12) As procedures to respond to the request for the disclosure of Possessed Personal Information, specify the matters listed in Applicable Laws and Ordinances. (13) If it is determined not to make notification of the purpose of use under (7), not to disclose Possessed Personal Information under (8), not to make Corrections under (10), or not to perform Suspension of Use under (11), notify the subject of the Research of such determination attempting to explain the reason. (14) If Samples are provided, from the perspective of the protection of personal information, attempt to take measures to delete all or part of personal information. (15) When Samples including personal information are provided to or by a person abroad, create records concerning the matters listed in Applicable Laws and Ordinances.

17. Submission of Trial Plan	Article 5, paragraph (1) of the Act; Article 39 of the Ordinance
(1) Before the start of Specified Clinical Research, submit Trial Plan in Form 1 under the Ordinance to the Minister of Health, Labour and Welfare. (2) In the submission under (2), promptly notify the Certified Review Board provided in the Trial Plan thereof.	

18. Procedures in submission of Trial Plan to the Minister of Health, Labour and Welfare	Article 5, paragraph (3) of the Act; Article 40 of the Ordinance
(1) When attempting to seek the opinion of Certified Review Board, submit documents listed in Article 40, paragraph (1) of the Ordinance to the Certified Review Board. (2) After seeking the opinion of Certified Review Board, submit documents specified in the documents under (1) and other documents requested by Manager of the Research Institution for the approval of implementation of the Specified Clinical Research at the Research Institution by the manager.	

19. Submission of revised Trial Plan	Article 6, paragraphs (1) and (3) of the Act; Articles 41 to 43 of the Ordinance
(1) For revision of Trial Plan, submit revised Trial Plan and a notification in Form 2 under the Ordinance by the following deadlines: A) Without delay after modification of the progress of Specified Clinical Research, for the matters involving the progress of those specified in Article 5, paragraph (1), item (v) of the Act; or B) Before modification, for the matters other than those listed under A). (2) For the change in the name of the person who engages in Specified Clinical Research, which is not associated with the change in the person who engages in Specified Clinical Research, or the change associated with that in the name of region or parcel number (minor change), notify Certified Review Board listed in the protocol of content thereof within ten days of the change date, and submit a notification in Form 3 under the Ordinance to the Minister of Health, Labour and Welfare.	

20. Prohibition of the change in Certified Review Board	Article 44 of the Ordinance
After submission of Trial Plan to the Minister of Health, Labour and Welfare, except the case Certified Review Board is abolished or other unavoidable circumstances, do not change the Certified Review Board listed in Trial Plan.	

21. Notification of discontinuation of the Research	Article 8 of the Act; Article 45 of the Ordinance

In discontinuation of the Research, within ten days of the discontinuation, notify the Certified Review Board listed in the Trial Plan thereof and submit a notification in Form 4 under the Ordinance to the Minister of Health, Labour and Welfare.	
22. Explanation to subjects of the Research and obtaining their consent	Article 9 of the Act; Articles 46 to 52 of the Ordinance
Explain about the matters set forth in Applicable Laws and Ordinances to subjects of the Research in compliance with Applicable Laws and Ordinances, and obtain written consent from them. If all or part of the consent is withdrawn or rejected, take measures depending on the content of the withdrawal or rejection and explain thereon to subjects of the Research without delay (excluding exceptions provided in Applicable Laws and Ordinances).	
23. Retention of records of the Research	Article 12 of the Act; Article 53 of the Ordinance
(1) For five years after the date of completion of the Research, create records on dates and locations with use of the Medical Device, matters identifying subjects of the Research, matters involving clinical practice and examinations in them, matters involving participation in the Research, and matters necessary for implementation of the Research, and retain such records along with Protocol, Trial Plan, documents for explanation to and obtaining consent from subjects of the Research, the document prepared by itself such as Clinical Study Report or its copy, the document on opinions by review received from Certified Review Board, documents concerning monitoring and audit, Source Documents, this agreement, document summarizing medical devices for use in the Research, and records created or obtained under 14. (2) and other documents necessary for implementation of the Research. (2) If records specified under (1) are modified, record the name of the person who modifies and the date of the modification, and retain them along with modified records.	
24. Report of diseases to Certified Review Board	Article 13 of the Act; Article 54 of the Ordinance
Regarding implementation of the Research, when recognizing the onset of any disease set forth in Applicable Laws and Ordinances, report it during the period provided in Applicable Laws and Ordinances to Manager of the Research Institution, and then to Certified Review Board.	
25. Report of diseases to the Minister of Health, Labour and Welfare	Article 14 of the Act; Article 56 of the Ordinance
Regarding implementation of the Research, when recognizing the onset of any disease set forth in Applicable Laws and Ordinances, report it to the Minister of Health, Labour and Welfare as provided in Applicable Laws and Ordinances	
26. Periodic report to Certified Review Board	Article 17, paragraph (1) of the Act; Article 59 the Ordinance
(1) Regarding the status of implementation of the Research, report the matters specified in the items of Article 59, paragraph (1) of the Ordinance to Manager of the Research Institution and then to Certified Review Board provided in the Trial Plan. (2) In principle, the report under (1) shall be made within two months after expiration of the period, every one year starting from the date of submission of Trial Plan to the Minister of Health, Labour and Welfare.	
27. Periodic report to the Minister of Health, Labour and Welfare	Article 18 of the Act; Article 60 of the Ordinance
(1) Regarding the status of implementation of the Research, report the name of Certified Review Board provided in Trial Plan, appropriateness of the continuation of the Specified Clinical Research by the Certified Review Board, and the number of subjects who participate in the Research, to the Minister of Health, Labour and Welfare. (2) The report under (1) shall be made within one month after the date on which Certified Review Board offers any opinion.	
28. Obligation of confidentiality	Articles 11 and 21 of the Act; Article 61 of the

	Ordinance
Do not disclose any secret concerning subjects of the Research obtained in connection with implementation of the Research.	
29. Creation and retention of records on those whose Samples existing are used for the Research	Articles 12 and 21 of the Act; Article 62 of the Ordinance
When creating and retaining records on those whose Samples existing are used for the Research, attempt to take necessary measures.	
30. Response to access and inspection by authorities	Articles 19, 20 and 35 of the Act
Following any access and inspection, collection of reports, emergency order, order for improvement or order for suspension (hereinafter collectively "Access and Inspections") by authorities, report the fact, course and results of the Access and Inspections to Company without delay.	

If Applicable Laws and Ordinances are amended, make replacements as appropriate in accordance with amended Applicable Laws and Ordinances.

Annex 4. Materials for Publications and Schedule (pertinent to Article 15, paragraph (2), item (i))

Materials for Publications	Deadline of Submission to Company by Investigator	Deadline of response to Investigator by Company
A manuscript, and figures and tables in accordance with ICMJE and the requirements for manuscript submission of the journal to which the manuscript is scheduled to be submitted (including Supplemental data)	By XX days before the scheduled date of the submission	Within XX days of the receipt from Investigator
An abstract as specified by an academic conference for which a subject of speech is scheduled to be registered	By XX days before the deadline of subject registration for the academic conference	Within XX days of the receipt from Investigator
Materials for Publications as specified by an academic conference at which they are scheduled to be presented (slide, poster manuscript)	By XX days before the first day of the academic conference	Within XX days of the receipt from Investigator
Others (manuscripts, and figures and tables for press releases)	By XX days before the scheduled publication date	Within XX days of the receipt from Investigator

Annex 5. Ownership and Use of Source Documents (pertinent to Article 16, paragraph (1))

Source Documents	The Research Institution or Investigator	Company
Source document		
Statistical Analysis Plan	○	--
Dataset for statistical analysis (fixed)	○	△
[Addition or amendment as appropriate]	○	--

○ means (Ownership).

△ means (Right to use)[26]

[26] If the right to use is on the side of Company or the right itself belongs to Company, the consent thereto needs to be obtained from subjects of the clinical research in advance.

Annex 6. Provided Goods and Loaned Goods (pertinent to Article 7 and/or 8)

1. Provided Goods

2. Loaned Goods